Development of Medical Adjunctive Treatment for Acute Penetrating Head Injury

Annual Report

Andres M. Salazar, M.D.

April 1, 1988

Supported by

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Fort Detrick, Frederick, Maryland 21701-5012

Army Project Order No. 87PP7824

Uniformed Services University
of Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814-4799

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
FORT DETRICK, FREDERICK, MD. 21701-5012

REPLY TO
ATTENTION OF

May 23, 1988

SGRD-RMI-S

SUBJECT: Review of Draft Annual Report, April 1, 1988, (for the period October 1, 1986 through October 31, 1987) for Army Project Order No. 87PP7824

Andres M. Salazar, M.D.
Uniformed Services University
of Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814-4799

Dear Dr. Salazar:

We have completed review of the subject report. Annotations have been made on a copy of your draft report. Add the enclosed cover page, DD Form 1473, Foreword, and Distribution List to your report. You may now distribute your report in accordance to the enclosed distribution list provided you make revisions.

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Sincerely,

Patricia A. Madigan
Chief, Research Data
Management Branch

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19. ABSTRACT *(Continue on reverse if necessary and identify by block number)*

The overall objective of the Army Penetrating Head Injury Project (APHIP) is to establish a collaborative multicenter system that can conduct rigorous, standardized scientific clinical trails in head injured patients; and then to use that system to study the pathophysiology and behavioral consequences of head injury and to develop and test promising new therapies and management strategies in such patients.

The first half of this objective has now been accomplished. A four-university medical center network with a directorate has been established; standardized basic treatment algorithms and extensive multidisciplinary outcome parameters to be measured have been agreed upon. Personnel have been hired at the central office (a statistician/study manager, a neuropsychologist, a research coordinator, and a research support specialist). Research nurses, M.D. head trauma fellows, neurobehavioral testers, and data management clerks have been hired and trained at each remote site. A computerized data entry, editing, and polling system, including extensive data entry forms has been developed, tested in the field on over 30 patients, and finalized. An administrative manual has been prepared.

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22a. NAME OF RESPONSIBLE INDIVIDUAL Mrs. Virginia M. Miller	22b. TELEPHONE *(Include Area Code)* 301-663-7325	22c. OFFICE SYMBOL SGRD-RMI-S

19. Abstract (Continued)

The second half of the project is now ready to begin. A promising new drug, PEG-Superoxide Dismutase (PEG-SOD) has been selected for the initial therapeutic trials and collaboration has been established with Enzon, Inc., the company which developed the drug and holds the FDA IND exemption. Two protocols have been completed, and final IRB approvals have been obtained from the four medical centers, USUHS, and The Surgeon General's Human Subjects Research Review Board (HSRRB) as of 22 September 1988. Randomization of the first patients into these trials is now projected for the Fall, 1988.

Ancillary studies include a national survey of over 3000 neurosurgeons regarding management of penetrating head injury (PHI). This has now been completed with over 35% response rate and shows wide variability and general lack of consensus on the management of PHI; a manuscript has been prepared. Other studies include collaborative development of a rat model of head injury for biochemical studies (protocol completed, pending USUHS approval), and continued analysis of long-term PHI outcome data generated in the Vietnam Head Injury Study (VHIS).

FOREWORD

For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45CFR56.

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NEUROLOGY

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ANNUAL REPORT (1 October 1986-31 October 1987)
ARMY PENETRATING HEAD INJURY PROJECT (APHIP), 87PP7824
Uniformed Services University of the Health Sciences
Andres M. Salazar, M.D., COL, MC, USA
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Washington, DC 20307-5001
202-576-1348/1345

1. The overall objective of the Army Penetrating Head Injury Project (APHIP) is to establish a collaborative multicenter system that can conduct rigorous standardized scientific clinical trials in head injured patients, and then to use that system to develop and test promising new therapies and management strategies in such patients.

Since the inception of full funding in the spring of 1987, the first half of this objective has been accomplished, and we are now poised to begin our first therapeutic trial using a promising new agent, PEG-Superoxide Dismutase (PEG-SOD).

2. The following goals outlined in the Statement of Work dated 7 February 1987 (DA Form 2213) have been attained.

a. Collaborative agreements have been established and formal Memoranda of Understanding have been signed with the following medical centers:

(1) The University of Texas at Galveston, Howard E. Eisenberg, M.D., Principal Investigator.

(2) Baylor College of Medicine, Houston, Texas, Raj K. Narayan, M.D., Principal Investigator.

(3) Medical College of Virginia, Richmond, Harold F. Young, M.D, Principal Investigator.

(4) Louisiana State University, New Orleans, Michael E. Carey, M.D. (COL, MC, USAR), Principal Investigator.

An APHIP Directorate has been established consisting of the Principal Investigators (PI) from each of the participating centers, the Project Director (Andres M. Salazar, COL, MC), the Neurosurgical Consultant to the Army Surgeon General (Eugene George, COL, MC), and Howard Kaufman, M.D. (LTC, MC, USAR), Chairman of Neurosurgery, West Virginia University Medical School. Doctors George, Carey, and Young have extensive experience with battlefield neurosurgery in Vietnam.

b. Standardized baseline evaluation and treatment algorithms have been agreed upon and finalized. These are outlined in Chapter III of the accompanying APHIP Administrative Manual (Appendix A).

c. A standardized data gathering system has been established at each of the four centers. Personnel have been hired at the central office (a neuropsychologist, a research coordinator, a statistician, and a research support specialist), as well as at each of the participating centers (research nurse clinicians, trauma fellows, data entry clerks, and neuropsychology testers). An initial training meeting of all personnel involved was held at the University of Texas Medical Center in Galveston (see Appendix B, Minutes of the 21-22 September 1987 Directorate meeting).

Extensive data entry forms and instructions for their use have been developed and agreed upon (Appendix A, Chapter IV). Potentially relevant therapeutic endpoints have been identified and neuropsychological and behavioral test measures specific for head injury outcome have been developed. A contract has been let for a computerized front-end data entry, editing and polling system, which has now been adapted to our specific needs (Administrative Manual, Chapter IV). Initial training of data entry personnel has been accomplished. Baseline treatment has been standardized at all centers.

d. A "dry run" test of the data collection system has now started at two centers.

e. A promising new drug, PEG-SOD, has been selected for the initial trial. The drug will be supplied by Enzon, Inc., which has the patent and holds the FDA IND exemption for the drug. The mechanism of action of the drug is via reduction of the oxygen free radicals produced after brain injury. A particularly attractive feature of this PEG conjugated form of SOD from a military point of view is its extremely low toxicity and very long half-life (four to six days). We thus intend to treat patients with only two doses (IV infusions), one on the day of injury and one four days later (see accompanying Protocol, Appendix C).

f. A standardized Protocol has been prepared and agreed upon by the APHIP Directorate and Enzon (Appendix C). After local Institutional Review Board (IRB) approval, it will be submitted to the USUHS and USAMR&DC Human Use Review Officers before the onset of clinical trials.

As reported previously, patients have been divided into two separate groups: (1) those who are in deep coma (Glasgow Coma Score [GCS] 3-5, and (2) those in light coma or awake, GCS 6-15. Although patients with an initial GCS 3-5 have a very poor prognosis (98% fatality), there is still considerable controversy nationwide over their management, particularly with regard to early surgery (see below). We have thus chosen a factorial design to address two questions simultaneously on the same group of GCS 3-5 patients: the value of early surgery in this group, and the value of PEG-SOD. GCS 6-15 patients will all undergo early surgery and then be entered in the PEG-SOD trial. All patients participating in the trial are expected to benefit from it, since they will all receive intensive standardized ICU care.

3. Nationwide Survey of Neurosurgical Standards of Care: early in the discussions of the members of the APHIP directorate, it became apparent that there was some controversy over the management of patients with penetrating head injury (PHI). We thus decided to undertake a nationwide survey on the matter in order to better guide our clinical studies. A survey questionnaire was prepared and pretested on a sample of 300 neurosurgeons belonging to the American Association of Neurological Surgeons and the Congress of Neurological Surgeons. With minor modifications, this survey was then mailed to the entire national membership (approximately 3000 neurosurgeons). A second mailing was recently sent to initial nonresponders. An overall response rate of about 35-40% is expected.

Preliminary analysis shows a wide variation in the attitudes toward and management of gunshot wounds to the head. Almost 30% of neurosurgeons responding would not do intracranial debridement (the standard US Army treatment) on PHI patients who are awake, while 85% would not do it on patients in deep coma. About 45% routinely use corticosteroids, in spite of the fact that at least four major trials have shown steroids to be useless in head injured patients. About 21% do not use antibiotics routinely. One hundred percent (100%) use CT scanning, and 75% use it in every case. A final report on the results of the survey is expected to be completed by the end of 1987, and will be submitted for publication (see Appendix D).

ANDRES M. SALAZAR, M.D.
COL, MC, USA
Director, APHIP

Enclosures

ARMY PENETRATING HEAD INJURY PROJECT (APHIP)

ADMINISTRATIVE MANUAL

July 1988

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ARMY PENETRATING HEAD INJURY PROJECT (APHIP)

ADMINISTRATIVE MANUAL

JULY 1988

CHAPTER I

PROJECT OVERVIEW AND GOALS

OVERVIEW

Goals

To establish a standardized multicenter collaborative research effort that can address the following objectives.

1. Refine the indications for intracranial neurosurgical debridement in the management of penetrating head injury (PHI).

2. Develop logistically simple, adjunctive medical treatments for PHI which will delay or minimize the need for intracranial neurosurgical debridement for days to over one week and/or will minimize ultimate tissue loss.

3. Study the metabolic, biochemical, and vascular responses to head injury in humans.

4. Develop and further refine practical therapeutic outcome criteria or end-points for drug trials in head injury patients.

5. Determine predictors of mortality and both short and long-term neurological, neuropsychological, and psychosocial outcome after PHI.

BACKGROUND

Introduction

Head injury is the major cause of death and disability in young adults today. The average annual incidence of head injury is about 200/100,000. The incidence for penetrating head injury in the USA is about 12/100,000, the highest of any developed country in the world.

Similarly, penetrating head injury accounts for a large proportion of serious casualties in the military setting. About 40% of battlefield fatalities in the Vietnam war were due to head and neck wounds. Eighty percent of those surviving to reach the hospital received surgical treatment, and 90% of those survived long term. The overwhelming majority of those long-term survivors could be classified as having moderate or good long-term outcomes, about 30% were returned to some duty.

Surgical Issues

Acute surgical debridement of missile tracts is the commonly accepted management for patients with gunshot wounds and other penetrating brain injuries. This time honored strategy of care, however, has never been subject to rigorous investigation (e.g., in a randomized trial), and a recent survey of neurosurgical management practices reveals that only about 15% of neurosurgeons believe that intracranial surgical debridement is helpful in severely injured patients in deep coma (GCS 3-5). There are reasons to believe that such patients may actually be harmed by an acute operation that requires manipulation and retraction of their brains. This may increase the risk of death or

further injury due to elevated intracranial pressure; a period of stabilization before surgery may thus improve on their outcome. This group of patients has had a particularly poor prognosis in civilian practice (they almost all die or remain vegetative regardless of treatment). On the other hand, GCS group 6-15 are able to tolerate early surgical debridement adequately. For purposes of analysis of treatment modalities, it is thus important to consider the two groups separately.

The current practice of providing prompt and thorough surgical debridement after penetrating head injury has evolved mostly from the experience in military conflicts over the past half century. The rationale has been that injured brain tissue serves as a nidus for delayed reaction and infection and must be removed as soon as possible. Yet a closer look at previous experience shows that the question is still controversial. As early as the mid-1950's, French neurosurgeons in Vietnam were able to successfully delay debridement for days by doing a superficial wound closure and providing general support and antibiotics. The Israeli military experience in the recent Lebanese war has also demonstrated that many patients with severe, deep penetrating wounds could be successfully managed with early resuscitation, antibiotics, superficial wound closure, ICP monitoring , and general medical support. Such patients generally had a good outcome and may have had less ultimate tissue loss. Computerized tomography played a crucial role in management decisions. In addition, recent long term re-evaluation of Vietnam veterans in the Vietnam Head Injury Study (VHIS) has shown that retained bone fragments, per se, do not result in increased complications, and their mere presence does not justify repeated operations for removal. Preliminary analysis of the same population has also shown that complication rates (including post-operative sepsis) did not begin to rise until surgical delays of longer than 48-72 hours post-injury were encountered. The implications of this controversy can be quite far reaching, not only for the individual patient, but in a military setting for the logistician who must plan for deployment of war-time medical and neurosurgical resources.

Secondary Injury Issues

Over the past decade, delayed secondary injury at the cellular level has come to be recognized as a major contributor to the ultimate tissue loss after CNS trauma, stroke and other injury. A cascade of biochemical events has been shown to be set in motion in injured tissue and involves a multitude of systems, including possible changes in neuropeptides, excitatory amino acids, arachidonic acid metabolites, and the formation of oxygen free radicals. These products can result in progressive secondary injury of otherwise viable tissue through a number of mechanisms, e.g., by producing further ischemia (via vasospasm, clot formation or secondary vascular occlusion), by injuring neurones and glia directly or activating macrophages that result in such injury, by producing brain swelling (edema or hyperemia), or by establishing conditions favorable to secondary infection. Classically, this problem has been managed through the surgical removal of the offending tissue, as outlined above, whether it was ultimately viable or not. One objective of the present study is to test an alternative medical adjunctive treatment for secondary injury that will not only minimize or delay the need for such surgery in the area of missile penetration, and minimize ultimate tissue loss, but can also be used to manage diffuse secondary injury not amenable to surgery. Such treatments can also be expected to be relevant to the management of other CNS disorders such as closed head injury and stroke.

Finally, much data is available from the VHIS and other postwar studies on chronic outcome of patients surviving PHI. However, less is known about their acute and subacute course and their pattern of functional recovery, particularly in the fields of

neurospychology and neurobehavior. A secondary goal of this project will be to collect data to address these questions.

Scope of Work

1. The eventual intent is to test drugs or other treatment modalities on penetrating head injured patients under uniform multicenter Phase I-II and Phase II-III clinical protocols. In overall design, the project will be modeled after the National Traumatic Coma Data Bank (NTCDB) developed by the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), in which a central office coordinates standardized protocols and data collection at multiple medical centers. The data entry system and data collection forms of the NTCDB will be modified for our use.

2. Clinical protocol details including patient selection, drug and other treatment selection, and clinical parameters to be followed will be arrived at jointly by the principal investigators from each of the participating centers and USUHS. An individual center could vary from the main protocol in order to take advantage of a particular evaluation method or technique available to it (i.e., PET scanning, BEAM, evoked responses, cerebral blood flow, or dialysis probe), but a minimum set of basic, standardized parameters will be measure at all centers. Such parameters will be arrived at jointly, but might include a standardized neurologic examination, MRI for evaluation of edema, CT, CSF chemical analysis, neuropsychological testing, power spectral EEG, and intracranial pressure monitoring.

3. Data will be collected centrally and statistical support provided by the Army Penetrating Head Injury Project (APHIP), USUHS. USUHS will also provide neuropsychological support, including a modified basic test battery standardized on the VHIS population. Investigational New Drug (IND) exemptions will generally be held by the supplier.

4. Given the major difficulties posed in such a study by factors such as patient comparability, response measurement, informed consent, and follow-up, principally drugs or prospective therapies expected to have a large effect (based on animal studies) will be tested.

5. Use of severe closed head injury patients in clinical trials might considerably accelerate data collection, but we believe that such patients are not totally adequate for this project. Previous war studies, as well as ongoing data analysis in the VHIS, have shown that penetrating head injury differs from closed head injury in a number of ways. Most importantly, the wounds are focal; they are contaminated with metal, bone, and other debris; and they usually lack an acceleration-deceleration component with diffuse axonal injury. For this reason, their management will differ in items such as drug and antibiotic usage and surgical technique; and treatments developed for closed head injury in civilian studies will likely not be fully applicable to the military situation, particularly if they require elaborate intensive care units. Thus, while parallel drug rials on closed head injury patients could be extremely helpful, particularly in establishing drug safety and dosage (Phase I-II trials), the principal thrust of the present project will remain penetrating head injury.

6. Patients with severe penetrating brain wounds who are alive and relatively stable on admission, but who might otherwise be triaged for expectant treatment, might be considered for inclusion in certain of these drug treatment protocols under a stratified randomization.

CHAPTER II

PROJECT ROLES AND RELATIONSHIPS

PROJECT DIRECTORATE

The Project Directorate consists of the Principal Investigators (PI) from each of the participating centers and the Project Director. The directorate will meet periodically, organize workshops, and have responsibility for:

1. Approval of additional vocabulary and operational definitions.
2. Implementation of the data collection protocol and approval of changes to same.
3. Continuous review of data.
4. Adoption of and adherence to a publication policy and guidelines for collaborative studies.

PROJECT ADVISORY GROUP

An external group will meet periodically with the APHIP staff and Project Directorate to review the utilization of the quality of the data and make recommendations relevant to the conduct of the project. The Advisory Group will be under the aegis of the APHIP, which will also select the members of that group and provide its mandate.

APHIP CLINICAL CENTERS

Basic Requirements for Center Participation

1. University affiliation and neurosurgical residency program.
2. A fully functioning neurosurgical intensive care unit.
3. Late model CT readily available to the neurosurgical ICU.
4. An expected volume of at least 15-20 penetrating head injuries per year documented by the previous three years experience.
5. Ability to assign a trauma fellow to the project.

Responsibilities

1. Participate in good faith in the decision making process and abide by reasonable decisions of the Project Directorate, which includes attendance at scheduled meetings and adherence to publication policy.
2. Provide for randomization into the study all penetrating head injured patients which meet the criteria established jointly by the Project Directorate. These criteria will include appropriate legal patient consent.

3. Provide standardized baseline ICU and neurosurgical management and follow-up to study patients, as will be determined jointly the Project Directorate.

4. Provide data collection and prompt (within 15 days of collection) data entry and transmission to USUHS using the computerized system selected. Items to be entered will be determined jointly by the Project Directorate. Copes of CT and MRI films will be sent to USUHS. Local PI's will be responsible for the quality o the data and any corrections needed. Provide an IBM PC XT or equivalent computer for data entry (see budgets).

5. Provide dedicated and named personnel as outlined in accompanying budget. Notify USUHS of personnel changes. These changes will be kept to a minimum to ensure continuity.

6. Secure approval for individual protocols from the local Institutional Review Board and/or Human Use Committee. Such protocols will generally be based on a master protocol developed by the Project Directorate.

7. Obtain appropriate legal patient consent. USUHS and the Department of Defense will not assume legal responsibility for potential problems deriving from patient care or outcome.

8. Studies involving human volunteers will be in compliance with 45 CFR 46 and Title 10, §980. Enrollment of human volunteers can begin only after an appropriate Institutional Review Board assurance has been accepted by USUHS.

9. Participate in development of quality control procedures and assuring quality of data collected.

10. Training of health care professionals participating in the project.

11. Participate in the design, implementation, and analysis of data for studies aimed at research questions of interest.

CENTRAL FACILITY: ARMY HEAD INJURY UNIT, USUHS/WRAMC

Responsibilities

1. Provide funding as outlined in the individual budget documents. It is not the intent of USUHS to cover costs for routine ICU patient care or expensive new ICU monitoring equipment. However, costs of data collection and testing for study purposes beyond routine care may be included.

2. Provide final human use approval after local Institutional Review Board approval.

3. Provide central coordination, management, and monitoring of the project.

4. Provide a front-end data collection system and statistical support, including printed data collection forms and software for data entry, editing and transmission to USUHS. Statistical analysis of the overall data will generally be performed at USUHS under the guidance of the Project Directorate.

Funding

It is emphasized that funds in support of this project are contingent upon the continuation of the grant to USUHS from the US Army Medical Research and Development Command (USAMR&DC). All personnel employed under this project must be made aware of this condition Likewise, any commitment made for the out years of this program should state this funding contingency.

CHAPTER III

STANDARD CARE ALGORITHMS

RAJ K. NARAYAN, M.D.

PREHOSPITAL CARE

No special procedures or treatments will be given in the prehospital phase as part of this study. However, each center will make every effort to inform rescue squads and other agencies involved in such care of the study and will encourage them to record as much data as possible relating to the circumstances and nature of the injury. Particularly relevant information would include time of injury, weapon, distance, seizures, anoxia, progression of neurological deficits, drugs/alcohol, vital signs and GCS (Appendix 1). Standard measures to normalize vital signs will be undertaken, but therapies such as steroids will be specifically discouraged. Prehospital care providers will be encouraged not to use glucose in their IV fluids.

EMERGENCY ROOM (ER) CARE

Stabilization

All patients will be stabilized in the ER using standard measures. Except in patients with documented hypoglycemia, glucose infusions will not be used. Ringer's lactate or normal saline will be used for IV fluids, supplemented when necessary with colloids. Every effort will be made to rapidly normalize vital signs. All patients who are comatose (not following commands in the absence of dysphasia) or who have respiratory compromise will be intubated. The GCS, pupillary reaction, doll's eye movements, corneal responses and respiratory efforts should be recorded prior to intubation and paralysis. Management of associated non-CNS injuries will be coordinated with the appropriate services. The treatment of immediately life-threatening injuries such as hemorrhage from major vessels, tension pneumothorax, etc., will naturally take precedence over all other activities.

Laboratory Tests

Blood will be drawn for the following tests: CBC, platelets, PT/PTT thrombin time, fibrinogen, fibrinogen split products, electrolytes, BUN, creatinine, liver enzymes, uric acid, blood sugar, type and cross, ABG's and alcohol level. Urine will be sent for toxic screen (Appendix 2).

Radiology

Skull x-rays, AP and lateral, plus any other views deemed necessary will be obtained in all cases. Other x-rays will be obtained as indicated.

Respiratory Support

Forty percent (40%) oxygen will be delivered via face mask to all patients who are able to ventilate normally, as needed. All comatose patients and those with respiratory difficulties will be intubated and paralyzed. If there is any evidence of frank or impending tentorial herniation, they will be hyperventilated in order to achieve a pCO_2 of around

25 mmHg. One hundred percent (100%) oxygen will be used initially until repeat ABG's can be obtained and the FiO_2 adjusted accordingly.

Medical Therapies

All patients will receive phenytoin sodium 500 mg over a 20-30minute period for seizure prophylaxis within the first 24 hours. Nafcillin 1 gm IV and chloramphenicol 1 gm IV will be administered ASAP on a prophylactic basis. If they are GCS <8 or if there is any evidence of neurological deterioration, mannitol 1-2 gm/Kg IV will be administered rapidly as the patient is enroute to the CT scanner. Steroids, aspirin containing products, and barbiturates will not be used at this stage.

CT SCANNING

All patients will undergo CT scanning of the head ASAP after admission, but certainly within three (3) hours. Normally, a noncontrast study using 10 mm cuts will be obtained, preferably with and without bone window settings. Duplicates of the scan will be prepared for the central file at USUHS.

RANDOMIZATION (Appendix 3)

All patients with PHI (acute missile injuries of the head) will be candidates for the study and will be entered in an ER log sheet. If a patient is not then randomized into the study, the reasons will be recorded. Initial randomization will occur as soon as possible after admission, but not more than 24 hours after injury. Patients with a GCS of 3-5 and 6-15 after resuscitation, will be treated as two distinct groups. Within each group, patients will be randomized to Regimen A or Regimen B using a sealed opaque envelope method. Drug therapy will be initiated ASAP after randomization. Exlcusions from the study will be:

Age < 15.

Brain dead (no neurologic function after resuscitation).

No informed consent.

All patients in the GCS 6-15 group will receive prompt (within 24 hours) surgical debridement and closure of the penetrating head injury, as indicated (see below p. 4).

Patients in the GCS 3-5 group will undergo a second randomization into two subgroups (again using the sealed opaque envelope method) after the CT scan has been obtained. One subgroup will have surgical debridement acutely (within 24 hours), while the other subgroup will be treated with superficial wound closure without extensive debridement. Patients will be excluded from the second randomization only for the following reasons:

The CT demonstrates an accessible intracranial mass (hematoma or mixed hyperdense mass) with a volume of 30 ml or more (or 20 cc in the temporal lobe).

The patient has an uncontrolled coagulopathy.

Patients who do not qualify for the second randomization because of hematoma or uncontrolled coagulopathy will nevertheless continue to be treated with drugs as per their first randomization.

Patients with a GCS 3-5 who have been randomized to the nonsurgical subgroup may be operated on within the first 120 hours only if the PI or a documented co-investigator (not a resident) feels it is required because of:

A late mass (not seen on the pre-randomization CT scan).

Uncontrollable ICP (over 30 mmHg for three [3] hours; over 40 mmHg for 15 minutes), provided that maximal ICP treatment including sedation, paralysis, hyperventilation, mannitol or barbiturates has been given (see below); or development of a unilateral dilated pupil; provided that maximal ICP treatment has been given, including: sedation, paralysis, hyperventilation (PACO2 <25 torr); and mannitol (1 gram per kilogram body weight or osmolarity >310) before declaration of uncontrolled ICP.

After 120 hours, patients in the nonsurgical subgroup may be operated on at the discretion of the attending neurosurgeon.

SURGICAL PROCEDURES

The surgical procedure performed will naturally depend upon the nature of the injury. In general terms, however, a craniectomy or craniotomy will be performed at the entry (and exit) wound site. All necrotic brain, blood clot and bone fragments will be removed as completely as possible. Intraoperative echo will be used to assist in locating fragments. Aerobic, anaerobic, and fungus cultures will be sent from all operation sites. All bone fragments will be carefully looked for, but not at the expense of damaging normal brain. Bullet fragments will be dealt with similarly. In through-and-through injuries, two separate craniectomy debridements will be performed at the entrance and exit sites, rather than attempting a complete debridement from one side. At the completion of the procedure, the dura will be closed, using lyophilized dura or autologous pericranium whenever necessary. Cranioplasties will not be performed in the acute setting. Patients will not be reoperated on purely for purposes of removing retained bone or bullet fragments.

A ventriculostomy, or other ICP monitoring device will be placed in all patients who were not following commands prior to surgery. A right frontal insertion site will be used unless there is some clear reason for using an alternative site (left frontal, right or left parietal). The ventriculostomy catheter will be tunneled under the scalp and sutured into place. If ICP monitoring is indicated for over five (1-) days due to persistent ICP elevation, the ventriculostomy will be removed and a new monitoring device inserted at a separate location.

Standard neuro-anesthetic agents will be used. These usually consist of either a nitrous oxide-narcotic combination, or Isoflurane. IV fluids used during surgery will be Ringer's lactate (without glucose) or normal saline.

ICU CARE

All patients with PHI will be admitted to the Neurosurgical Intensive Care Unit (NICU) for observation, either directly from the ER, or after surgery. Certain patients may be treated in regular care units if they are fully alert and awake (GCS 13-15), and, in the judgment of their attending neurosurgeon, do not require ICU care.

Monitoring

All comatose patients will have their ICP monitored, as discussed earlier. In addition, maximal physiological monitoring including arterial, urinary and central venous catheterization (Swan-Ganz when needed) will be performed. Additional parameters, such as cerebral blood flow, compliance and metabolic rate may be monitored at individual centers, but are not mandatory for purposes of this study. Sensory and motor evoked potential studies are also optional.

Clinical Examination

In addition to the hourly neurochecks that are a standard part of NICU care, patients included in this study will have serial neurological evaluations (Form N) performed by a qualified physician, or by the Research Nurse Clinician as outlined in Table I. In addition, a complete neurologic examination by a qualified physician will be recorded at the time of discharge, and at six (6) and 12 months whenever possible. The patient is paralyzed, sedated and intubated, all medications should be withheld for as long as it takes to obtain a neurological examination on the specified days. This requirement will be waived only if the patients ICP cannot be kept under control, even with CSF drainage and mannitol when sedation and pancuronium are withdrawn.

Radiological Studies

All patients will have plain x-rays of the skull (AP and lateral) postoperatively. In addition, a nonenhanced CT scan will be obtained on post-injury days 2, 7, and discharge, and at other times indicated clinically. Contrast enhanced scans will be obtained when a stroke, abscess, or cerebritis is suspected. The CT scan obtained at discharge will use 5 mm cuts for better definition of the anatomy. MRI scans will be considered optional.

Medications

All patients will be started on phenytoin sodium (500 mg loading dose x2, followed by 400 mg per day), and dosage adjusted based on serum levels obtained on day 3 to maintain therapeutic levels. This medication can be given by the p.o. route when the patient is able to take oral medication.

All patients will be kept on prophylactic antibiotics for one week after injury or operation; i.e., if surgery is performed on the fifth day, antibiotics are received for 12 days. Nafcillin 1 gm q 6 hours and chloramphenicol 1 gm q 6 hours will be used in all cases. These drugs may be changed based on the results of cultures. Nafcillin and chloramphenicol will not be administered for longer than 14 days. In cases of a drug allergy, a cephalosporin such as cefazolin (Ancef) or ceftriaxone (Rocephin) can be substituted.

ICP Control

All comatose and intubated patients will receive morphine sulphate 4-12 mg IV q 2-4 hours to provide analgesia and sedation. In addition, some patients will be paralyzed using pancuronium 4 mg q 2-4 hours IV, if they are combative (Appendix 4). ICP monitoring will be routinely performed in these cases. If the ICP remains greater than 20 mmHg with these measures, the patient will be hyperventilated to achieve a pCO_2 of not less than 25 mmHg. Ventricular drainage via the ventriculostomy will be simultaneously employed.

Mannitol will be used when a patient's ICP cannot be maintained below 20 mmHg with hyperventilation and CSF drainage. Boluses of 0.25 gm/kg will be used every four hours, except that serum osmolarity must be below 310 to administer mannitol. If all these measures fail, barbiturate coma will be instituted, as described in the following section.

If the patient needs to be put into barbiturate coma because of uncontrollable intracranial hypertension, pentobarbital will be used. The initial loading dose of 10 mg/kg will be given over a 30-minute period with close monitoring of the blood pressure. Following the initial loading dose, an additional 5 mg/kg will be given within the first 15 minutes of each additional hour x3, so that by four hours approximately 20-25 mg/kg have been administered. This should result in a serum level of around 2.5 mg% within four hours. Subsequently, maintenance doses of 1 mg/kg/hr can be used to maintain a serum level of 3-4 mg%. Serum levels will be checked at four, 12, and 24 hours, as well as daily thereafter. Patients must be under age 45 to receive barbiturate coma.

It should be stressed that ICP elevation is a sign and not a diagnosis. When there is a progressive increase in ICP, causes should be looked for. Usually a CT scan should be obtained to rule out a hematoma, mass, hydrocephalus, intraventricular hemorrhage, etc. Other causes, such as hyponatremia and seizures should also be ruled out. Less common causes would include thrombosis of the venous sinuses secondary to injury.

To quantify the amount of therapy required for ICP control, the therapeutic intensity level (TIL) scale will be used (Appendix 4).

Blood Tests

The following tests will be routinely obtained in all patients daily while in the ICU, as a minimum (additional tests and more frequent studies may be necessary):

CBC, platelets, PT/PTT, fibrinogen, fibrinogen split products, thrombin time, electrolytes, sugar, BUN, creatinine, osmolality, liver enzymes, arterial blood gases, CSF cultures, and cell counts.

Nutritional Support

All patients will be maintained with blood sugar determinations q 6 hours for the first 24 hours in awake patients, and for the first seven days in comatose patients. Oral or nasogastric feeding will be started as soon as normal GI function is established. The usual enteral feeding preparations provide 1 calorie/cc. Patients will receive 100 ml/hour (2400 calories/day). Blood sugars will be carefully controlled for either one day (awake patients) or seven days (comatose patients) to maintain blood sugar levels below 120 mg%. Total parenteral nutrition (TPN) will be used in cases where the GI tract is nonfunctional.

FOLLOW-UP

As stated earlier, all patients will have sequential neurological examinations as outlined in Table I. A complete neurologic examination will also be performed at the time of discharge from the hospital. The examinations will follow the standard format of the APHIP forms and include the Glasgow Outcome Scale (Appendix 5).

Similarly, CT scans will be obtained at post-injury days 2 and 7, in addition to the admission and discharge (5 mm cuts) study.

Arrangements will be made with the medical examiner to obtain an autopsy on all patients who die.

PUBLICATION

Authorship

All publications using APHIP data will be reviewed by the Directorate.

THE GLASGOW COMA SCALE

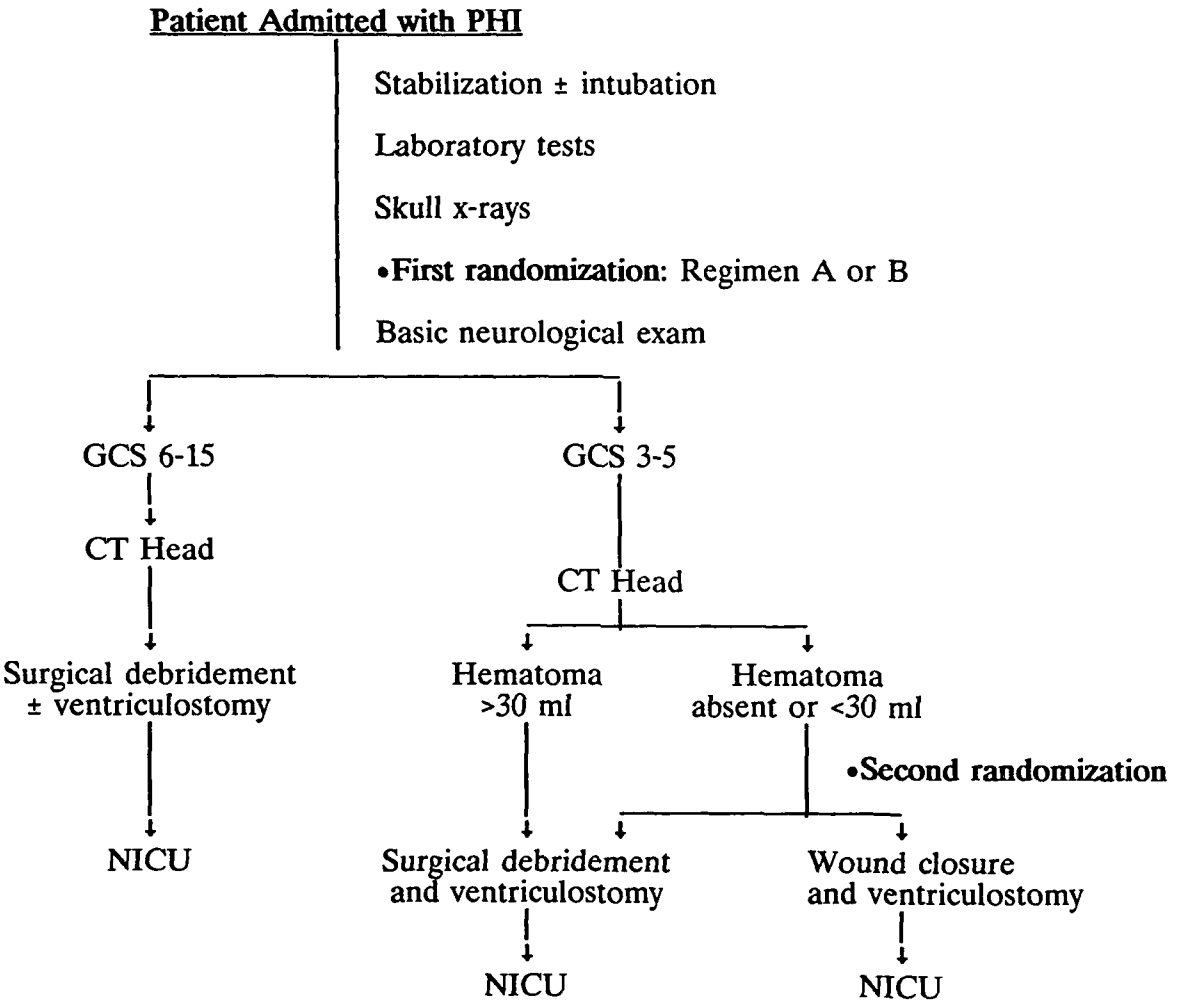
EYE OPENING (E)	
Spontaneous	4
To Call	3
To Pain	2
None	
MOTOR RESPONSE (M)	
Obeys Commands	6
Localizes Pain	5
Normal Flexion (withdrawal)	4
Abnormal Flexion (decorticate)	3
Extension (decerebrate)	2
None (flaccid)	1
VERBAL RESPONSE (V)	
Oriented	5
Confused Conversation	4
Inappropriate Words	3
Incomprehensible Sounds	2
None	1

GCS Score = (E+M+V)

Best Possible Score = 15

Worst Possible Score = 3

MANAGEMENT OF APHIP: FLOW CHART OF PROTOCOL



THERAPEUTIC INTENSITY LEVEL

Sedation		1
Paralysis		1
Hyperventilation	pCO_2>30	1
	pCO_2<30	2
Ventricular drainage	<4/hr	1
	>4/hr	2
Mannitol	<1 gm/kg/shift	3
	>1 gm/kg/shift	6
Barbiturate coma		3

MAXIMUM LEVEL = 15

MINIMUM LEVEL = 0

THE GLASGOW OUTCOME SCALE

GOOD RECOVERY (G)

Complete neurological recovery, or minor deficits that do not prevent the patient from returning to his or her former level of function.

MODERATELY DISABLED (MD)

Deficits present that prevent normal function, but allow self-care.

SEVERELY DISABLED (DS)

Marked deficits present that prevent self-care.

VEGETATIVE (V)

No evidence of higher mental function.

DEAD (D)

APHIP DATA COLLECTION TABLE
MARCH 1988

PARAMETER:	APHIP Forms	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 10	Day 15	Day 20	Day30† or Discharge
GCS	E,U,N	TID	TID	TID	TID	TID	TID	2x/Wk††				Yes
GOS/ Mortality	N,F	PRN										Yes
Vital Signs	H	Daily x 30 days; or discharge, whichever is sooner										
ICP & TIL	O	Hourly while monitor in place										
Drug Side Effects	K	PRN										
Neurologic History&Exam	F	Yes						Yes				Yes
Neurologic Screen (DSS)	N	Yes	Yes	Yes	Yes	Yes	Yes	2xWk		Yes		Yes
Neuropsych Acute Battery	Y		Yes*									
Full Standard Neuropsych	Q								Yes**			
Psychosocial Battery	P,Z											Yes
LABORATORY:	E,U,L											
Coagulation Profile		Yes	Yes	Yes	Yes	Yes	Yes	Yes	PRN	PRN	PRN	PRN
Blood Gases/pH		PRN										
ETOH/ Drug Screen		Yes										
Serum Osmolarity		Yes	PRN	PRN								
SMAC Profile		Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes		Yes
CBC		Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes		Yes
CSF***		Yes	BID	BID	BID	BID		Yes				
Cultures		Surgery	PRN									
Anticonvulsant Levels				Yes						Yes		Yes
SOD Levels		q 8-12 hr post treatment(see Protocol)										
CT Scan	C	Yes	(48±24h) Yes					(d7±1) Yes				(5mm) Yes
MRI (Optional)	R							(d7±1) Yes				Yes
Skull X-Ray	W	Yes										
Physical Examination	N	Yes						Yes				Yes

*Starting when following command for 24h: do neuropsychological screen daily x3, then q.o.d. x3.

**On final day of acute battery or discharge, whichever is sooner.

***When possible via ventricular catheter (see Protocol).

†Or at discharge, whichever is sooner.

††Until stable at 15 for 48 h.

APHIP DATA COLLECTION TABLE
MARCH 1988

OTHER FORMS

(COMPLETE ONCE; EXCEPT S & A FORMS, AS NEEDED)

	APHIP Forms	By Day 14	By Discharge
Base Data	B	X	
Patient Identification	I	X	
Surgical Treatment	S	X	
Patient Diagnoses	D		X
Multiple Injury	M		X
Chronology of Events	V		X
Wound Ballistics	W		X
Complications Summary	X		X
Study Termination Record	A		X

FOLLOW-UP DATA

	APHIP Forms	3 Mos	6 Mos	12 Mos	24 Mos
PARAMETER:					
GOS/Mortality	F	Yes	Yes	Yes	Yes
Neurologic History & Examination	F	Yes	Yes	Yes	Yes
Neurologic Screen (DSS)	F	Yes	Yes	Yes	Yes
Neuropsychological Acute Battery	Y	Yes	Yes	Yes	Yes
Full Standard Neuropsychological	Q	Yes	Yes	Yes	Yes
Psychosocial Battery	P,Z		Yes	Yes	Yes
LABORATORY:	E,U,L				
Coagulation Profile		PRN	PRN		
Anticonvulsant Levels			Yes	Yes	
CT Scan	C				
MRI (Optional)	R		Yes		

CHAPTER IV

INSTRUCTIONS FOR COLLECTION AND TRANSMISSION OF DATA

Eligibility for Patient Entry Into Study

All penetrating head injured patients above age 15 admitted to the hospital who are not brain dead (after resuscitation) will be entered into the study after legal consent is obtained, regardless of gender or the social circumstances of their injury. Patients who are more than 24 hours postinjury will be excluded from the study. A penetrating brain wound is one in which a foreign body or missile has penetrated the skull and dura.

To summarize, study patients include all penetrating head injured patients:

1. Age 15 or older.
2. For whom legal consent is obtained within 24 hours postinjury (24 hours or less).
3. Not brain dead.

The process of entering patients into the study includes assignment of a patient record number, completion of pertinent forms, and administering study treatment as specified in the current protocol.

The quality of the relationship between the nurse clinician and the patient will greatly influence the ability to follow study subjects over time. The higher proportion retained for follow-up, the better our ability to judge long-term effectiveness of the treatments tested.

General Instructions

Once the patient has been entered into the study, folders will be established at the research hospital and at the central facility at Walter Reed Army Medical Center. Original copies of the forms will be sent to Walter Reed, with the research hospitals retaining copies. Data will be entered and stored at the research hospital and transmitted in accordance with the Instructions Section of this manual.

Patient Record Numbers will be assigned to patients by the research hospital with the following prefix:

01 University of Texas Medical Branch, Galveston

02 Baylor College of Medicine, Houston

03 Louisiana State University Medical Center, New Orleans

04 Medical College of Virginia, Richmond

Digits 3-5 are reserved for the sequential number provided for the drug (coded 000 when no drug is being tested). The remainder of the digits are to be filled with the hospital's identifying number assigned the patient.

The first form in this manual is the Emergency Room Log which contains the Reject Log. These logs contain necessary information on patients accepted into, as well as those rejected from the study. The Form Completion form lists forms in the batches in which they need to be transmitted, as well as providing spaces for the nurse clinician to record completion dates. The Patient Identification Form identifies the patient and records information about people likely to have contact with the patient in the future (for follow-up purposes). The remainder of the forms provide places for the standardized recording of the patient's injury, treatment, progress, and outcome through the period of time the patient will be followed in the study. Each data element on the forms is given a complete code with a unique letter and number. Once these forms are completed they will be entered locally into a computer, the data will undergo a series of checks, and then be transmitted.

Each data element has several possible answers. Enter the number which best applies to each individual patient. If you repeatedly find that the answers for a particular data element do not "fit" patients, particularly during the forms testing phase of the study, contact the staff at Walter Reed. "Yes" is generally designated by a 1 and "No" by a 0. When requested, as in the case of laboratory tests and vital signs, fill in the appropriate spaces with the actual values. In the cases where times are requested, a 24-hour clock should be used (i.e., 12:01 p.m. is 1201,) Date are entered into the system as Day/Month/Year (i.e., 01 January 1988).

The observer will fill out a form by writing in the appropriate codes, i.e., O for female. Elements have code U for responses of unknown or untestable, except dates, times and text fields. A high proportion of U codes may be justification for removal of an element from the form.

Some forms are required. All patients will have these filled out; for example, the Patient Identification form. Other forms, such as the Death form, may or may not be filled out, depending on the patient's outcome. If a particular form is not relevant, only the first few items including the Form Completion Code, need to be coded and transmitted.

An accuracy element has been added for some dates and times. These elements will be used to determine whether each duration of time calculated by the computer is accurate or a "best guess".

The data entry clerk and the nurse clinician should both review data forms for accuracy and completeness of the entries.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Name _____

FORM COMPLETION

For Record Keeping Only

Not for Computer Entry

(MAR 88)

DATA COLLECTION FLOW CHART

Form		Current Date	Completed (Check)
I	Patient Identification (Enter [+ Phone Notification] Immediately)		
ER Log	Emergency Room Patient Log (Submit on Monthly Basis)		
B (1B–6B)	Base Data (Enter Within 24 Hours)		
	BATCH I (Due Two Weeks After Admission)		
B	Base Data (Remainder of Form)		
V	Chronology of Events		
E	Early (Pre-Hospital and ER) Evaluation and Treatment		
	BATCH II (Due at Discharge)		
M	Multiple Injury (Acute)		
S	Surgical Treatment		
U	ICU		
O	Intracranial Pressure Monitoring		
N	Neurological Evaluation		
L	Laboratory Data		
C	CT Scan		
R	MRI Scan (Optional)		
W	Wound Ballistics		
X	Complications Summary		
F	Full Neurologic History and Examination		
D	Patient Diagnoses		
A	Study Termination Record		
Y/Q	Neuropsychological		
P/Z	Psychosocial		
H	Vital Signs/Concomitant Therapy Report		
K	Medication Side Effect Report		

FOLLOW-UP EXAMINATION (Fill in Date Completed) (Due two weeks postexamination)

		3 Months	6 Months	1 Year	2 Years
C	CT Scan				
R	MRI Scan (Optional)				
F	Full Neurologic History and Examination				
A	Death Information (if applicable)				
Y	Neuropsychological				
	Patient				
	Family				
Z	Psychosocial				
	Patient				
	Family				

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number ________________

EMERGENCY ROOM PATIENT LOG

TO BE COMPLETED BY NURSE CLINICIAN/RESEARCH COORDINATOR

Not for computer entry.

(MAR 88)

LOG OF ALL PENETRATING HEAD INJURY PATIENTS

(OBTAINED BY NURSE CLINICIAN/RESEARCH COORDINATOR FROM EMERGENCY ROOM RECORDS, ETC.)
[Population: All patients with penetrating brain wounds]

PATIENT NAME/ID	SEX AGE	DATE OF INJURY	CAUSE OF INJURY	ER GCS	ENTERED TRIAL	OUT-COME	DATE OF DISCHARGE	METHOD OF TRANSPORT	REJECT LOG REASON NOT ENTERED INTO TRIAL
	M/F	DD/MM/Yr	☐Suicide ☐Homicide ☐Accident ☐Unknown		☐Yes ☐No If no, enter patient on Reject Log	GOS at Dis-charge ____ U=Unk	DD/MM/Yr	☐Ambulance ☐Private vehicle ☐Helicopter ☐Other (specify)	☐Refused consent ☐Consent not obtainable ☐Brain dead(as defined) ☐Age < 15 ☐>24h postinjury ☐Other (specify)
	M/F	DD/MM/Yr	☐Suicide ☐Homicide ☐Accident ☐Unknown		☐Yes ☐No If no, enter patient on Reject Log	GOS at Dis-charge ____ U=Unk	DD/MM/Yr	☐Ambulance ☐Private vehicle ☐Helicopter ☐Other (specify)	☐Refused consent ☐Consent not obtainable ☐Brain dead(as defined) ☐Age < 15 ☐>24h postinjury ☐Other (specify)
	M/F	DD/MM/Yr	☐Suicide ☐Homicide ☐Accident ☐Unknown		☐Yes ☐No If no, enter patient on Reject Log	GOS at Dis-charge ____ U=Unk	DD/MM/Yr	☐Ambulance ☐Private vehicle ☐Helicopter ☐Other (specify)	☐Refused consent ☐Consent not obtainable ☐Brain dead(as defined) ☐Age < 15 ☐>24h postinjury ☐Other (specify)
	M/F	DD/MM/Yr	☐Suicide ☐Homicide ☐Accident ☐Unknown		☐Yes ☐No If no, enter patient on Reject Log	GOS at Dis-charge ____ U=Unk	DD/MM/Yr	☐Ambulance ☐Private vehicle ☐Helicopter ☐Other (specify)	☐Refused consent ☐Consent not obtainable ☐Brain dead(as defined) ☐Age < 15 ☐>24h postinjury ☐Other (specify)
	M/F	DD/MM/Yr	☐Suicide ☐Homicide ☐Accident ☐Unknown		☐Yes ☐No If no, enter patient on Reject Log	GOS at Dis-charge ____ U=Unk	DD/MM/Yr	☐Ambulance ☐Private vehicle ☐Helicopter ☐Other (specify)	☐Refused consent ☐Consent not obtainable ☐Brain dead(as defined) ☐Age < 15 ☐>24h postinjury ☐Other (specify)
	M/F	DD/MM/Yr	☐Suicide ☐Homicide ☐Accident ☐Unknown		☐Yes ☐No If no, enter patient on Reject Log	GOS at Dis-charge ____ U=Unk	DD/MM/Yr	☐Ambulance ☐Private vehicle ☐Helicopter ☐Other (specify)	☐Refused consent ☐Consent not obtainable ☐Brain dead(as defined) ☐Age < 15 ☐>24h postinjury ☐Other (specify)

EMERGENCY ROOM PATIENT LOG

To Be Completed by Nurse Clinician/Research Coordinator

This form is to be filled out as soon as possible for every patient entering the Emergency Room with a penetrating brain wound without exception, whether they enter the study or not. This form briefly describes the whole population of patients with penetrating brain wounds and contains a Reject Log. It will be our only basis for comparing patients accepted into the study with those rejected from the study. Originals of this form will be sent periodically to the central facility located at Walter Reed Army Medical Center.

ER GCS. GCS after nonsurgical resuscitation.

Include all patients dead on arrival to the hospital; code as Brain Dead.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number_____

Patient Initials_____

STUDY TERMINATION RECORD* FORM A

To Be Completed by Nurse Clinician in Consultation with Study M.D. (Mar 88)

*Complete this form at 30 days from date of injury or at death. If patient remains in follow-up study, complete again when terminated from follow-up study.

1A. This Record Refers to:
- 1 Termination of acute drug study
- 2 Termination of follow-up study

110A. Reason for Discontinuation of Participation in Study
- 0 Study completed
- 1 Protocol violation
- 2 Intolerance to study medication
- 3 Serious adverse reaction (Complete Form K)
- 4 Noncompliance to dosage regimen
- 5 Intercurrent illness
- 6 Death (Complete Cause of Death section below)

120A. If Protocol Violation, specify

_____

130A. If Intolerance to Study Medication, specify

_____

140A. If Noncompliance to Dosage Regimen, specify

_____

2A. Observer (Hospital keeps list of codes)(0–99)

_____

210A. Form Completion Code
Not Completed Because:
- 0 Completed
- 1 Not Relevant
- 2 Other

220A. If Other, specify

_____

3A. Date

__ ___ __
Day Mo Yr

4A. Status of Patient
- 1 Still being observed in hospital
- 2 Discharged from hospital

410A. If Discharged From Hospital (date)
(Leave blank if still in hospital)

__ ___ __
Day Mo Yr

Cause of Death

5A. Reason (text limit 50 words)_____

510A. _____

520A. _____

6A. Date of Death

__ ___ __
Day Mo Yr

6A$. Time of Death

_____:____

7A. Primary Cause of Death
- 0 Not determined
- 1 Not possible to determine
- 2 Systemic wound
- 3 Medical complications
- 4 Head wound

8A. Secondary Cause of Death
- 0 Not determined
- 1 Not possible to determine
- 2 Systemic wound
- 3 Medical complications
- 4 Head wound

9A. Organ Donation
- 0 No
- 1 Yes

10A. Death Occurred
- 1 On arrival
- 2 During resuscitation
- 3 After resuscitation
- 4 After discharge from APHIP hospital

Autopsy

11A. Autopsy Performed By
0 None
1 Pathologist
2 Coroner/medical examiner
3 Neuropathologist

12A. Type of Autopsy
1 Total
2 Head only
3 Incomplete

13A. Date of Autopsy
__ ___ __
Day Mo Yr

13A$. Time of Autopsy
_____ : _____

14A. Did the autopsy findings support the physician's clinical impressions?
0 No*
1 Yes
U Unable to determine
*Enter pertinent information in narrative text

15A. Is a copy of the autopsy report available for examination?
0 No
1 Yes

16A. Narrative (Text limit 50 words)_____

1610A. _____

1620A. _____

1630A. _____

17A. Name of Principal Investigator (PI) (Please print)_____

1710A. Signature of PI_____

1720A. Date __ ___ __
Day Mo Yr

FORM A

STUDY TERMINATION RECORD

To Be Completed by Nurse Clinician
in Consultation with PI or Trauma Fellow

This record is to be completed (1) at termination of participation in the drug study either because of death, withdrawal from study, discharge, or end of 30-day postinjury period; and (2) at termination of follow-up study either because of death, withdrawal from study, or completion of two-year follow-up period.

110A. REASON FOR DISCONTINUATION. Other than because of death or normal completion of study at hospital discharge or 30 days, patients will be discontinued from participation in study only after consultation with PI and USUHS. Presence of items 1-5 will not necessarily result in study termination for the patient.

2A. OBSERVER. If nurse clinician or physician collects the autopsy information, enter appropriate code. Otherwise, code Observer=20 (representing data collected by one of the choices in 7A).

210A. FORM COMPLETION CODE. This item must always be completed.

Cause of Death

If no autopsy is performed, complete items 6A through 10A only.

6A. DATE OF DEATH. Enter dd/mm/yr.

6A$. TIME OF DEATH. Enter time of death using 24-hour clock.

When coding primary and secondary causes of death, every effort should be made to determine if death was caused by the head injury, other trauma, or medical complications of coma. if this is impossible, for instance in the case of a multiple trauma victim who develops sepsis without an identified source, code *"not possible to determine"*.

Codes: 0=Not Determined
1=Not Possible to Determine
2=Systemic Wound
3=Medical Complications
4=Head Wound

7A. PRIMARY CAUSE OF DEATH. Enter appropriate code.

8A. SECONDARY CAUSE OF DEATH. Enter appropriate code.

9A. ORGAN DONATION. 0=No 1=Yes

10A. DEATH OCCURRED.

1=**On Arrival.** Includes DOA's and organ donors.
2=**During Resuscitation.** During nonsurgical resuscitation for the head injury, or during surgical resuscitation for a nonintracranial injury.
3=**Post Resuscitation.** Expiration after resuscitation.
4=**After Discharge from APHIP Hospital.** Include patients who expire after transfer to rehabilitation.

Autopsy

11A. AUTOPSY PERFORMED BY.

0=None
1=Pathologist
2=Coroner/Medical Examiner
3=Neuropathologist

12A. TYPE OF AUTOPSY.

1=Total 2=Head Only 3=Incomplete

13A. DATE OF AUTOPSY. Enter dd/mmm/yr of autopsy.

13A$. TIME OF AUTOPSY. Enter time of autopsy using 24-hour clock.

14A. DID THE AUTOPSY FINDINGS SUPPORT YOUR CLINICAL IMPRESSIONS?

0=No (enter pertinent information as to why it did not in narrative text)
1=Yes
U=Unable to Determine (Enter pertinent information as to why in narrative text)

15A. IS A COPY OF THE AUTOPSY REPORT AVAILABLE FOR EXAMINATION?

0=No
1=Yes (If yes, a copy must be in patient's study file and be submitted to the central office)

16A. NARRATIVE. Narrative of autopsy findings.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

BASE DATA

To Be Completed by Nurse Clinician

FORM B

(Mar 8)

1B. **Date**

__ __ __
Day Mo Yr

110B. **Date of Injury**

__ __ __
Day Mo Yr

110B$. **Time of Injury**

_____:_____

2B. **Observer** (Hospital keeps list of codes)(0–99)

_____

210B. **Form Completion Code**
0 Completed
1 Not Completed

220B. **If Not Completed, specify**

_____

3B. **Accuracy of Date of Injury**
1 Date correct
2 Day guessed
3 Day & month guessed
4 Day, month & year guessed

4B. **Accuracy of Time of Injury**
1 Time correct
2 Minutes guessed
3 Hours & minutes guessed

5B. **Source of Information** (Circle all that apply)
1 Patient
2 Family
3 Friend
4 Ambulance Attendant
0 Other

510B. **If Other, specify**

_____

6B. **Medical Record Number**

_____

7B. **GCS** (Determined at Time of Randomization, Post Nonsurgical Resuscitation)

_____(3-15)

8B. **GCS at Administration of Drug**

_____(3-15)

9B. **Date Patient Randomized**

__ __ __
Day Mo Yr

9B$. **Time Patient Randomized** (24 Hour Clock)

_____:_____

10B. **Surgical Randomization**
0 Delayed surgery
1 Prompt surgery
2 Not applicable, GCS 6-15 or CT lesion > 30cc

11B. **GCS Just Prior to Surgery**
(enter 00 if no surgery)

_____(3-15)

MEDICAL HISTORY

Neurological Problems

		No	Yes	Unknown
1210B.	Head Injury	0	1	U
1220B.	Spinal Injury	0	1	U
1230B.	Stroke	0	1	U
1240B.	Seizures/Posttraumatic acquired	0	1	U
1250B.	Seizures/Idiopathic	0	1	U
1260B.	Seizures/Alcohol	0	1	U

Mental-Psychiatric Problems

1310B.	Retardation	0	1	U
1320B.	Psychosis	0	1	U
1330B.	Dementia	0	1	U

Medical Problems

1410B.	Hypertension	0	1	U
1420B.	Cardiovascular	0	1	U
1430B.	Pulmonary Insufficiency	0	1	U
1440B.	Renal	0	1	U
1441B.	Other Genitourinary	0	1	U
1450B.	Hepatic	0	1	U
1460B.	GI Bleeding	0	1	U
1461B.	Other Gastrointestinal	0	1	U
1470B.	Coagulopathy	0	1	U
1471B.	Other Hematologic	0	1	U
1480B.	Diabetes Mellitus	0	1	U
1481B.	Other Endocrine	0	1	U
1482B.	Dermatologic	0	1	U
1483B.	Allergies	0	1	U
1484B.	Lymphatic	0	1	U
1485B.	Eyes, Ears, Nose, & Throat	0	1	U
1486B.	Musculoskeletal	0	1	U

Prescribed Medications Used Regularly

1510B.	Antihypertensive	0	1	U
1520B.	Anticonvulsants	0	1	U
1530B.	Anticoagulants	0	1	U
1540B.	Psychotropic	0	1	U
1550B.	Other	0	1	U

1551B. If Other (specify)_____

16B. Alcohol Intake (Choose One)
- 0 None (<2 times/year)
- 1 Occasional (<2 times/week)
- 2 Regular (at least 2 times/week)
- 3 Excessive
- U Unknown

17B. Nonprescribed Drug Intake (Choose One)
- 0 None (<times/year)
- 1 Occasional (<2 times/week)
- 2 Regular (at least 2 times/week)
- 3 Excessive
- U Unknown

18B. Previous Major Neurologic Deficit (see Manual)

		No	Yes	Amputation	Unknown
1810B.	Left Arm	0	1	2	U
1820B.	Right Arm	0	1	2	U
1830B.	Left Leg	0	1	2	U
1840B.	Right Leg	0	1	2	U

		No	Diminished Acuity	Removed/ Blind	Unknown
1850B.	Left Eye	0	1	2	U
1860B.	Right Eye	0	1	2	U
1870B.	Facial	0	1		U

19B. Handedness
- 1 Right
- 2 Left
- 3 Ambidextrous
- U Unknown

20B. Other Pertinent Prior Medical History, Comments (Text limit 50 words)

2010B. _____

2020B. _____

2030B. _____

2040B. _____

2110B. **Written Informed Consent**
2111B. Person Giving Consent_____

2112B. Witness (M.D.)_____

2113B. Other Witness_____

2120B. **Telephone Informed Consent**
2121B. Person Giving Consent_____

2122B. Witness(es) (M.D.)_____

2123B. Other Witness_____

22B. **Birth Date**

__ __ ____
Day Mo Yr

23B. **Age** (16-99) __

24B. **Accuracy of Age**
1 Age correct
2 Age guessed

25B. **Sex**
1 Female
2 Male

26B. **Hispanic Origin**
0 No
1 Yes
U Unknown

27B. **Marital Status** (Choose One)
1 Never married
2 Married
3 Separated
4 Single, unspecified
5 Divorced
6 Widowed
7 Living together
U Unknown

28B. **Education**
1 None
2 1-8 years
3 Some high school
4 High school graduate
5 Vocational
6 Some college
7 College graduate
8 Postgraduate
U Unknown

29B. **Total Household Income**
1 <3,000
2 3,000-4,999
3 5,000-6,999
4 7,000-9,999
5 10,000-11,999
6 12,000-14,999
7 15,000-24,999
8 25,000-34,999
9 ≥35,000
U Unknown

30B. **Race** (Choose One)
1 White
2 Black
3 American Indian/Alaskan
4 Asian/Pacific Islander
U Unknown

31B. **Primary Language** (Choose One)
1 English
2 Spanish
3 Other
U Unknown

32B. **Medical Insurance**
0 No
1 Yes
U Unknown

33B. **Employment Status** (Choose One)
1 Full-time
2 Part-time
3 Homemaker
4 Student
5 Unemployed
6 Retired
U Unknown

34B. **Unemployed or Retired for Medical Reason**
0 No
1 Yes
U Unknown

35B. **Major Occupation** (see Occupation Code List)

_____Code
998 Other
U Unknown

351B. **If Other** (Code 998), Specify

_____

36B. **County of Residence**
(see Manual; Use Codes 1–300)

_____Code
A Out of state
U Unknown

37B. **How Long Married** (0-75)

_____Years
U Unknown

38B. **How Many Times Married** (0-10)

_____
U Unknown

FORM B

BASE DATA AND PAST MEDICAL HISTORY

To Be Completed by Nurse Clinician in Consultation with Study Physician

Information gathered related to PAST MEDICAL HISTORY will obviously be dependent upon the quality of the family as historians. In most categories, previous diagnosis by an M.D. will be the major prerequisite. These conditions must have been diagnosed prior to the current traumatic event.

1B-110B$. DATE AND TIME OF INJURY. Enter the date and time of the patient's injury. If exact date is unknown, approximate the closest one. If exact time is unknown, attempt to approximate closest time. In the event that a time approximation is impossible, enter 12:00 (use 24 hour clock).

2B. OBSERVER. Hospital maintains list of codes. Enter 0-99.

3B-4B. ACCURACY. See page 6 of this Manual.

6B. MEDICAL RECORD NUMBER. Enter numerals only, followed by two digit center code.

10=Galveston
20=Houston
30=Richmond
40=New Orleans

7B. GCS AT TIME OF RANDOMIZATION. This is the GCS score that determined the patient's grouping for randomization. It is determined AFTER initial resuscitation.

8B. GCS AT ADMINISTRATION OF STUDY DRUG (this is usually the same as 7B)

9B. DATE OF RANDOMIZATION.

9B$. TIME OF RANDOMIZATION (24 hour clock).

10B. SURGICAL RANDOMIZATION GROUP.

11B. GCS JUST PRIOR TO SURGERY.

1210B-1551B. PAST MEDICAL HISTORY

CODES. 0=No 1=Yes U=Unknown

NEUROLOGICAL PROBLEMS

1210B. HEAD INJURY. Injury to the head resulting in hospitalization; include penetrating injuries. Exclude facial trauma unless it results in unconsciousness and hospitalization.

1220B. SPINAL INJURY. Diagnosed by M.D., by either radiographic or neurological signs.

1230B. STROKE. Diagnosed by M.D.

1240B. SEIZURES: POST TRAUMATIC ACQUIRED. One or more focal or generalized seizure which began after a *previous* head injury.

1250B. SEIZURES: IDIOPATHIC. One or more focal or generalized seizures with no proven predisposing cause. Include birth trauma here.

1260B. SEIZURES: ALCOHOL. Seizures which occur only during period of high alcohol consumption or withdrawal from alcohol.

MENTAL-PSYCHIATRIC PROBLEMS. Any of the following conditions *diagnosed by a physician.*

1310B. RETARDATION.

1320B. PSYCHOSIS.

1330B. DEMENTIA.

MEDICAL PROBLEMS (If Yes, expand in "Comments" section)

1410B. HYPERTENSION. Diagnosed by M.D.

1420B. CARDIOVASCULAR DISEASE. Diagnosed by M.D.

1430B. PULMONARY INSUFFICIENCY. Diagnosed by M.D. Include all lung diseases.

1440B. RENAL. Diagnosed by M.D.

1441B. OTHER GENITOURINARY.

1450B. HEPATIC. Diagnosed by M.D.

1460B. GI BLEEDING. Vomited blood or passed melanotic stools.

1461B. OTHER GASTROINTESTINAL.

1470B. COAGULOPATHY. Diagnosed by M.D.

1471B. OTHER HEMATOLOGIC.

1480B. DIABETES MELLITUS. Diagnosed by M.D., and treated with diet or medication.

1481B. OTHER ENDOCRINE. Diagnosed by M.D.

1482B. DERMATOLOGIC. Diagnosed by M.D.

1483B. ALLERGIES. Diagnosed by M.D.

1484B. LYMPHATIC. Diagnosed by M.D.

1485B. EYES, EARS, NOSE, & THROAT. Diagnosed by M.D.

1486B. MUSCULOSKELETAL. Diagnosed by M.D.

MEDICATIONS. Indicate if patient is using medications specified regularly.

1510B. ANTIHYPERTENSIVES.

1520B. ANTICONVULSANTS.

1530B. ANTICOAGULANTS.

1540B. PSYCHOTROPIC.

16B. ALCOHOL INTAKE. By family's report. Include any report of beer, wine, or any alcoholic beverage taken in any quantity.

0=None. Less than two times/year.
1=Occasional. More than none, but less than two times/week.
2=Regular. At least two times/week or more.
3=Excessive. Previous hospitalization for alcoholism, family report of drinking problem.
U=Unknown.

17B. DRUG INTAKE. By family's report. *Drug* is intended to refer to a pharmacological agent taken orally, parenterally, or insufflated, that was not prescribed by a physician. It includes sedatives, narcotics, neuroleptics, amphetamines, street drugs, antipsychotics. It does not include such things as antibiotics, antacids, or others which are not known to alter consciousness in any way.

0=None. Less than two times/year.
1=Occasional. More than none, but less than two times/week.
2=Regular. At lease two times/week or more.
3=Excessive. History of drug abuse.
U=Unknown.

PREVIOUS NEUROLOGIC DEFICIT. Include any condition which was present before the current injury and might affect the neurological exam in the listed extremity or area.

1810B.	LEFT ARM.	0=No	1=Yes	2=Amputation	U=Unknown
1820B.	RIGHT ARM.	0=No	1=Yes	2=Amputation	U=Unknown
1830B.	LEFT LEG.	0=No	1=Yes	2=Amputation	U=Unknown
1840B.	RIGHT LEG.	0=No	1=Yes	2=Amputation	U=Unknown

1850B. LEFT EYE. 0=No 1=Diminished Acuity 2=Removed/Blind U=Unknown

1860B. RIGHT EYE. 0=No 1=Diminished Acuity 2=Removed/Blind U=Unknown

1870B. FACIAL. 0=No 1=Diminished Acuity U=Unknown

19B. HANDEDNESS. Hand used for writing.

2010B-2040B. OTHER MEDICAL HISTORY. Text item limit, 50 characters. Describe other pertinent past medical history.

2111B. 2121B. Relationship of person giving consent; i.e., patient, next-of-kin, or legal guardian.

2112B. 2122B. Name of physician counselling patient.

2113B. 2123B. Name of nurse or other witness.

22B. BIRTH DATE. If age unknown, estimate year and use 01 July as the date.

25B. SEX. 0=Female 1=Male

26B. HISPANIC ORIGIN (CHOOSE ONE). A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture of origin regardless of race, may be considered Hispanic.

Codes: 0=No 1=Yes
U=Unknown

27B. MARITAL STATUS (CHOOSE ONE). Enter the *current* marital status of the patient.

1=Never Married. Currently single and never previously married.
2=Married. Currently married.
3=Separated. Married, but not living with spouse.
4=Single. Unspecified. Currently living with a partner, prior marital status unknown.
5=Divorced. Currently legally divorced.
6=Widowed. Married until spouse died.
7=Living Together. An unmarried couple sharing a home.
U=Unknown.

28B. EDUCATION. Choose highest grade level completed.

1=**None.** Has had no formal education (include preschoolers).
2=**1-8 Years.** Last school grade completed was grade 8 or lower.
3=**Some High School.** Attended some high school, but did not receive a diploma. Grade 9 or above completed.
4=**High School Graduate.** Received high school diploma, and did not continue formal education.
5=**Vocational Training.** Noncollege business or technical schooling (i.e., beautician or secretarial training).
6=**Some College.** Attended college classes, but did not receive a degree.
7=**College Graduate.** Received BA, BS, AA, or similar degree from college or university.
8=**Postgraduate.** Attended a graduate or professional (medical, law, or business) school or university (with or without receiving a graduate degree).
U=**Unknown.**

29B. TOTAL HOUSEHOLD INCOME of all family members living in household with patients. For a child, the parent(s) income (gross income).

1=<$ 3,000	6= $12,000-$14,999
2= $ 3,000-$ 4,999	7= $15,000-$24,999
3= $ 5,000-$ 6,999	8= $25,000-$34,999
4= $ 7,000-$ 9,999	9=>$35,000
5= $10,000-$11,999	U=Unknown

30B. RACE (CHOOSE ONE). By observation or by patient's choice (US Census Categories).

1=**White:** A person having origins in any of the original peoples of Europe, North Africa, or the Middle Ease.
2=**Black:** A person having origins in any of the Black racial groups of Africa.
3=**American Indian or Alaskan Native:** A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.
4=**Asian or Pacific Islander:** A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian Subcontinent, or the Pacific Islands. This area includes for example: China, India, Japan, Korea, the Philippine Islands, and Samoa.
U=**Unknown.**

31B. PRIMARY LANGUAGE. Language(s) most frequently used at present. If fluent in English and Spanish, circle both.

33B. EMPLOYMENT STATUS at the time of accident.

1=**Full Time.** Approximately 40 hours/week or more.
2=**Part Time.** Generally less than 35 hours/week.
3=**Homemaker.** Homemaker, not paid for work outside the home.
4=**Student.** Registered, full time student.
5=**Unemployed.** Not currently employed.
6=**Retired.** Retired and not working another job.
U=**Unknown.**

34B. UNEMPLOYED OR RETIRED FOR MEDICAL REASON. Self-explanatory.

35B. MAJOR OCCUPATION. Data collector should record occupation as specifically as possible. Data entry person will code the occupation from the Census derived code list in Regional Appendix V. Enter 1-999.

998=**Other** U=**Unknown**

36B. COUNTY OF RESIDENCE. Each hospital has a list of local counties which are kept in Regional Appendix II. Enter 1-300.

A=**Universal code for out-of-state resident.**
U=**Unknown**

37B. HOW LONG MARRIED. Enter number of years patient married to present spouse.

38B. HOW MANY TIMES MARRIED. Enter number of times patient married, including present marriage.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

CT SCAN

TO BE COMPLETED BY THE RADIOLOGIST OR STUDY M.D.

FORM C

(Mar 88)

		Pretreat			
1C.	DATE				
1C$.	TIME				
2C.	OBSERVER (Hospital keeps list of codes) (0–99)				
210C.	FORM COMPLETION CODE: 0=Completed 1=Not Completed				
220C.	IF NOT COMPLETED (Specify)				
3C.	VISIT TYPE: 1=Hospital admission 2=ICU admission 3=In hospital ICU 4=Discharge from ICU 5=In hospital, not ICU 6=Hospital discharge 7=Follow–up 8=Death 9=Recovery room 12=Other				
310C.	SCAN STATUS: 0=New Scan 1=Recode 2=Re–entry of original data 3=Unable to read; CT obtained, scan missing 4=Neuroradiology report				
4C.	EXAM RESULT: 0=Normal 1=Abnormal				
5C.	QUALITY OF CT SCAN: 4=Readable 5=Unreadable U=Unknown				
510C.	COMPLETENESS OF SCAN: 0=Complete 1=Incomplete U=Unknown				
7C.	IV CONTRAST INJECTION: 0=No 1=Yes U=Unknown				
810C.	LEFT LATERAL VENTRICLE: 0=Normal 1=Enlarged 2=Small 3=Absent U=Unknown				
820C.	RIGHT LATERAL VENTRICLE: 0=Normal 1=Enlarged 2=Small 3=Absent U=Unknown				
9C.	VENTRICULAR BRAIN RATIO* (1–35.0) 1=Ventricles too small to measure U=Unknown				
10C.	SYMMETRY OF VENTRICULAR SYSTEM: Code=1 if frontal horns and body asymmetric in any cut 0=Symmetric 1=Asymmetric U=Unknown				
11C.	MESENCEPHALIC CISTERNS: 0=Absent or compressed (may be unilateral) 1=Present U=Unknown				
12C.	INTRAVENTRICULAR BLOOD: 0=No 1=Small 2=Moderate 3=Large U=Unknown				
121C.	LOCATION OF BLOOD: 1=Right lateral ventricle 2=Left lateral ventricle 3=Third ventricle				
13C.	MIDLINE STRUCTURES(Choose One): 0=Normal 1=Left to right supratentorial shift 2=Right to left supratentorial shift U=Unknown				
14C.	SHIFT SIZE (mm): Measure the largest extent of shift of any midline structure (0–35) U=Unknown				
15C.	POSTERIOR FOSSA (Choose One): 0=Normal 1=Left to right infratentorial shift 2=Right to left infratentorial shift 3=Not visible U=Unknown				
16C.	DIFFUSE BRAIN ATROPHY: 0=No 1=Yes U=Unknown				
17C.	EXTRACEREBRAL AIR: 0=No 1=Yes U=Unknown				
18C.	INTRAPARENCHYMAL AIR: 0=No 1=Yes U=Unknown				
19C.	INTRAVENTRICULAR AIR: 0=No 1=Yes U=Unknown				
20C.	SUBARACHNOID HEMORRHAGE: 0=No 1=Yes U=Unknown				

Note: When other codes are not appropriate due to insufficient information, poor scan, not enough cuts, etc., use code for unknown.

*VBR's should be measured on those patients surviving at discharge. Measure on the first scan and on the scans closest to 30 days and six months post–injury; otherwise code unknown.

Side Codes	Site Codes			Foreign Body Codes
0=None	0=None	6=Thalamus	13=Posterior Fossa	0=None
1=Right	1=Frontal	7=Cerebellum	U=Unknown	1=Bone
2=Left	2=Temporal	9=Corpus Callosum	N=Nonconfluent	2=Metal
3=Midline	3=Parietal	10=Pons		3=Bone and Metal
6=Bilateral	4=Occipital	11=Midbrain		4=Other (specify in commands)
U=Unknown	5=Basal Ganglia	12=Medulla		U=Unknown

Lesions are measured if the volume of the total lesion is ≥ 10cc. The total lesion mass volume includes both the high or mixed density and the associated low density components. The total volume of the mass must be ≥ either component. Measure volumes by cursing the area of the lesion component on each slice, and stack the slices. The low density component is determined by measuring the volume of the total lesion and subtracting the high density component. Components of lesions less than 10cc total will be coded as 0 (absent) or X (1–9cc).

All junctional lesion sites are coded with multiple numbers (i.e., frontal parietal=1,3).

Lesion identification will remain constant throughout all scans; i.e., Lesion A, or Lesion 1, etc.

N is added to site codes if lesion becomes nonconfluent.

EXTRACEREBRAL LESIONS

21C.	Lesion A				
	Side				
2110C.	Site(s) (Code 0, 1, 2, 3, 4, and/or 13)				
2120C.	Vol High or Mixed Density Component(0–600 cc)(code 0 or X if total lesion <10cc)				
2130C.	Vol Low Density Component (0–600 cc)(code 0 or X if total lesion <10cc)				
22C.	Lesion B				
	Side				
2210C.	Site(s) (Code 0, 1, 2, 3, 4, and/or 13)				
2220C.	Vol High or Mixed Density Component(0–600 cc)(code 0 or X if total lesion <10cc)				
2230C.	Vol Low Density Component (0–600 cc)(code 0 or X if total lesion <10cc)				
23C.	Lesion C				
	Side				
2310C.	Site(s) (Code 0, 1, 2, 3, 4, and/or 13)				
2320C.	Vol High or Mixed Density Component(0–600 cc)(code 0 or X if total lesion <10cc)				
2330C.	Vol Low Density Component (0–600 cc)(code 0 or X if total lesion <10cc)				
24C.	Lesion D				
	Side				
2410C.	Site(s) (Code 0, 1, 2, 3, 4, and/or 13)				
2420C.	Vol High or Mixed Density Component(0–600 cc)(code 0 or X if total lesion <10cc)				
2430C.	Vol Low Density Component (0–600 cc)(code 0 or X if total lesion <10cc)				

INTRACEREBRAL LESIONS (Enter by order of size)

25C.	Lesion 1				
	Side				
2510C.	Site(s)				
2520C.	Foreign Body				
2530C.	Vol High Density Component (cc)(code 0 or X if total lesion <10cc)				
2540C.	Vol Associated Low Density Component(Edema)(cc)(code 0 or X if lesion <10cc)				
26C.	Lesion 2				
	Side				
2610C.	Site(s)				
2620C.	Foreign Body				
2630C.	Vol High Density Component (cc)(code 0 or X if total lesion <10cc)				
2640C.	Vol Associated Low Density Component(Edema)(cc)(code 0 or X if lesion <10cc)				
27C.	Lesion 3				
	Side				
2710C.	Site(s)				
2720C.	Foreign Body				
2730C.	Vol High Density Component (cc)(code 0 or X if total lesion <10cc)				
2740C.	Vol Associated Low Density Component(Edema)(cc)(code 0 or X if lesion <10cc)				

Side Codes	Site Codes			Foreign Body Codes
0=None	0=None	6=Thalamus	13=Posterior Fossa	0=None
1=Right	1=Frontal	7=Cerebellum	U=Unknown	1=Bone
2=Left	2=Temporal	9=Corpus Callosum	N=Nonconfluent	2=Metal
3=Midline	3=Parietal	10=Pons		3=Bone and Metal
6=Bilateral	4=Occipital	11=Midbrain		4=Other (specify in commands)
U=Unknown	5=Basal Ganglia	12=Medulla		U=Unknown

28C.	Lesion 4				
	Side				
2810C.	Site(s)				
2820C.	Foreign Body				
2830C.	Vol High Density Component (cc)(code 0 or X if total lesion <10cc)				
2840C.	Vol Associated Low Density Component(Edema)(cc)(code 0 or X if lesion <10cc)				
29C.	Lesion 5				
	Side				
2910C.	Site(s)				
2920C.	Foreign Body				
2930C.	Vol High Density Component (cc)(code 0 or X if total lesion <10cc)				
2940C.	Vol Associated Low Density Component(Edema)(cc)(code 0 or X if lesion <10cc)				
30C.	Lesion 6				
	Side				
3010C.	Site(s)				
3020C.	Foreign Body				
3030C.	Vol High Density Component (cc)(code 0 or X if total lesion <10cc)				
3040C.	Vol Associated Low Density Component(Edema)(cc)(code 0 or X if lesion <10cc)				
31C.	Lesion 7				
	Side				
3110C.	Site(s)				
3120C.	Foreign Body				
3130C.	Vol High Density Component (cc)(code 0 or X if total lesion <10cc)				
3140C.	Vol Associated Low Density Component(Edema)(cc)(code 0 or X if lesion <10cc)				
32C.	Lesion 8				
	Side				
3210C.	Site(s)				
3220C.	Foreign Body				
3230C.	Vol High Density Component (cc)(code 0 or X if total lesion <10cc)				
3240C.	Vol Associated Low Density Component(Edema)(cc)(code 0 or X if lesion <10cc)				
33C.	Lesion 9				
	Side				
3310C.	Site(s)				
3320C.	Foreign Body				
3330C.	Vol High Density Component (cc)(code 0 or X if total lesion <10cc)				
3340C.	Vol Associated Low Density Component(Edema)(cc)(code 0 or X if lesion <10cc)				
34C.	Lesion 10				
	Side				
3410C.	Site(s)				
3420C.	Foreign Body				
3430C.	Vol High Density Component (cc)(code 0 or X if total lesion <10cc)				
3440C.	Vol Associated Low Density Component(Edema)(cc)(code 0 or X if lesion <10cc)				
35C.	Device Used To Measure Lesions 0=No longer measured 1=Planimeter 2=Computer 3=Grid				

68C. Comments (Text limit 50 words)

6810C.

6820C.

6830C.

FORM C

CT SCAN

This form is to be completed by the neurosurgeon treating the patient, or the designated study radiologist. Record the date and time that the scan was performed.

1C. **DATE.** Enter dd/mmm/yr.

1C$. **TIME.** Record time of CT scan.

2C. **OBSERVER.** Hospital keeps list of codes. Enter M.D. code(s).

210C. **Scan Status.**

3C. **VISIT TYPE.** Record most appropriate code.

1=Hospital Admission	6=Hospital Discharge
2=ICU Admission	7=Follow-Up
3=In-Hospital ICU	8=Death
4=Discharge from ICU	9=Recovery Room
5=In Hospital, not ICU	12=Other

4C. **EXAM RESULT.** Code as **normal** only if it is a totally normal scan; otherwise, code **abnormal**. Disregard skull fractures unless indriven bone fragments present.

5C. ***QUALITY OF SCAN.***

1=Readable
2=Unreadable
3=Unknown

510C. **COMPLETENESS OF SCAN.** Complete=≤10 mm slices of entire brain.

7C. **CONTRAST.**

0=No
1=Yes, if contrast material was used
U=Unknown

810C. **LEFT VENTRICLE SIZE.**

0=Normal	2=Small	U=Unknown
1=Enlarged	3=Absent	

820C. **RIGHT VENTRICLE SIZE.**

0=Normal	2=Small	U=Unknown
1=Enlarged	3=Absent	

9C. VENTRICULAR BRAIN RATIO. Using the CT slice showing the ventricles at their largest extent (through the body of the lateral ventricles), curse the perimeter of the lateral ventricles and the inner table of the skull. Divide the ventricular area by the intracranial area and multiply by 100 to yield a ventricle-brain percent ratio (VBR). The procedure should be repeated three times, by the same examiner, and the average score entered as the VBR. If the ventricles are too small to measure, enter an arbitrary value of 1.
U=Unknown; Enter 1.0-35.0

10C. SYMMETRY OF VENTRICULAR SYSTEM.

0=Symmetric
1=Asymmetric
U=Unknown

11C. MESENCEPHALIC CISTERNS.

0=Absent or Compressed (may be unilateral)
1=Present
U=Unknown

12C. INTRAVENTRICULAR BLOOD.

0=No
1=Small
2=Moderate
3=Large
U=Unknown

13C. *MIDLINE STRUCTURES.*

0=Normal
1=Left to Right Supratentorial Shift
2=Right to Left Supratentorial Shift
U=Unknown

14C. SHIFT SIZE. Record in millimeters using conversion factor appropriate for your scanner. U=Unknown, Enter 0-35 mm.

15C. POSTERIOR FOSSA.

O=Normal
1=Left to Right Infratentorial Shift
2=Right to Left Infratentorial Shift
3=Not Visible
U=Unknown

16C.	DIFFUSE BRAIN ATROPHY.	0=No	1=Yes	U=Unknown
17C.	EXTRACEREBRAL AIR.	0=No	1=Yes	U=Unknown
18C.	INTRAPARENCHYMAL AIR.	0=No	1=Yes	U=Unknown
19C.	INTRAVENTRICULAR AIR.	0=No	1=Yes	U=Unknown
20C.	SUBARACHNOID HEMORRHAGE.	0=No	1=Yes	U=Unknown

EXTRACEREBRAL LESIONS

Use this section to code those extracerebral lesions which are >10 cc in volume.

Side Codes:	**0=None**	**2=Left**	**6=Bilateral**
	1=Right	**3=Midline**	**U=Unknown**
Site Codes:	**0=None**	**5=Basal Ganglia**	**11=Midbrain**
	1=Frontal	**6=Thalamus**	**12=Medulla**
	2=Temporal	**7=Cerebellum**	**13=Posterior Fossa**
	3=Parietal	**9=Corpus Callosum**	**U=Unknown**
	4=Occipital	**10=Pons**	**N=Nonconfluent**
Foreign Body Codes:	**0=None**	**3=Bone and Metal**	
	1=Bone	**4=Other** (Specify in Commands)	
	2=Metal	**U=Unknown**	

Lesions are measured if the volume of the total lesion is ≥ 10cc. The total lesion mass volume includes both the high or mixed density and the associated low density components. The total volume of the mass must be ≥ either component. Measure volumes by cursing the area of the lesion component on each slice, and stack the slices. The low density component is determined by measuring the volume of the total lesion and subtracting the high density component. Components of lesions less than 10cc total will be coded as 0 (absent) or X (1-9cc).

All junctional lesion sites are coded with multiple numbers (i.e., frontal parietal=1,3).

Lesion identification will remain constant throughout all scans; i.e., Lesion A, or Lesion 1, etc.

N is added to site codes if lesion becomes nonconfluent.

Lesion identification remains constant throughout all scans; e.g., if Lesion "A" disappears by the second or third scan, then it is still coded with a volume of "0". If a new lesion appears after the initial scan, then begin coding it on that date with the next available letter (for extracerebral lesions) or number (for intracerebral lesions).

Small lesion (under 10cc <u>total</u> volume) need not be measured. For estimated volumes between 1-9 cc, record as "X". If a large lesion becomes smaller than 10cc, then its volumes can be coded as "X" (or "0" if it becomes absent).

When a lesion is first recorded, it must have either a number (cc's) or an "X" in either the high density or low density boxes, or both.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

PATIENT DIAGNOSES*

TO BE COMPLETED BY NURSE CLINICIAN
(ONLY IN CONSULTATION WITH STUDY M.D.)

FORM D
(Mar 88)

*Complete on hospital discharge or death only.

1D. Date ___ ___ ___
Day Month Yr

1D$. Time _____ : _____

2D. Visit Type 6=Hospital discharge 8=Death

3D. Observer (Hospital keeps list of codes) (0–99)
_____

4D. Intracranial Diagnosis
(Use Codes 1–16 on back of form)
(Multiple Codes May be Used)
_____

5D. Penetrating Injury
1=GSW
2=Other

6D. If Gun, Type of Gun
1=Hand 4=Other
2=Rifle A=Not a gunshot wound
3=Shotgun U=Unknown

7D. Caliber of Gun
1=Small (22 or 25)
2=Medium (32, 38, 357, or 9mm)
3=Large (41, 44, or 45)
4=Shotgun
A=Not a gunshot wound
U=Unknown

8D. Distance Between Gun and Patient
1=Contact
2=Close(noncontact and<2 feet)
3=Far (greater than 2 feet)
A=Not a gunshot wound
U=Unknown

Mass Lesion (9D-11D)
(>15 cc or evacuated)
Codes: 0=None 1=Subdural 2=Intra-cerebral 3=Epidural 4=Hemorrhagic contusion 5=Intracerebellar

9D. Primary _____
10D. Secondary _____
11D. Tertiary _____

Skull Fracture (12D-17D)
Codes: 0=No 1=Yes U=Unknown

12D. Compound _____
13D. Linear _____
14D. Depressed _____
15D. Basilar _____
16D. Multiple _____
17D. Other _____
171D. If Other, specify
_____

18D. Glasgow Outcome Scale
1=Good
2=Moderate
3=Severe
4=Vegetative
5=Dead

Factors Contributing to Outcome in Rank Order
(Use Codes 1–28 on back of form)

19D. Primary _____
20D. Secondary _____
21D. Tertiary _____

22D. Date of Discharge from ICU
___ ___ ___
Day Mo Yr

23D. Date of Discharge from Study Hospital
___ ___ ___
Day Mo Yr

24D. Narrative (Text limit 135 words)
2410D. _____
2420D. _____
2430D. _____
2440D. _____
2450D. _____
2460D. _____
2470D. _____
2480D. _____

DIAGNOSES CODES

Choose the Most Appropriate Code(s) (1-16) and Enter in Item 4D.

Choose the Most Appropriate Code (1-28) and Enter in Items 19D, 20D, 21D

1. Focal Penetrating Injury.
2. Focal Penetrating Injury Plus Focal Brain Stem Dysfunction.
3. Focal Penetrating Injury with Swelling.
4. Focal Penetrating Injury Plus Diffuse Injury with Shift.
5. Focal Penetrating Injury Plus Evacuated Mass Lesion.
6. Focal Penetrating Injury Plus Non-Evacuated Mass Lesion.
7. Focal Penetrating Injury with Remote Effects.
8. Anoxic Encephalopathy.
9. Cerebral Infarct.
10. Aneurysmal Subarachnoid Hemorrhage.
11. Hydrocephalus.
12. Meningitis.
13. Abscess.
14. Wound infection.
15. Seizures.
16. Brain Dead.
17. Pulmonary Complications
18. Cardiovascular Complications
19. Peripheral Vascular Complications
20. Renal Complications
21. Hepatic Complications
22. Gastrointestinal Complications
23. Coagulopathy
24. Electrolyte Complications
25. Septicemia
26. Spinal Cord Injury, Complete
27. Spinal Cord Injury, Incomplete
28. Multiple Injury (Complete each category of the Multiple Injury Form. Any category with a severity code of 3, 4, 5, or 6 constitutes a multiple injury when associated with a head injury.)

FORM D

PATIENT DIAGNOSES

To Be Completed by Nurse Clinician
Only in Consultation with Study M.D.
at Discharge or Death

This form must be completed on all patients, including those who expire in the emergency room.

1D. DATE. Enter date of patient's discharge or death, using abbreviation for month.

1D$. TIME. Enter time of patient's discharge or death.

2D. VISIT TYPE. 6=Hospital Discharge 8=Death

3D. OBSERVER. Hospital keeps list of codes. Enter 0-99. Code both nurse and M.D.

4D. INTRACRANIAL DIAGNOSIS. Using the criteria defined below, enter the most appropriate diagnosis.

Criteria for Intracranial Diagnosis

1=FOCAL PENETRATING INJURY. No intracranial pathology clinically or on CT scan, aside from focal area of missile penetration.
2=FOCAL PENETRATING INJURY PLUS FOCAL BRAIN STEM DYSFUNCTION. Cisterns present with shift 0-5 mm and/or lesion densities present, but no high or mixed density lesion >25 cc. May include bone fragments and foreign bodies.
3=FOCAL PENETRATING INJURY WITH SWELLING. Cisterns compressed or absent, shift 0-5 mm, no high or mixed density lesion >25 cc.
4=FOCAL PENETRATING INJURY PLUS DIFFUSE INJURY WITH SHIFT. Shift >5 mm, no high or mixed density lesion >25 cc.
5=FOCAL PENETRATING INJURY PLUS EVACUATED MASS LESION. Any lesion surgically evacuated.
6=FOCAL PENETRATING INJURY PLUS NON-EVACUATED MASS LESION. High or mixed density lesion >25 cc, not surgically evacuated.
7=FOCAL PENETRATING INJURY WITH REMOTE EFFECTS.
8=ANOXIC ENCEPHALOPATHY.
9=CEREBRAL INFARCT.
10=ANEURYSMAL SUBARACHNOID HEMORRHAGE.
11=HYDROCEPHALUS.
12=MENINGITIS.
13=ABSCESS.
14=WOUND INFECTION.
15=SEIZURES.
16=BRAIN DEAD. On admission patient exhibits (and never improves beyond) no brainstem reflexes, flaccid, fixed and nonreactive pupils, and no spontaneous respirations with a normal $PaCO_2$. Spinal reflexes are permitted.

5D. PENETRATING INJURY. 1=Gunshot Wound 2=Other

The following information may be obtained from the investigating officer, relatives, or pathologist.

6D. TYPE OF GUN. Record appropriate type.

1=Hand	4=Other
2=Rifle	A=Not a Gunshot Wound
3=Shotgun	U=Unknown

7D. CALIBER OF GUN. If injury is the result of a gunshot wound, indicate caliber of gun.

1=Small (22 or 25)	4=Shotgun
2=Medium (32, 38, 357, or 9mm)	A=Not a Gunshot Wound
3=Large (41, 44, or 45)	U=Unknown

8D. DISTANCE BETWEEN GUN AND PATIENT. Record appropriate distance.

1=Contact	A=Not a Gunshot Wound
2=Close (noncontact and <2 feet)	U=Unknown
3=Far (greater than 2 feet)	

Mass Lesion

If the intracranial diagnosis is a mass lesion (Diagnosis code 5 or 6), enter the appropriate lesion type. If not a mass lesion, enter [0].

0=None	2=Intracerebral	4=Hemorrhagic Contusion
1=Subdural	3=Epidural	5=Intracerebellar

9D. PRIMARY. Enter appropriate code.

10D. SECONDARY. Enter appropriate code.

11D. TERTIARY. Enter appropriate code.

Skull Fracture

Record appropriate answer. Penetrating head injured patients will almost invariably have at least a compound skull fracture.

0=No 1=Yes U=Unknown

12D. COMPOUND. Enter appropriate code.

13D. LINEAR. Enter appropriate code.

14D. DEPRESSED. Enter appropriate code.

15D. BASILAR. Enter appropriate code.

16D. MULTIPLE. Enter appropriate code.

17D. OTHER. Enter appropriate code.

19D-21D. FACTORS CONTRIBUTING TO OUTCOME

Using codes 1-28, enter those factors which most significantly influenced the patient's outcome.

Codes: 1=FOCAL PENETRATING Injury
2=FOCAL PENETRATING Injury Plus Focal Brain Stem Dysfunction
3=FOCAL PENETRATING Injury with Swelling
4=FOCAL PENETRATING INJURY PLUS Diffuse Injury with Shift
5=FOCAL PENETRATING INJURY PLUS Evacuated Mass Lesion
6=FOCAL PENETRATING INJURY PLUS Nonevacuated Mass Lesion
7=FOCAL PENETRATING Injury with Remote Effects
8=ANOXIC ENCEPHALOPATHY.
9=CEREBRAL INFARCT.
10=ANEURYSMAL SUBARACHNOID HEMORRHAGE.
11=HYDROCEPHALUS.
12=MENINGITIS.
13=ABSCESS.
14=WOUND INFECTION.
15=SEIZURES.
16=Brain Dead
17=Pulmonary Complications
18=Cardiovascular Complications
19=Peripheral Vascular Complications
20=Renal Complications
21=Hepatic Complications
22=Gastrointestinal Complications
23=Coagulopathy
24=Electrolyte Complications
25=Septicemia
26=Spinal Cord Injury (complete)
27=Spinal Cord Injury (incomplete)
28=Multiple Injury

18D. GLASGOW OUTCOME SCALE AT DISCHARGE.

1=Good Recovery. Able to participate in normal social life and may return to work.
2=Moderate Disability (Independent but Disabled). Can travel on public transportation and may work, but retains a disability such as visual defect, hemiparesis, dysphasia, memory or personality changes, epilepsy, or major cranial nerve defect.
3=Severe Disability (Conscious but Dependent). May be "Independent for ADL". Depends on help at least once in 24 hours. Includes both marked "physical deficits, such as spastic paralysis and aphasia, or severe organic mental disorder, including behavioral changes.
4=Vegetative State. No evidence of higher mental function.
5=Dead.

22D. DATE OF DISCHARGE FROM ICU. Enter dd/mm/yr. If patient expires prior to ICU admission, enter date of death.

23D. DATE OF DISCHARGE FROM STUDY HOSPITAL. Enter date of discharge or death. If patient is transferred from acute care to a rehabilitation floor at the APHIP hospital, consider transfer as discharge and enter date.

24D-2480D. NARRATIVE. Narrative summary of injury and hospitalization. Continue on reverse side.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

EARLY (PRE-HOSPITAL AND ER) EVALUATION AND TREATMENT

FORM E (Mar 88)

TO BE COMPLETED BY NURSE CLINICIAN IN CONSULTATION WITH TRAUMA FELLOW

	Pretreat			
1E. Date				
1E$. Time				
110E. Accuracy of Time 1 Time correct 2 Minutes guessed 3 Hours & minutes guessed				
2E. Observer (Hospital keeps list of codes) (0-99)				
210E. Form Completion Code: 0 Completed Not Completed Because: 1 Not Relevant 2 Other				
220E. If Other (specify)				
3E. Place of Evaluation 1 Place of injury 2 In transit to first hospital 3 At emergency room of first hospital 4 Interim transit 5 Interim hospital 6 In transit to APHIP hospital 7 At emergency room of APHIP hospital				
Glasgow Coma Scale				
4E. Best Eye Opening (Choose one) 1 None 2 To pain 3 To sound 4 Spontaneous 5 Patched/tarsorrhaphy 6 Injured/swollen 7 Barbiturates, narcotics, or pharmacologic paralysis 10 Other untestable				
5E. Best Verbal Response (Choose one) 1 None 2 Unintelligible sounds 3 Inappropriate words 4 Confused 5 Oriented 6 Intubation/tracheostomy 7 Oral/facial injury 8 Aphasia/dysarthria 9 Barbiturates, narcotics, or pharmacologic paralysis 10 Other untestable				
6E. Best Right Arm Motor Response (Choose one) 1 None 2 Extensor 3 Abnormal flexion 4 Withdrawal 5 Localizes 6 Obeys commands 7 Limb injury/immobilization 8 Spinal cord injury 9 Barbiturates, narcotics, or pharmacologic paralysis 10 Other untestable				
7E. Best Right Leg Motor Response (Choose one) 1 None 2 Extensor 3 Abnormal flexion 4 Withdrawal 5 Localizes 6 Obeys commands 7 Limb injury/immobilization 8 Spinal cord injury 9 Barbiturates, narcotics, or pharmacologic paralysis 10 Other untestable				
8E. Best Left Arm Motor Response (Choose one) 1 None 2 Extensor 3 Abnormal flexion 4 Withdrawal 5 Localizes 6 Obeys commands 7 Limb injury/immobilization 8 Spinal cord injury 9 Barbiturates, narcotics, or pharmacologic paralysis 10 Other untestable				

	Pretreat			
Date				
Time				
9E. Best Left Leg Motor Response (Choose one) 1 None 7 Limb injury/immobilization 2 Extensor 8 Spinal cord injury 3 Abnormal flexion 9 Barbiturates, narcotics, or 4 Withdrawal pharmacologic paralysis 5 Localizes 10 Other untestable 6 Obeys commands				
Pupillary Response				
10E. Right Pupil Response 0 No reaction 1 Reaction 2 Sluggish U Unknown				
11E. Right Pupil Size(1–9mm) U Unknown				
12E. Right Pupil Shape 1 Round 2 Elliptical 3 Other U Unknown				
13E. Left Pupil Response 0 No reaction 1 Reaction 2 Sluggish U Unknown				
14E. Left Pupil Size(1–9mm) U Unknown				
15E. Left Pupil Shape 1 Round 2 Elliptical 3 Other U Unknown				
150E. Capillary Refill 1 Normal:nailbed, forehead, 2 Delayed: >2 sec U Unknown or lip color refill in <2 sec 3 No capillary refill				
Cardiovascular/Pulmonary Evaluation				
16E. Initial Blood Pressure Systolic (0–300)				
17E. U Unknown Diastolic** (0–200)				
18E. Blood Pressure-High Systolic (0–300)				
19E. U Unknown Diastolic** (0–200)				
20E. Blood Pressure-Low Systolic (0–300)				
21E. U Unknown Diastolic** (0–200)				
22E. Initial Pulse Rate U Unknown (0–250)				
23E. Initial Respiratory Rate U Unknown (0–90) A Manual ventilation **Palpable blood pressure: Diastolic is U				
Complicating Events				
39E. Hypoxia (PO_2<60mm) 0 No 2 Suspected (apnea or cyanosis reported) 1 Yes (documented PO_2<60) U Unknown				
40E. Hypotension (Shock, SBP<90) 0 No 2 Suspected (patient reported to be "shocky") 1 Yes (documented SBP<90) U Unknown				
41E. Aspiration 0 No 1 Yes 2 Suspected U Unknown				
410E. Esophageal Intubation 0 No 1 Yes U Unknown				
42E. Cardiopulmonary Arrest 0 No 1 Yes U Unknown				
420E. CPR Given 2 Yes, initiated more than 0 No three minutes of arrest 1 Yes, within three A Not applicable, no CP arrest minutes of arrest U Unknown				
421E. Was Patient Breathing When First Found? 0 No 1 Yes U Unknown				
43E. Respiration (Prior to airway control) (Choose one) 0 Absent 2 Abnormal A Not applicable 1 Normal U Unknown				

	Pretreat			
Date				
Time				
44E. Seizure Type (Choose one) 0 None 2 Focal 4 Suspected 6 Combination 1 General 3 Partial Complex 5 Type unknown U Unknown				
45E. Number of Seizures (Choose one) 0 None 2 Multiple U Unknown 1 Single 3 Status epilepticus				
Treatment				
46E. IV Fluids 0 None 2 Adequate volume U Unknown 1 Inadequate volume 3 Overhydration				
460E. Type IV Fluids 0 None 2 Normal saline 4 D_5/saline U Unknown 1 Ringers 3 D_5/water 5 Other				
47E. Type Airway (Choose one) 0 None 3 Esophageal 5 Other 1 Nasopharyngeal obturator tracheostomy, etc. 2 Oropharyngeal 4 Endotrachael U Unknown				
48E. Date Airway Inserted (dd/mmm/yy)				
48E$. Time Airway Inserted (24 hour clock)				
49E. Accuracy of Time Airway Inserted 1 Time correct 2 Minutes guessed 3 Hours & minutes guessed				
50E. FiO_2 of Inspired Air U Unknown				
51E. Chest Tubes Inserted 0 No 1 Yes U Unknown				
52E. Mini Lap 0 No 1 Yes U Unknown				
53E. Thoracotomy 0 No 1 Yes U Unknown				
Medications (Enter Dosage in Units Specified) Codes: 0 None G Given, dosage unknown U Unknown				
Diuretics				
54E. Mannitol (grams) (0.0–300.0)				
541E. Furosemide (mg) (Lasix) (0.0–300.0)				
542E. Other (Text limit 10 words)				
Steroids				
55E. Dexamethasone (Decadron) (mg) (0–50)				
551E. Methylprednisolone (Solu–medrol) (mg) (0–500)				
552E. Other (Text limit 10 words)				
Anticonvulsants				
56E. Phenytoin Sodium (mg) (Dilantin) (0–1500)				
561E. Phenobarbital (mg) (0–1500)				
562E. Diazepam (mg) (Valium) (0.0–50.0)				
563E. Other (Text limit 10 words)				
Paralytic Agents				
57E. Pancuronium bromide (mg) Pavulon) (0.0–95.0)				
571E. Succinylcholine (mg) (Anectine) (0–1200)				
572E. Tubocurarine HCL (mg) (Curare) (0–200)				
573E. Other (Text limit 10 words)				

		Pretreat			
	Date				
	Time				
58E.	Study Drug or Placebo Given (dose mg)				
581E.	Specify Time				
59E.	Disposition From APHIP ER (Complete only upon discharge from ER) 1 ICU 3 Radiology 5 Morgue 2 OR 4 Ward				
Laboratory					
2L.	Initial pH of Blood (6.00–9.00) (Code only once)				
3L.	Initial Blood Gas PO_2 (0–600) (Code only once)				
4L.	Initial Blood Gas PCO_2 (0–200) (Code only once)				
5L.	Worst pH of Blood* (lowest) (6.00–9.00)				
6L.	Worst Blood Gas PO_2* (lowest) (0–600)				
7L.	Worst Blood Gas PCO_2* (highest) (0–200)				
	*Need not be from the same sample.				
8L.	Delivered Oxygen Concentration(%)(0–100)				
9L.	Hemoglobin (5.0–20.0)				
910L.	Hematocrit (lowest) (5.0–60.0) (gm%)				
920L.	Red Blood Cells (2–8)(Millions)				
10L.	White Blood Count (1000–20,000) (least optimal value; low or high)				
101L.	Platelets (lowest) (1,000–800,000)				
102L.	Granulocytes (%) (0–100)				
103L.	Lymphocytes (%) (0–100)				
11L.	PT (highest) (5.0–30.0 sec)				
12L.	PT Corresponding Control (8.0–15.0 sec)				
13L.	PTT (longest) (20.0–200.0 sec)				
14L.	PTT Corresponding Control (20.0–40.0 sec)				
15L.	Fibrinogen Split Products (0.0–30.0 mcg%)				
16L.	Thrombin Time (0–10 sec)				
17L.	Na (least optimal value furthest from 140) (90–190 meq/L)				
18L.	K (least optimal value furthest from 4.0) (1.5–8.0 meq/L)				
19L.	Chloride (50–150 meq/L)				
20L.	Glucose (0.0–500.0) (highest) (mg%)				
201L.	Glucose (0.0–500.0) (lowest) (mg%)				
21L.	BUN (0–100 mg%)				
22L.	Creatinine (0–5 mg%)				
23L.	Calcium (5–15 mg%)				
24L.	Inorganic Phosphorus (0–10 mg%)				
25L.	Total Protein (0–10 mg%)				
26L.	Bilirubin (0–5 mg%)				
27L.	Uric Acid (0–20 mg%)				
28L.	Alkaline Phosphatase (0–1000 u/L)				
29L.	LDH (0–1000 u/L)				
30L.	SGOT (0–1000 u/L)				
31L.	SGPT (0–500 u/L)				
32L.	Serum Osmolality (highest) (least optimal value furthest from 285)(200–400)				
320L.	Serum Osmolality (lowest) (least optimal value furthest from 285)(200–400)				
33L.	Urine Protein (0–4+)				
330L.	White Cells (0.0–1000.0 mg%)				
34L.	CSF Protein (0.0–1000.0 mg%)				
340L.	White Cells (0.0–1000.0 mg%)				
341L.	RBC (0.0–5000.0 mg%)				

Note: For serum glucose and serum osmolality: If only one value available for the shift, enter the number for both highest and lowest.

FORM E

EARLY EVALUATION AND TREATMENT

To Be Completed by Nurse Clinician
in Consultation with PI or Trauma Fellow

At every location where data was recorded, at least one column of data should be collected. Time recorded should be the time the patient was first encountered and treated by the rescue personnel or emergency room personnel. Any significant change in patient status or treatment should prompt a separate entry. Therefore, more than one entry may be possible for each place of evaluation. **At least one column should be collected before treatment with the experimental drug.**

This form is to be completed by either the physician or nurse caring for the patient in the APHIP hospital. It should be completed as soon as possible after admission and should include all data pertinent and retrievable from the areas noted in the section, *Place of Evaluation*. If adequate data is not available from other institutions or in transit, minimally it should include evaluation and treatment on admission to the APHIP hospital. If sufficient time is spent at any of the *Places of Evaluation* to warrant more than one evaluation, then enter the initial evaluation information, unless worst or best is requested. If data is available from both the place of injury or in transit to any facility, then enter that data in the proper column; i.e., chronologically. Choose the location where the examination and treatment to be recorded in the column was done. Interim hospital (code 5) is not the first and not the APHIP hospital.

The "pretreatment column" is reserved for values at the time of the first administration of study drug, even though other columns may precede it in time.

1E. DATE. Enter dd/mmm/yr.

1E$. TIME. See first paragraph above.

2E. OBSERVER. The code for the person (M.D. or nurse) whose physical exam findings are to be recorded. Enter 19 for unspecified physician; enter 20 for unspecified other.

3E. PLACE OF EVALUATION. The findings and laboratory values for a particular column will refer to measures and observations made at the location specified.

Glascow Coma Scale (see Table 1 for instructions)

4E. BEST EYE OPENING. For patients whose eyes are patched or sewn shut (tarsorrhaphy) [5]; severely injured or swollen [6]; on barbiturates, narcotics or paralytic agents [7]; or who are otherwise untestable [10]; the Glasgow Coma Score is calculated with Eyes=1.1. Choose codes 1-4 in preference to codes 5-10.

5E. **BEST VERBAL.** Codes for patients who are intubated or trached [6]; have oral or facial injuries [7]; who are aphasic or dysarthric [8]; who are on barbiturates, narcotics, or paralytic agents [9]; or who are otherwise untestable [10] for verbal response are entered, but the Glasgow Coma Score is calculated with **Verbal=1.1.** Use any testable response when available (i.e., when patients lighten from Pavulon use that score 1-5, rather than "10").

6E-9E. **BEST MOTOR.** Choose the best *motor* response for each of the four extremities individually. Codes for patients who are on barbiturates, narcotics, or paralytic agents [9]; who have high spinal cord injuries [8]; amputations or limb immobilizations [7]; or who are otherwise not testable [10] for motor response are entered, and the Glasgow Coma Score is calculated with **Motor=1.1.**

Pupillary Response

10E,13E. **PUPILLARY RESPONSE.** Patients whose eyes are severely injured or closed by swelling may be entered as not testable [U] for *pupillary response*, and unknown for pupil size [U]. No reaction coded [0], reaction is coded [1], sluggish [2], unknown coded [U].

11E,14E. **PUPILLARY SIZE** in mm for each eye. Enter 1-9; if >9, enter 9, or **U=Unknown.**

12E,15E. **PUPIL SHAPE.**

1=Round	**3=Other**
2=Elliptical	**4=Unknown**

150E. **CAPILLARY REFILL** (return of color after pressure). Best of nailbed, forehead or lip mucosa.

1=Normal: nailbed, forehead, or lip color refill in <2 sec
2=Delayed: >2 sec
3=No Capillary Refill
U=Unknown

Cardiovascular/Pulmonary Evaluation

16E-17E. **INITIAL BLOOD PRESSURE** is the first blood pressure taken or recorded for each *"Place of Evaluation"* as defined in Item 3E. Enter 0-300 systolic, 0-200 diastolic.

18E-19E. Enter *highest recorded systolic* pressure and corresponding diastolic. Enter 0-300 systolic, 0-200 diastolic. Palpable blood pressure diastolic, **U=Unknown.**

20E-21E. Enter *lowest recorded systolic* pressure and corresponding diastolic. Enter 0-300 systolic, 0-200 diastolic. Palpable blood pressure diastolic, **U=Unknown.**

22E. The first recorded *pulse rate* for each location. (0-250) **U=Unknown**

23E. **INITIAL RESPIRATORY RATE** (0-90). Enter [A] if patient is being manually ventilated. **U=Unknown**

Complicating Events

39E. HYPOXIA is defined as PO_2 of less than 60mm Hg. Enter Yes if measured PO_2 is less than 60mm Hg. Enter **Suspected** if the patient was observed to be cyanotic or apneic or had a pH of <7.25.

0=No 1=Yes 2=Suspected U=Unknown

40E. HYPOTENSION is defined as systolic arterial pressure of less than 90mm Hg. Enter [1] if documented SBP 90. Enter 2 if patient reported to be in shock. Enter [U] if unknown.

0=No 1=Yes 2=Suspected U=Unknown

41E. ASPIRATION. Enter Yes if any foreign material (i.e., vomitus, gasoline, blood) was aspirated, if radiographic evidence of aspiration is reported, or if tracheal aspirate is found to have a pH less than 7.0. Enter **Suspected** if such material was suctioned from the oral pharynx, but actual aspiration was not observed and no radiographic evidence is found.

0=No 1=Yes 2=Suspected U=Unknown

410E. ESOPHAGEAL INTUBATION. Enter Yes if MD or CXR Document tube in esophagus.

0=No 1=Yes U=Unknown

42E. CARDIOPULMONARY ARREST. Record Yes if the patient had a documented cardiopulmonary (CP) arrest, with cessation of heartbeat.

0=No 1=Yes U=Unknown

420E. CPR GIVEN. Enter [0] if patient did not receive CPR. Enter [1] (Yes) if CPR administered within three minutes of injury. Enter [2] (Yes) if CPR was administered but equal to or greater than three minutes after injury. Enter [A] if patient did not suffer a cardiac arrest.

42E. WAS PATIENT BREATHING WHEN FIRST FOUND? This information should come from rescue personnel records.

0=No 1=Yes U=Unknown

43E. RESPIRATION PRIOR TO AIRWAY CONTROL. **Abnormal** refers to patterned respirations, hyperapnea greater than 30 breaths per minute, or a respiratory rate less than 10 breaths per minute. If respirations are abnormal or absent at any time while the patient is at the location defined in Item 3E, it should be recorded here.

0=Absent
1=Normal
2=Abnormal
U=Unknown
A=Not Applicable

44E. SEIZURE TYPE observed posttrauma (not past history) at this location.

0=None.
1=General Seizure. Tonic clonic movements involving the entire body.
2=Focal Seizure. Lateralizing disturbance that does not become bilateral.
3=Partial Complex Seizure (i.e., minor motor or "Temporal Lobe" seizure).
4=Suspected.
5=Type Unknown/Other. Includes myoclonus or others not well described.
6=Combination.
U=Unknown.

If patient is paralyzed or in barbiturate coma, code unknown unless there is EEG evidence of seizures, then code Yes, type unknown.

45E. Enter number of seizures reported for each location.

0=None
1=Single
2=Multiple
3=Status Epilepticus
U=Unknown

46E. IV FLUIDS. Indicate if IV therapy was adequate for volume repletion.

0=None
1=Inadequate Volume
2=Adequate Volume
3=Over Hydration
U=Unknown

460E. TYPE IV FLUIDS. Obtain this information from rescue personnel report, ER reports.

0=None
1=Ringers
2=Normal Saline
3=D_5/Water
4=D_5/Saline
5=Other
U=Unknown

47E. TYPE AIRWAY. Enter the most *"advanced"* type of airway used at each location, where *"advanced"* is defined in the following order: none, oral pharyngeal, nasopharyngeal, esophageal obturator, endotracheal, tracheostomy. If a new type of airway was inserted at this location, record this new type and ate and time it was inserted.

0=None
1=Nasopharyngeal
2=Oropharyngeal
3=Esophageal Obturator
4=Endotracheal
5=Other, Tracheostomy, etc.
U=Unknown

48E. DATE AIRWAY INSERTED. Enter dd/mmm/yr.

48E$. TIME AIRWAY INSERTED. Enter the time that the airway was inserted. If *"type of airway"* remains the same, but was changed or replaced, note time this occurred.

49E. ACCURACY OF TIME AIRWAY INSERTED. See page 5 of this manual.

50E. INSPIRED AIR. Enter highest FiO_2 recorded for each location. Enter (.21-1.00), U=Unknown

51E. CHEST TUBES INSERTED. Enter [1] if chest tubes were inserted, including pericardial ones (even if removed later).

0=No 1=Yes U=Unknown

52E. MINI-LAP. Minilap=peritoneal lavage.

0=No 1=Yes U=Unknown

53E. THORACOTOMY.

0=No 1=Yes U=Unknown

Medications

Enter all listed medications (and any pertinent others) which are given during the period of time at this location. Record dosage in units indicated beside each entry. Enter [0] for drug not given. If medication given, but dosage unknown, enter [G] (given). If unknown whether patient received the medication, enter [U].

Diuretics

54E. MANNITOL (grams) (0.0-300.0)

541E. FUROSEMIDE (mg). LASIX (0.0-300.0)

542E. OTHER. Specify drug and dosage as text, 10 word limit.

Steroids

55E. DECADRON.

551E. METHYLPREDNISOLONE.

552E. OTHER. Any other steroid which may have been administered. Specify drug and dosage as text, 10 word limit.

Anticonvulsants

56E. PHENYTOIN SODIUM. Dilantin (mg) (0-1500)

561E. PHENOBARBITAL (mg) (0-1500)

562E. DIAZEPAM-VALIUM (mg) (0.0-50.0)

563E. OTHER. Specify drug and dosage as text, 10 word limit.

Paralytic Agents

57E. PANCURONIUM BROMIDE - PAVULON (mg) (0.0-95.0)

571E. SUCCINYLCHOLINE ANECTINE (mg) (0-1200)

572E. TUBOCURARINE HCL - CURARE (mg) (0-200)

573E. OTHER. Specify drug and dosage as text, 10 word limit.

58E. STUDY DRUG OR PLACEBO GIVEN.

581E. SPECIFY TIME. Enter 0 if not given.

59E. DISPOSITION FROM APHIP ER. Complete only once when 3E=7. Indicate where the patient was moved from the emergency room.

1=ICU 3=Radiology 5=Morgue
2=OR 4=Ward

Laboratory

2L-4L. Record the pH, PO_2, PCO_2 of the first blood gas drawn at each location, or the time span for that entry.

5L-7L. If more than one ABG is drawn, enter the least desirable values for pH, PO_2, and PCO_2. These need not be from the same sample. Least desirable pH is the lowest. The words PO_2 is the lowest, the worst PCO_2 is the highest. *If only one ABG is drawn, the values for worst ABG will be the same* as initial ABG.

910L. HEMATOCRIT. Enter the lowest recorded. Enter 5.0-60.0

101L. PLATELETS. Enter the lowest value. Enter 1,000-800,000

11L. PT. Enter the highest value. Enter 5.0-30.0

12L. PT CORRESPONDING CONTROL. Enter the control value that corresponds to the sample recorded in 35L. Enter 8.0-15.0

13L. PTT. Enter the longest PTT. Enter 20.0-200.0

14L. PTT CORRESPONDING CONTROL. Enter the control value that corresponds to the sample recorded in 37L. Enter 20.0-40.0

17L. SODIUM. Enter the least optimal-value furthest from 140. Enter 90-190

18L. POTASSIUM. Enter the least optimal-value further from 4.0. Enter 1.5-8.0

32L. SERUM OSMOLALITY. Enter the least optimal-value furthest from 285. Enter 200-400

34L-341L. CSF. This will generally be ventricular fluid.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

FULL NEUROLOGIC HISTORY AND EXAMINATION

FORM F

(Mar 88)

TO BE COMPLETED BY STUDY M.D. AT DISCHARGE AND AT EACH FOLLOW-UP STARTING AT THREE MONTHS

1F. **Date**

__ ___ __
Day Mo Yr

1F$. **Time** ____:____

2F. **Observer** (Hospital keeps list of codes)(0–99)

_____

210F. **Form Completion Code** 0 Completed
Not Completed Because: 1 Not Relevant
2 Other

220F. **If Other, specify**_____

230F. **Evaluation**
1 In hospital 3 Follow-up
2 Discharge 4 Other

240F. **If Follow-up, specify**(3,6,12,24 mos)____mos

250F. **If Other, specify**_____mos

INTERVAL MEDICAL HISTORY

(Enter Data or Circle Appropriate Choice)

(All information pertains to interval since last exam; **except** discharge, which pertains to preinjury history.)

3F. **Reliability**
1 History deemed reliable, confirmed with records
2 History deemed reliable, not confirmed with records
3 History sketchy
4 History unobtainable, go to examination

4F. **Date of Last Examination**
(Leave blank if this is the first examination)

__ ___ __
Day Mo Yr

5F. **Other Significant Head Injury**
(>5 min LOC, skull fracture, or admission >1 day)
0 None 2 Two
1 One 3 Three or more

6F. **Other Significant CNS Disease**
0 No U Unknown
1 Yes

610F. **If Yes, Specify Diagnosis**

_____

7F. **Headaches**
0 No 2 Yes, constant
1 Yes, intermittent U Unknown

710F. **If Yes, Specify Type**
0 Vascular 2 Mixed
1 Muscle contraction 3 Other

720F. **If Other, Specify**

_____

8F. **Degree of Incapacitation by Headache**
0 None or mild 8 Unsure
1 Yes, moderate U Unknown
2 Yes, severe

9F. **Increased Irritability**
(expressed in behavior)
0 None 8 Upset, unsure why
1 Upset by noise U Unknown
2 Upset by light
3 Upset by noise and light

10F. **Violent Behavior**
0 None
1 Yes, against things
2 Yes, against people
3 Yes, against both
U Unknown

11F. **Increased Sensitivity to Alcohol**
(subsequent to PHI)
0 No 8 Unsure
1 Yes U Unknown

12F. **Episodes of Loss of Consciousness**
0 No
1 Yes
U Unknown

13F. **Seizures** (since PHI)
0 No
1 Yes
U Unknown

1310F. **If Yes, Date of First Seizure**

__ ___ __
Day Mo Yr

14F. **Date of Last Seizure**

__ ____ __
Day Mo Yr

15F. **Number of Seizures Since Last Exam** (0-99)

_____

16F. **Predominant Seizure Type**
1 Partial simple
2 Partial complex
3 Partial generalized
4 Generalized

17F. **Anticonvulsant Medication Since Last Exam** (daily dose, mg)
171F. Dilantin_____mg (0–600)
172F. Carbamazepine_____mg (0–1000)
173F. Phenobarbital_____mg (0–1500)
174F. Other (dosage)_____mg

1740F. **If Other, Specify Drug**

_____

EXAMINATION

Code for Questions 19F, 21F, 24F, 27F: Code all that apply:
0 None
1 Right
2 Midline
3 Left

18F. **Palpable Skull Defect**
1 None (Go to 23F)
2 One
3 More than one

First Skull Defect (location)
191F. Frontal_____
192F. Parietal_____
193F. Occipital_____
194F. Temporal_____

20F. **Size of the First Skull Defect**
1 Small (less than 2 cm in diameter)
2 Medium (2-6 cm)
3 Large (greater than 6 cm)

Second Skull Defect (location)
211F. Frontal_____
212F. Parietal_____
213F. Occipital_____
214F. Temporal_____

22F. **Size of the Second Skull Defect** (location)
1 Small (less than 2 cm in diameter)
2 Medium (2-6 cm)
3 Large (greater than 6 cm)

23F. **Scalp Scars or Wounds**
1 None (Go to 30F)
2 One
3 More than one

First Scalp Scar or Wound (location)
241F. Frontal_____
242F. Parietal_____
243F. Occipital_____
244F. Temporal_____

25F. **Swelling or Redness in Surrounding Scalp**
0 None 1 Yes

26F. **Open Wound**
1 No
2 Yes, without purulent drainage
3 Yes, with purulent drainage (Code 31F)

Second Scalp Scar or Wound (location)
271F. Frontal_____
272F. Parietal_____
273F. Occipital_____
274F. Temporal_____

28F. **Swelling or Redness in Surrounding Scalp**
0 None 1 Yes

29F. **Open Wound**
1 No
2 Yes, without purulent drainage
3 Yes, with purulent drainage (Code 31 F)

30F. **Facial Scars**
1 None
2 One
3 More than one

		No	Yes
31F.	**CSF Leakage:**		
311F.	CSF rhinorrhea	0	1
312F.	CSF otorrhea	0	1
313F.	CSF leakage through scalp scar	0	1
314F.	CSF leakage through facial scar	0	1

		No	Yes
32F.	**Bruits:**		
	(If "Yes", specify in Remarks)		
321F.	Cranial	0	1
322F.	Orbital	0	1
323F.	Cervical	0	1
324F.	Remarks_____		
33F.	**Meningismus**	0	1

Mental Status

35F. **Level of Consciousness**
1 Alert (go to 36F)
2 Lethargic or worse (elaborate in Remarks)
353F. Remarks_____

		No	Yes
36F.	**General Impression:**		
361F.	Uncooperative	0	1
362F.	Euphoric	0	1
363F.	Depressed	0	1
364F.	Indifferent	0	1
365F.	Hostile	0	1
366F.	Anxious	0	1
367F.	Agitated	0	1
37F.	**Disorientation:**		
371F.	Time	0	1
372F.	Place	0	1
373F.	Person	0	1
374F.	Circumstances of injury	0	1

		No	Yes	Untestable
38F.	**Aphasia:**			
381F.	Broca (motor)	0	1	A
382F.	Wernicke (sensory)	0	1	A
383F.	Global	0	1	A
384F.	Conduction	0	1	A
385F.	Dysnomia	0	1	A
386F.	Dyslexia	0	1	A
387F.	Aphemia (mutism)	0	1	A
388F.	Dysgraphia	0	1	A
389F.	Transcortical mixed	0	1	A
3891F.	Transcortical motor	0	1	A
3892F.	Transcortical sensory	0	1	A
39F.	**Apraxia**			
391F.	Ideomotor	0	1	A
392F.	Limb kinetic	0	1	A

Sensation

40F. **Testable**
1 No (Go to 44F)
2 Yes
3 Yes, Reliability Questionable

Code for Questions 41F through 4351F: Code all that apply:
0 No abnormality 1 Diminished or absent 2 Dysesthetic response

		Right	Left	Right	Left
Touch and Pain		Touch		Pain (pin prick)	
4110F.	Face and neck	0 1 2	4111F. 0 1 2	4112F. 0 1 2	4113F. 0 1 2
4120F.	Body	0 1 2	4121F. 0 1 2	4122F. 0 1 2	4123F. 0 1 2
4130F.	Upper Extremity	0 1 2	4131F. 0 1 2	4132F. 0 1 2	4133F. 0 1 2
4140F.	Lower Extremity	0 1 2	4141F. 0 1 2	4142F. 0 1 2	4143F. 0 1 2
Vibration and Proprioception		Vibration		Proprioception	
4210F.	Upper Extremity	0 1	4211F. 0 1	4212F. 0 1	4213F. 0 1
4220F.	Lower Extremity	0 1	4221F. 0 1	4222F. 0 1	4223F. 0 1
Cortical Sensory Loss					
4310F.	Code Astereognosis	0 1	4311F. 0 1		
4320F.	Agraphesthesia	0 1	4321F. 0 1		
4330F.	Tactile extinction	0 1	4331F. 0 1		
4340F.	Finger agnosia	0 1	4341F. 0 1		
4350F.	Two point discrimination	0 1	4351F. 0 1		

Code for Questions 44F-4931F:
0=No 1=Yes A=Not testable

	Impairment of Cranial Nerves	Right	Left
4410F.	Olfactory Loss	0 1 A	4411F. 0 1 A
	Optic Nerve and Retina		
4510F.	Absent globe	0 1 A	4511F. 0 1 A
4520F.	Abnormal globe	0 1 A	4521F. 0 1 A
4530F.	Abnormal retina	0 1 A	4531F. 0 1 A
4540F.	Optic atrophy	0 1 A	4541F. 0 1 A
4550F.	Papilledema	0 1 A	4551F. 0 1 A
4560F.	Visual acuity, corrected (10–800)	20/____	4561F. 20/____
	Visual Fields Confrontation		
4610F.	Hemianopsia, temporal	0 1 A	4611F. 0 1 A
4620F.	Hemianopsia, nasal	0 1 A	4621F. 0 1 A
	Quadrantanopsia		
4630F.	Upper temporal	0 1 A	4631F. 0 1 A
4640F.	Lower temporal	0 1 A	4641F. 0 1 A
4650F.	Upper nasal	0 1 A	4651F. 0 1 A
4660F.	Lower nasal	0 1 A	4661F. 0 1 A
	Cranial Nerves III, IV, VI		
4710F.	Abnormal direct pupillary response	0 1 A	4711F. 0 1 A
4720F.	Abnormal consensual response	0 1 A	4721F. 0 1 A
4730F.	Ptosis	0 1 A	4731F. 0 1 A
4740F.	Horner's syndrome	0 1 A	4741F. 0 1 A
	Extraocular Muscles		
4750F.	III Nerve palsy	0 1 A	4751F. 0 1 A
4760F.	IV Nerve palsy	0 1 A	4761F. 0 1 A
4770F.	VI Nerve palsy	0 1 A	4771F. 0 1 A
4780F.	Conjugate gaze palsy	0 1 A	4781F. 0 1 A
4790F.	Nystagmus on lateral gaze	0 1 A	4791F. 0 1 A
	Trigeminal Nerve		
4810F.	Diminished or absent corneal sensation	0 1 A	4811F. 0 1 A
4820F.	Abnormal motor	0 1 A	4821F. 0 1 A
	Abnormal Sensory		
4840F.	First division	0 1 A	4841F. 0 1 A
4850F.	Second division	0 1 A	4851F. 0 1 A
4860F.	Third division	0 1 A	4861F. 0 1 A
	Facial Nerve		
4910F.	Abnormal peripheral, taste	0 1 A	4911F. 0 1 A
4920F.	Abnormal peripheral, voluntary facial expression	0 1 A	4921F. 0 1 A
4930F.	Abnormal central	0 1 A	4931F. 0 1 A

Code for Questions 50F-539F and Questions 55F-5531F:
0 No 1 Yes A Not testable

		Right		Left	
Acoustic Nerve					
5010F.	Rubbed fingers not heard at one foot	0 1 A		5011F.	0 1 A
Glossopharyngeal and Vagus Nerves					
5110F.	Diminished or absent gag	0 1 A		5111F.	0 1 A
5120F.	Abnormal elevation palate	0 1 A		5121F.	0 1 A
Spinal Accessory Nerve					
5210F.	Diminished or absent sternocleidomastoid muscle power	0 1 A		5211F.	0 1 A
5220F.	Trapezius muscle power diminished	0 1 A		5221F.	0 1 A
Bilateral Cranial Nerve Dysfunction					
5310F.	Optokinetic nystagmus	0 1 A			
5320F.	Difficulty swallowing liquids	0 1 A			
5330F.	Diminished rapid alternating movements, tongue	0 1 A			
5340F.	Vertical gaze palsy	0 1 A			
5350F.	Primary position nystagmus	0 1 A			
5360F.	Pseudobulbar palsy	0 1 A			
5370F.	Impersistence of eye closure	0 1 A			
5380F.	Abnormal convergence	0 1 A			
5390F.	Abnormal smooth pursuit	0 1 A			

Motor Power

Code:
- **0** *No contraction*
- **1** *Flicker or trace of contraction without actual movement (0-10%)*
- **2** *Partial arc of movement with gravity eliminated (11-25% normal)*
- **3** *Complete arc of movement against gravity 26-50% normal)*
- **4** *Complete arc of movement against gravity with variable amounts of resistance (51-75% normal)*
- **5** *Complete arc of movement against gravity and maximum resistance which can be repeated several times without fatigue (76% to normal)*
- **6** *Normal strength*
- **8** *Missing Limb*
- **9** *Give-way weakness*
- **A** *Not testable*

5410F.	Shoulder abduction	_____	5411F.	_____
5420F.	Elbow extension	_____	5421F.	_____
5430F.	Wrist extension with closed fist	_____	5431F.	_____
5440F.	Hip abduction	_____	5441F.	_____
5450F.	Knee flexion	_____	5451F.	_____
5460F.	Ankle dorsiflexion	_____	5461F.	_____
Paresis				
5510F.	Face	0 1 A	5511F.	0 1 A
5520F.	Upper extremity	0 1 A	5521F.	0 1 A
5530F.	Lower extremity	0 1 A	5531F.	0 1 A

Code for Questions 56F-5991F and 61F-6121F:
0 No 1 Yes A Not testable

		Right		Left	
Gait Abnormalities					
5610F.	Hemiparetic	0 1 A		5611F.	0 1 A
5620F.	Encumbered by prosthesis	0 1 A		5621F.	0 1 A
5630F.	Impaired by peripheral nerve injury	0 1 A		5631F.	0 1 A
5640F.	Other	0 1 A		5641F.	0 1 A
5650F.	Ataxic	0 1 A			
Voluntary Movements					
5710F.	Diminished rapid finger movements	0 1 A		5711F.	0 1 A
5720F.	Diminished rapid foot movements	0 1 A		5721F.	0 1 A
Dysmetria					
5730F.	Upper extremity	0 1 A		5731F.	0 1 A
5740F.	Lower extremity	0 1 A		5741F.	0 1 A
Station and Posture					
5810F.	Abnormal Romberg test	0 1 A			
5820F.	Truncal ataxia	0 1 A			
5830F.	Abnormal defense of equilibrium	0 1 A			
5840F.	Abnormal spinal curvature	0 1 A			
Involuntary Movements					
5910F.	Head Nodding	0 1 A	(If No, go to 60F)		
Tremor					
5920F.	Static (Parkinsonism)	0 1 A		5921F.	0 1 A
5930F.	Postural (action)	0 1 A		5931F.	0 1 A
5940F.	Intentional (ataxic)	0 1 A		5941F.	0 1 A
5950F.	Athetoid movements	0 1 A		5951F.	0 1 A
5960F.	Choreic movements	0 1 A		5961F.	0 1 A
5970F.	Dystonic movements	0 1 A		5971F.	0 1 A
5980F.	Facial tic or mannerism	0 1 A		5981F.	0 1 A
5990F.	Dyskinesia	0 1 A		5991F.	0 1 A

Code for Questions 60F-6021F:
0 No 1 Yes, spastic 2 Yes, rigid

		Right		Left	
Increased Muscle Tone					
6010F.	Upper extremity	0 1 2		6011F.	0 1 2
6020F.	Lower extremity	0 1 2		6021F.	0 1 2
Decreased Muscle Tone					
6110F.	Upper extremity	0 1		6111F.	0 1
6120F.	Lower extremity	0 1		6121F.	0 1

Code for Questions 62F-6261F:
0 Absent 1 Decreased 2 Normal 3 Increased

		Right	Left
Tendon Reflexes			
6210F.	Triceps	0 1 2 3	6211F. 0 1 2 3
6220F.	Biceps	0 1 2 3	6221F. 0 1 2 3
6230F.	Brachioradialis	0 1 2 3	6231F. 0 1 2 3
6240F.	Knee jerk	0 1 2 3	6241F. 0 1 2 3
6250F.	Ankle jerk	0 1 2 3	6251F. 0 1 2 3
6260F.	Jaw jerk	0 1 2 3	6261F. 0 1 2 3

Code for Questions 63F-630F:
0 Flexor (normal) 1 Extensor 8 Equivocal

6310F.	**Plantar Responses**	0 1 8	6311F. 0 1 8

Code for Questions 64F-6530F:
0 No 1 Yes

6410F.	**Clonus** (ankle)	0 1	6411F. 0 1

Frontal Lobe Release Signs			
6510F.	Grasp, simple	0 1	6511F. 0 1
6520F.	Grasp, forced	0 1	6521F. 0 1
6530F.	Snout	0 1	

66F. **Glasgow Outcome Score** (Circle one)

5 **Dead**

4 **Vegetative State** (No Higher Mental Function)

3 **Severe Disability** (Conscious but Dependent)
May be "Independent for ADL". Depend on help at least once in 24 hours. Includes both marked "physical" deficits, such as spastic paralysis and aphasia, or severe organic mental disorder, including behavioral changes.

2 **Moderate Disability** (Independent but Disabled)
Can travel on public transportation and may work but retains a disability such as visual defect, hemiparesis, dysphasia, memory or personality changes, epilepsy or major cranial nerve defect.

1 **Good Recovery**
Able to participate in normal social life and may return to work.

Neurologic Status Summary
Modified Kurtzke Score (use attached coding guide, pages 8-9)

Date				
Time				
Systems				
67F. Pyramidal Functions (0-6 or U)				
68F. Cerebellar Functions (0-6 or U)				
69F. Brain Stem Functions (0-5 or U)				
70F. Sensory Functions (0-4 or U)				
71F. Visual (or optic) Functions (0-4 or U) (Right)				
72F. Visual (or optic) Functions (0-4 or U) (Left)				
73F. Cerebral (or mental) Functions (0-6 or U)				
74F. Other Functions (0,1, or U)				
75F. Expanded Disability Status Scale (0.0-10.0)				
76F. Ambulation Index (0-9)				

FUNCTIONAL SYSTEMS (FS)

Pyramidal Functions
0. Normal
1. Abnormal signs without disability
2. Minimal disability
3. Mild or moderate paraparesis or hemiparesis; severe monoparesis
4. Marked paraparesis or hemiparesis; moderate quadri paresis; or monoplegia
5. Paraplegia, hemiplegia, or marked quadriparesis
6. Quadriplegia
U Unknown

Cerebellar Functions
0. Normal
1. Abnormal signs without disability
2. Mild ataxia
3. Moderate truncal or limb ataxia
4. Severe ataxia, all limbs
5. Unable to perform coordinated movements due to ataxia
6. Undetermined because of pyramidal weakness
U Unknown

Brain Stem Functions
0. Normal
1. Signs only
2. Moderate nystagmus or other mild disability
3. Severe nystagmus, marked extraocular movement abnormality, or moderate disability of other cranial nerves
4. Marked dysarthria, pseudobulbar palsy, or marked disability of other cranial nerves
5. Inability to swallow or speak (not aphasia)
U Unknown

Sensory Functions (revised 1982)
0. Normal
1. Mild decrease in touch or pain in one or two limbs
2. Moderate decrease in touch, pain, position sense, or cortical sensation in one or two limbs
3. Marked decrease in touch, pain, or cortical proprioception, sensation in one or two limbs
4. Loss (essentially) of sensation in two limbs
U Unknown+

Visual (or Optic) Functions (Right)
0. Normal
1. Decreased visual acuity
2. Quadrantanopsia
3. Hemianopsia
4. Blind
U Unknown

Visual (or Optic) Functions (Left)
0. Normal
1. Decreased visual acuity
2. Quadrantanopsia
3. Hemianopsia
4. Blind
U Unknown

Cerebral (or Mental) Functions
0. Normal
1. Mood alteration only (does not affect DDS score)
2. Mild decrease in mentation, language, attention, or calculation
3. Moderate decrease in mentation language, attention, or calculation; disoriented to time
4. Marked decrease in mentation (aphasia, acalculia)
5. Dementia, incompetent
6. Comatose or vegetative
U Unknown

Other Functions
0. None
1. Any other neurologic findings attributed to head injury
U Unknown

Expanded Disability Status Scale

0=Normal neurologic exam (all grade 0 in functional systems [FS]; cerebral grade 1 acceptable)

1.0=No disability, minimal signs in one FS (i.e., grade 1, excluding cerebral grade 1)

1.5=No disability minimal signs in more than one FS (more than one grade 1, excluding cerebral grade 1)

2.0=Minimal disability in one FS (one FS grade 2, others 0 or 1)

2.5=Minimal disability in two FS (two FS grade 2, other 0 or 1)

3.0=Moderate disability in one FS (one FS grade 3, others 0 or 1), or mild disability in three or four FS (three/four FS grade 2, others 0 or 1), although fully ambulatory

3.5=Fully ambulatory but with moderate disability in one FS (one grade 3) and one or two FS grade 2; or two FS grade 3; or five FS grade 2 (others 0 or 1)

4.0=Fully ambulatory without aid, self-sufficient, up and about some 12 hours a day despite relatively severe disability consisting of one FS grade 4 (others 0 or 1), or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 500 meters

4.5=Fully ambulatory without aid, up and about much of the day, able to work full day, may otherwise have some limitation of full activity or require minimal assistance; characterized by relatively severe disability, usually consisting of one FS grade 4 (others 0 or 1), or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest for some 300 meters

5.0=Ambulatory without aid or rest for about 200 meters; disability severe enough to impair full daily activities (e.g., to work full day without special provisions) (usual FS equivalents are one grade 5 alone, other 0 or 1; or combinations of lesser grades, usually exceeding specifications for step 4.0)

5.5=Ambulatory without aid or rest for about 100 meters; disability severe enough to preclude full daily activities (usual FS equivalents are one grade 5 alone, others 0 or 1; or combinations of lesser grades, usually exceeding those for step 4.0)

6.0=Intermittent or unilateral constant assistance (cane, crutch, or brace) required to walk about 100 meters, with or without resting (usual FS equivalents are combinations with more than two FS grade 3+)

6.5=Constant bilateral assistance (canes, crutches or braces) required to walk about 20 meters without resting (usual FS equivalents are combinations with more than two FS grade 3+)

7.0=Unable to walk beyond about 5 meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day (usual FS equivalents are combinations with more than one FS grade 4+; very rarely, pyramidal grade 5 alone)

7.5=Unable to take more than a few steps; restricted to wheelchair; may need aid in transfer; wheels self but cannot carry on in standard wheelchair a full day; may require motorized wheelchair (usual FS equivalents are combinations with more than one FS grade 4+)

8.0=Essentially restricted to bed or chair or perambulated in wheelchair, but may be out of bed itself much of the day; retains many self-care functions; generally has effective use of arms (usual FS equivalents are combinations, generally grade 4+ in several systems)

9.0=Helpless bed patient; can communicate and eat (usually FS equivalents are combinations, most grade 4+)

9.5=Totally helpless bed patient; unable to communicate effectively or eat/swallow (usual FS equivalents are combinations, almost all grade 4+)

10.=Death

Ambulation Index

0 Asymptomatic; fully active

1 Walks normally, but reports fatigue that interferes with athletic or other demanding activities

2 Abnormal gait or episodic imbalance; gait disorder is noticed by family and friends; able to walk 25 feet (8 meters) in 10 seconds or less

3 Walks independently; able to walk 25 feet in 20 seconds or less

4 Requires unilateral support (cane or single crutch)

5 Requires bilateral support (canes, crutches, or walker) and walks 25 feet in 20 seconds or less; or requires unilateral support, but needs more than 20 seconds to walk 25 feet

6 Requires bilateral support and more than 20 seconds to walk 25 feet (may use wheelchair)

7 Walking limited to several steps with bilateral support; unable to walk 25 feet (may use wheelchair)

8 Restricted to wheelchair; able to transfer self independently

9 Restricted to wheelchair; unable to transfer self independently

FORM F

FULL NEUROLOGIC HISTORY AND EXAMINATION

To Be Completed by Study M.D. on Days 1, 7, and 30, or at Discharge, Whichever is Sooner, and at Each Follow-Up

Interval medical history refers to history since last F Form. for the Day 1 examination, it refers to preinjury history. The preinjury history may b completed/corrected after Day 1, but should only be recorded on the Day 1 F Form. Certain aspects of the examination will not be testable on patients in coma. However, history, response to pain, muscle tone, reflexes, and certain cranial nerve functions should be evaluable on most patients.

1F. **DATE.** Enter dd/mmm/yr.

1F$. **TIME.** Record actual time of examination.

2F. The **OBSERVER** is the physician who performs the examination of the patient. Hospital keeps list of codes. (0-99)

6F. **OTHER SIGNIFICANT CNS DISEASE** requiring visit to neurologist or neurosurgeon.

8F. **DEGREE OF INCAPACITATION.**

Mild=not interfering with activity
Moderate=interfering with work or activities
Severe=precludes work or other activities

1310F. **DATE OF FIRST SEIZURE.**

Leave blank if unknown

35F. **LEVEL OF CONSCIOUSNESS.**

Alert=GCS 15

38F. APHASIA. The following table is a guide to diagnosing various aphasias (after F.Benson).

LANGUAGE SYMPTOMATOLOGY IN APHASIA

Type of Aphasia	Spontaneous Speech	Paraphasia	Comprehension	Repetition	Naming
Broca's aphasia	Nonfluent	Uncommon	Good	Poor	Poor
Wernicke's aphasia	Fluent	Common (verbal)	Poor	Poor	Poor
Global	Nonfluent	Variable	Poor	Poor	Poor
Conduction aphasia	Fluent	Common (literal)	Good	Poor	Poor
Mixed transcortical	Nonfluent	Uncommon	Poor	Good (echolalia)	Poor
Transcortical motor	Nonfluent	Uncommon	Good	Good (echolalia)	Poor
Transcortical sensory	Fluent	Common	Poor	Good (echolalia)	Poor
Anomic	Fluent	Absent	Good	Good	Poor
Subcortical aphasia	Fluent or nonfluent	Common	Variable	Good	Variable

DEFINITIONS/TESTING

NONFLUENT SPEECH: Sparse output (<50 words/minute), effortful, dysarthric, short phrase length, dysprosodic (dysrhythmic).

PARAPHASIAS:
Literal: Phonetic substitution (i.e., "grass is greel").
Verbal: Semantic substitution (i.e., "the grass is blue").
Neologism: (new words) (i.e., "the grass is grumps").

REPETITION: Ask patient to repeat, "there are no ifs, ands, or buts about it". Echolalia is a strong, almost mandatory tendency to repeat examiner's words.

COMPREHENSION: Ask patient to follow a three-step command: "take the paper in your right hand, fold it in half, put the paper on the floor". (Caution: Do not confuse with apraxia.)

39F. APRAXIA.

IDEOMOTOR. Difficulty with selection, sequencing, and spatial orientation of movements. *"Show me how you use a comb, hammer, toothbrush."*

LIMB KINETIC. Patient unable to make a fine precise movement. Test by asking patient to pick up a dime from a flat surface. Simple repetitive movements, such as finger tapping are intact, but this apraxia may still be indistinguishable from subtle pyramidal dysfunction.

SENSATION

40F. **TESTABLE.** Patient need not be alert to test pain or touch.

4310F. **ASTEREOGNOSIS.** Test with dime *vs* nickel.

4320F. **AGRAPHESTHESIA.** Number writing with pencil on index finger. Explain with 1; test with 3, 4, and 7. Score abnormal if patient identified <2 out of 3.

4330F. **TACTILE EXTINCTION.** Test simultaneously on cheek and dorsum of hand. Score abnormal if patient extinguishes on >1 out of three trials. Sensation must be otherwise intact.

4340F. **FINGER AGNOSIA.** Show me your index finger, your thumb.

4350F. **TWO POINT DISCRIMINATION.** Detects 2 points, 1 cm apart on index finger.

4410F. **OLFACTORY LOSS.** Test with fresh coffee grounds. Score abnormal if patient cannot detect the presence of the odor with eyes closed.

4560F. **VISUAL ACUITY.** Record visual acuity with correction, 20/____, using card. If less than 20/800, record:

00 - for no light perception (blind)
01 - for light perception only
02 - for hand motion
03 - for finger counting

4790F. **NYSTAGMUS ON LATERAL GAZE.** Record presence of nystagmus on looking to right or to left.

4910F. **ABNORMAL TASTE.** Use sugar on anterior two-thirds of tongue.

5340F. **VERTICAL GAZE PALSY.** Unable to look either up or down.

5360F. **PSEUDOBULBAR PALSY.** Emotional incontinence, hyperactive jaw jerk, and spastic dysarthria.

5710F. **DIMINISHED RAPID FINGER MOVEMENTS.** When compared to examiner.

Neurologic Status Summary

Modified Kurtzke Score

67F. **PYRAMIDAL FUNCTIONS.** Enter 0-6 or U.

0=Normal
1=Abnormal signs without disability
2=Minimal disability
3=Mild or moderate paraparesis or hemiparesis; severe monoparesis
4=Marked paraparesis or hemiparesis; moderate quadri-paresis; or monoplegia
5=Paraplegia, hemiplegia, or marked quadriparesis
6=Quadriplegia
U=Unknown

68F. CEREBELLAR FUNCTIONS. Enter 0-6 or U.

0=Normal
1=Abnormal signs without disability
2=Mild ataxia
3=Moderate truncal or limb ataxia
4=Severe ataxia, all limbs
5=Unable to perform coordinated movements due to ataxia
6=Undetermined because of pyramidal weakness
U=Unknown

69F. BRAIN STEM FUNCTIONS. Enter 0-5 or U.

0=Normal
1=Signs only
2=Moderate nystagmus or other mild disability
3=Severe nystagmus, marked extraocular movement abnormality, or moderate disability of other cranial nerves
4=Marked dysarthria, pseudobulbar palsy, or marked disability of other cranial nerves
5=Inability to swallow or speak (not aphasia)
U=Unknown

70F. SENSORY FUNCTIONS. Enter 0-4 or U.

0=Normal
1=Mild decrease in touch or pain in one or two limbs
2=Moderate decrease in touch, pain, position sense, or cortical sensation in one or two limbs
3=Marked decrease in touch, pain, or cortical proprioception sensation in one or two limbs
4=Loss (essentially) of sensation in two limbs
U=Unknown

71F. VISUAL (OR OPTIC) FUNCTIONS (RIGHT). Enter 0-4 or U.

0=Normal
1=Decreased visual acuity
2=Quadrantanopsia
3=Hemianopsia
4=Blind
U=Unknown

72F. VISUAL (OR OPTIC) FUNCTIONS (LEFT). Enter 0-4 or U.

0=Normal
1=Decreased visual acuity
2=Quadrantanopsia
3=Hemianopsia
4=Blind
U=Unknown

73F. CEREBRAL (OR MENTAL) FUNCTIONS. Enter 0-6 or U.

0=Normal
1=Mood alteration only (does not affect DDS score)
2=Mild decrease in mentation, language, attention, or calculation
3=Moderate decrease in mentation, language, attention, or calculation; disoriented to time
4=Marked decrease in mentation (aphasia, acalculia)
5=Dementia, incompetent
6=Comatose or vegetative
U=Unknown

74F. OTHER FUNCTIONS.

0=None
U=Unknown
1=Any other neurologic findings attributed to head injury

75F. EXPANDED DISABILITY STATUS SCALE. Enter 0-10.

0=Normal neurologic exam (all grade 0 in functional systems [FS]; cerebral grade 1 acceptable)
1.0=No disability, minimal signs in one FS (i.e., grade 1, excluding cerebral grade 1)
1.5=No disability minimal signs in more than one FS (more than one grade 1, excluding cerebral grade 1)
2.0=Minimal disability in one FS (one FS grade 2, others 0 or 1)
2.5=Minimal disability in two FS (two FS grade 2, other 0 or 1)
3.0=Moderate disability in one FS (one FS grade 3, others 0 or 1), or mild disability in three or four FS (three/four FS grade 2, others 0 or 1), although fully ambulatory
3.5=Fully ambulatory but with moderate disability in one FS (one grade 3) and one or two FS grade 2; or two FS grade 3; or five FS grade 2 (others 0 or 1)
4.0=Fully ambulatory without aid, self-sufficient, up and about some 12 hours a day despite relatively severe disability consisting of one FS grade 4 (others 0 or 1), or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 500 meters
4.5=Fully ambulatory without aid, up and about much of the day, able to work full day, may otherwise have some limitation of full activity or require minimal assistance; characterized by relatively severe disability, usually consisting of one FS grade 4 (others 0 or 1), or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest for some 300 meters
5.0=Ambulatory without aid or rest for about 200 meters; disability severe enough to impair full daily activities (e.g., to work full day without special provisions) (usual FS equivalents are one grade 5 alone, other 0 or 1; or combinations of lesser grades, usually exceeding specifications for step 4.0)
5.5=Ambulatory without aid or rest for about 100 meters; disability severe enough to preclude full daily activities (usual FS equivalents are one grade 5 alone, others 0 or 1; or combinations of lesser grades, usually exceeding those for step 4.0)
6.0=Intermittent or unilateral constant assistance (cane, crutch, or brace) required to walk about 100 meters, with or without resting (usual FS equivalents are combinations with more than two FS grade 3+)
6.5=Constant bilateral assistance (canes, crutches or braces) required to walk about 20 meters without resting (usual FS equivalents are combinations with more than two FS grade 3+)
7.0=Unable to walk beyond about 5 meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day (usual FS equivalents are combinations with more than one FS grade 4+; very rarely, pyramidal grade 5 alone)
7.5=Unable to take more than a few steps; restricted to wheelchair; may need aid in transfer; wheels self but cannot carry on in standard wheelchair a full day; may require motorized wheelchair (usual FS equivalents are combinations with more than one FS grade 4+)

8.0=Essentially restricted to bed or chair or perambulated in wheelchair, but may be out of bed itself much of the day; retains many self-care functions; generally has effective use of arms (usual FS equivalents are combinations, generally grade 4+ in several systems)
9.0=Helpless bed patient; can communicate and eat (usually FS equivalents are combinations, most grade 4+)
9.5=Totally helpless bed patient; unable to communicate effectively or eat/swallow (usual FS equivalents are combinations, almost all grade 4+)
10.=Death

76F. AMBULATION INDEX. Enter 0-9.

0=Asymptomatic; fully active
1=Walks normally, but reports fatigue that interferes with athletic or other demanding activities
2=Abnormal gait or episodic imbalance; gait disorder is noticed by family and friends; able to walk 25 feet (8 meters) in 10 seconds or less
3=Walks independently; able to walk 25 feet in 20 seconds or less
4=Requires unilateral support (cane or single crutch)
5=Requires bilateral support (canes, crutches, or walker) and walks 25 feet in 20 seconds or less; or requires unilateral support, but needs more than 20 seconds to walk 25 feet
6=Requires bilateral support and more than 20 seconds to walk 25 feet (may use wheelchair)
7=Walking limited to several steps with bilateral support; unable to walk 25 feet (may use wheelchair)
U=Restricted to wheelchair; able to transfer self independently
9=Restricted to wheelchair; unable to transfer self independently

ARMY
PENETRATING
HEAD
INJURY
PROJECT

Patient Study Number_____

Patient Initials_____

VITAL SIGNS/ CONCOMITANT THERAPY REPORT

To Be Completed by Nurse Clinician

FORM H

(Jun 88)

VITAL SIGNS: Complete 3x Day for Day 1 - Day 7; 1x Day (A.M. preferred) for Day 8 - Day 30

1H. **Date** ___ ___ ___
Day Mo Yr

210H. **Form Completion Code** 0 Completed
Not Completed Because: 1 None Reported
2 Other

2H. **Observer** (Hospital keeps list of codes)(0–99)

220H. **If Other,** specify

	Day	Date (__1) (day/month/year)	Blood Pressure Systolic(__2) Diastolic(__3) (mmHg)	Pulse (__4) (beats/min)	Respiration (__5) (resp/min)	Temperature (__6) (°F)
3H.	1-1		/			
310H.	1-2		/			
320H.	1-3		/			
4H.	2-1		/			
410H.	2-2		/			
420H.	2-3		/			
5H.	3-1		/			
510H.	3-2		/			
520H.	3-3		/			
6H.	4-1		/			
610H.	4-2		/			
620H.	4-3		/			
7H.	5-1		/			
710H.	5-2		/			
720H.	5-3		/			
8H.	6-1		/			
810H.	6-2		/			
820H.	6-3		/			
9H.	7-1		/			
910H.	7-2		/			
920H.	7-3		/			

VITAL SIGNS: COMPLETE 3X DAY FOR DAY 1 - DAY 7; 1X DAY (A.M. PREFERRED) FOR DAY 8 - DAY 30

	Day	Date (__1) (day/month/year)	Blood Pressure Systolic(__2) / Diastolic(__3) (mmHg)	Pulse (__4) (beats/min)	Respiration (__5) (resp/min)	Temperature (__6) (°F)
10H.	8		/			
11H.	9		/			
12H.	10		/			
13H.	11		/			
14H.	12		/			
15H.	13		/			
16H.	14		/			
17H.	15		/			
18H.	16		/			
19H.	17		/			
20H.	18		/			
21H.	19		/			
22H.	20		/			
23H.	21		/			
24H.	22		/			
25H.	23		/			
26H.	24		/			
27H.	25		/			
28H.	26		/			
29H.	27		/			
30H.	28		/			
31H.	29		/			
32H.	30		/			

CONCOMITANT THERAPY: ENTER ALL CURRENT CONCOMITANT MEDICATION; INCLUDE ALL EMERGENCY TREATMENT GIVEN (mouthwashes, skin creams, etc., are not recorded).

	Name of Concomitant Medication or On-Drug Therapy (__1)	Drug Code (__2)	Total Daily Dose (Specify Unit) (__3)	Date Started (__4) (Day/Mo)	Date Ended (__5) (Day/Mo)
33H.					
34H.					
35H.					
36H.					
37H.					
38H.					
39H.					
40H.					
41H.					
42H.					
43H.					
44H.					
45H.					
46H.					
47H.					
48H.					
49H.					
50H.					
51H.					
52H.					
53H.					
54H.					
55H.					

CONCOMITANT THERAPY: ENTER ALL CURRENT CONCOMITANT MEDICATION; INCLUDE ALL EMERGENCY TREATMENT GIVEN (mouthwashes, skin creams, etc., are not recorded).

	Name of Concomitant Medication or On-Drug Therapy (__1)	Drug Code (__2)	Total Daily Dose (Specify Unit) (__3)	Date Started (__4) (Day/Mo)	Date Ended (__5) (Day/Mo)
56H.					
57H.					
58H.					
59H.					
60H.					
61H.					
62H.					
63H.					
64H.					
65H.					
66H.					
67H.					
68H.					
69H.					
70H.					

COMMENTS

71H. **Comments** (text limit 50 words) _____

7110H. _____

7120H. _____

7130H. _____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

PATIENT IDENTIFICATION

To Be Completed by Nurse Clinician

FORM I

(MAR 88)

1I. Medical Record _____ 2I. I.D. Number _____

Patient Name _____

3I. Last 4I. First 5I. Middle

6I. Street _____

7I. City _____ 8I. State _____ 9I. Zip Code _____

10I. Telephone Number (___) _____ 11I. Telephone Number (___) _____

(Home) (Work)

12I. Social Security Number ___ ___ ___ - ___ ___ - ___ ___ ___ ___

13I. Driver's License: State _____ 14I. Number _____

Next of Kin Information

Name _____

15I. Last 16I. First 17I. Middle

18I. Relationship _____

19I. Street _____ 20I. Telephone Number (___) _____

21I. City _____ 22I. State _____ 23I. Zip Code _____

Second Relative/Friend Information

Name _____

24I. Last 25I. First 26I. Middle

27I. Relationship _____ 28I. Telephone Number (___) _____

29I. Street _____

30I. City _____ 31I. State _____ 32I. Zip Code _____

Discharge Information

33I. Date of Discharge _____ 34I. Facility _____

35I. Street _____ 36I. Telephone Number (___) _____

37I. City _____ 38I. State _____ 39I. Zip Code _____

40I. Contact (M.D., R.N., or Social Worker) _____

FORM I

PATIENT IDENTIFICATION

This form is to be filled out as soon as possible after the patient is admitted.

1. MEDICAL HISTORY/UNIT RECORD NUMBER is used to retrieve data from the patient's hospital chart and to identify the patient.

2. ID NUMBER is assigned to the patient by the computer at the time of data entry.

3-14. Information requested includes the patient's name, address, telephone number, Social Security number, and driver's license information.

18-45. Identifying information is requested concerning the patient's referring physician, a relative or close friend, and work or school associations. These should be individuals who would always be aware of the patient's location. At discharge from the hospital, complete the discharge information section to facilitate follow-up. The form also calls for the details of the accident and a description of the injury.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number_____

Patient Initials_____

MEDICATION SIDE EFFECT REPORT

FORM K

(Mar 88)

To Be Completed by Nurse Clinician in Consultation with Study M.D.

COMPLETE SEPARATE PAGE FOR EACH SIDE EFFECT; CALL OR SEND TO ENZON

1K. Date

___ ___ ___
Day Mo Yr

2K. Observer (Hospital keeps list of codes)(0–99)

_____

210K. Form Completion Code
Not Completed Because:
0 Completed
1 None Reported
2 Other

220K. If Other, specify

_____

DESCRIPTION

3K. Date of Onset

___ ___ ___
Day Mo Yr

4K. Date Ended

___ ___ ___
Day Mo Yr

5K. Ongoing
0 No
1 Yes

6K. Description of Side Effect_____
(Text limit 50 words)

610K. _____

620K. _____

630K. _____

640K. _____

650K. _____

CHARACTERIZATION

7K. Severity
1 Mild
2 Moderate
3 Severe

8K. Source
1 Patient reported
2 Elicited by physician
3 Observed by physician
4 Other

810K. If Other, specify

_____

9K. Frequency
1 Once
2 Intermittent
3 Constant

10K. Course
1 Disappeared
2 Improved
3 Remained the same
4 Worsened
5 Other

1010K. If Other, specify

_____

ACTION TAKEN

11K. Any action taken for side effect?
0 No
1 Yes

12K. If Yes, where
1 Inpatient
2 Outpatient

13K. Study Drug
1 No change
2 Dosage reduced
3 Temporarily discontinued (go to 15K & 16K)
4 Discontinued (go to 15K)

14K. Treatment
0 None
1 Medication
2 Other
3 1&2 above

1410K. If Other, specify

_____

15K. Did reaction abate after stopping drug?
0 No
1 Yes

16K. Did reaction reappear after reintroduction?
0 No
1 Yes

INVESTIGATOR'S ASSESSMENT

17K. Study Drug Related to Side Effects
1 Definitely not
2 Probably not
3 Possibly
4 Probably

18K. Outcome of Side Effects
1 Treated with treatment drug
2 Recovered
3 Still under treatment for reaction
4 Resulted in severe disability
5 Death (go to 1810K)
6 None of the above

1810K. If Death, date

__ ____ __
Day Mo Yr

1820K. If None of the Above, specify

_____

COMMENTS

19K. Comments (text limit 50 words)_____

1910K. _____

1920K. _____

1930K. _____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

LABORATORY DATA

TO BE COMPLETED BY NURSE CLINICIAN OR TRAUMA FELLOW

FORM L

(Mar 88)

		Pretreat				
1L	Date					
1L$	Time					
110L	Observer (Hospital keeps list of codes) (0-99)					
2L	Initial pH of Blood (6.00–9.00) (Code only once)					
3L	Initial Blood Gas PO_2 (0–600) (Code only once)					
4L	Initial Blood Gas PCO_2 (0–200) (Code only once)					
5L	Worst pH of Blood* (lowest) (6.00–9.00)					
6L	Worst Blood Gas PO_2* (lowest) (0–600)					
7L	Worst Blood Gas PCO_2* (highest) (0–200)					
	*Need not be from the same sample.					
8L	Delivered Oxygen Concentration(%)(0–100)					
9L	Hemoglobin (5.0–20.0)					
910L	Hematocrit (lowest) (5.0–60.0) (gm%)					
920L	Red Blood Cells (2–8)(Millions)					
10L	White Blood Count (1000–20,000) (least optimal value; low or high)					
101L	Platelets (lowest) (1,000–800,000)					
102L	Granulocytes (%) (0–100)					
103L	Lymphocytes (%) (0–100)					
11L	PT (highest) (5.0–30.0 sec)					
12L	PT Corresponding Control (8.0–15.0 sec)					
13L	PTT (longest) (20.0–200.0 sec)					
14L	PTT Corresponding Control (20.0–40.0 sec)					
15L	Fibrinogen Split Products (0.0–30.0 mcg%)					
16L	Thrombin Time (0–10 sec)					
17L	Na (least optimal value furthest from 140) (90–190 meq/L)					
18L	K (least optimal value furthest from 4.0) (1.5–8.0 meq/L)					
19L	Chloride (50–150 meq/L)					
20L	Glucose (0.0–500.0) (highest) (mg%)					
201L	Glucose (0.0–500.0) (lowest) (mg%)					
21L	BUN (0–100 mg%)					
22L	Creatinine (0–5 mg%)					
23L	Calcium (5–15 mg%)					
24L	Inorganic Phosphorus (0–10 mg%)					
25L	Total Protein (0–10 mg%)					
26L	Bilirubin (0–5 mg%)					
27L	Uric Acid (0–20 mg%)					
28L	Alkaline Phosphatase (0–1000 u/L)					
29L	LDH (0–1000 u/L)					
30L	SGOT (0–1000 u/L)					
31L	SGPT (0–500 u/L)					
32L	Serum Osmolality (highest) (least optimal value furthest from 285)(200–400)					
320L	Serum Osmolality (lowest) (least optimal value furthest from 285)(200–400)					
33L	Urine Protein (0–4+)					
330L	White Cells (0.0–1000.0 mg%)					
34L	CSF Protein (0.0–1000.0 mg%)					
340L	White Cells (0.0–1000.0 mg%)					
341L	RBC (0.0–5000.0 mg%)					

Note: For serum glucose and serum osmolality: If only one value available for the shift, enter the number for both highest and lowest.

FORM L

LABORATORY DATA

To Be Completed by Nurse Clinician

This form provides for entry of laboratory data after the patient has left the Emergency Room (ER) and/or Intensive Care Unit (ICU). Laboratory data collected in the ER or ICU should be entered on Forms E or U, respectively. Enter the least optimal laboratory values as defined by each category for each eight (8) hour period. If there is more than one value from a shift that meets the definition of least optimal, enter the value that is indicative of the trend. If only one value is available, enter that value. Blood gas values need not be from the same sample.

1L. DATE.

1L$. TIME.

1L. INITIAL pH. Enter 6.00-9.00.

2L. INITIAL pO_2. Enter 0-600.

3L. INITIAL pCO_2. Enter 0-200.

4L. pH (lowest). Enter 6.00-9.00.

5L. pO_2 (lowest). Enter 0-600.

6L. pCO_2 (highest). Enter 0-200.

7L. PEEP (highest). Enter 0-30.

8L. HEMATOCRIT. Enter lowest for that shift (5.0-60.0).

9L. WHITE BLOOD COUNT (least optimal value: low or high) (1,000-20,000).

10L. NA. Least optimal is the value furthest from 140. Enter 90-190.

11L. K. Least optimal is the value furthest from 4.0. Enter 1.5-8.0.

12L. GLUCOSE.

13L. SERUM OSMOLALITY. Least optimal is the value furthest from 285. Enter 200-400.

14L. PLATELETS (lowest). Enter 0-800,000.

15L. PT (highest). Enter 5.0-30.0.

16L. PT CONTROL. Enter control value which corresponds to entry in 14L. Enter 8.0-15.0.

17L. PTT (highest). Enter 20.0-200.0.

18L. PTT CONTROL. Enter control value which corresponds to entry in 17L. Enter 20.0-40.0.

19L. FIBRINOGEN SPLIT PRODUCTS.

20L. THROMBIN TIME.

21L. BLOOD ALCOHOL (mg%).

22L. DRUG SCREEN.

1=Positive 2=Negative 3=Not Done

23L. URINE.

24L. CSF. Enter protein cells or RBC.

25L. BUN.

26L. ALKALINE PHOSPHATASE.

27L. SGOT.

28L. BILIRUBIN.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

MULTIPLE INJURY FORM (ACUTE)

FORM M
(Mar 88)

1M. Date

___ ____ ___
Day Mo Yr

1M$. Time _____:_____

2M. Observer (Hospital keeps list of codes)(0–99)

_____

210M. Form Completion Code 0 Completed
Not Completed Because: 1 Not Relevant
2 Other

220M. If Other, specify_____

INSTRUCTIONS (See APHIP Manual):

1. When locating injuries, review the following: ER and Admission notes; X-Ray/Angiography reports; CT Scan reports; Surgical Notes; Discharge Summary; Autopsy Report (if available).
2. Use severity codes found in the 1985 *Revision of the Abbreviated Injury Scale Manual*. Page numbers on Form M refer to the AIS Manual.
3. Check the AIS Manual injury dictionary if you cannot find an injury in the manual.
4. If no appropriate AIS Manual description of the injury is found, record the medical record injury description and assign a score of AIS 9 to the injury.
5. Do not record suspected injuries until they are verified by test, surgery, or autopsy.
6. Record injuries in correct subsections. If Form M has inadequate space to report all injuries in a subsection, make sure higher severity injuries receive priority.
7. Check instructions in APHIP Manual for coding tips.
8. Refer below for coding head injuries.

HEAD INJURIES

WORK SECTION FOR HEAD INJURY

1. Level of Consciousness AT ADMISSION pp 30-31. Use Length of Unconsciousness p 32 only if level of consciousness at admission is unknown.
2. In the unlikely event that there is brainstem crush or laceration (AIS code 6), enter injury code and description.
3. If level of consciousness AIS code is 5, proceed to next item (4M).
4. However, if level of consciousness AIS code is 4, continue to code head injuries. Head injuries are further subdivided into:
   A. Bony Skull injuries (p 28), and
   B. Verified Anatomic Brain lesion (p 29).

Head Injuries	AIS Code	Injury Description
Level of Consciousness pp 30–31 (preferred) or p 32		
Bony Skull p 28		
Verified Anatomic Brain Lesion p 29		
3M. Head	Highest Code from above	

Head Injuries	AIS Code	Injury Description
4M. Ear, Eye, Face pp 33–36		
5M. Neck pp 37–38		
6M. Thorax pp 39–42		
7M. Diaphragm p 44		
8M. Abdomen and pelvic contents pp 43–48		
9M. Cervical Spine p 49		
10M. Thoracic Spine p 50		
11M. Lumbar Spine pp 49–50		
12M. Extremities and bony pelvis pp 51–56		
13M. External pp 21–22		

FORM M

MULTIPLE INJURY

To Be Completed by Nurse Clinician
in Consultation with PI or Trauma Fellow

The **MULTIPLE INJURY** form should be completed after patient discharge. It should be completed on all patients, even those who are pronounced dead in the emergency department. Whenever possible, the following items in the medical record should be reviewed to locate injuries.

1. Emergency Department Notes
2. Admissions Notes
3. X-Ray Reports
4. CT Scan Reports
5. Angiography Reports
6. Surgery Reports
7. Discharge Summary
8. Autopsy Reports

It is important that the coder strictly adheres to the guidelines for using the Abbreviated Injury Scale (AIS) Manual. Therefore, it is necessary for the coder to initially and periodically familiarize him/herself with the AIS Manual. In order to use the AIS Manual properly, the coder MUST read several sections of the manual carefully; these include the Introduction, the Dictionary, and particular body region coding instructions.

Page numbers on **Form M** refer to the locations in the AIS Manual where injuries from a specific body region are located. BE SURE THAT INJURIES ARE RECORDED IN THE CORRECT SUBSECTIONS ON FORM M. If **Form M** has inadequate lines to report all the injuries in a body region or subsection, make sure high severity injuries receive priority. DO NOT RECORD INJURIES IN OTHER BODY REGIONS OR SUBSECTIONS IF YOU RUN OUT OF ROOM IN THE CORRECT BODY REGION OR SUBSECTION.

Sometimes the injury described in the medical record and the description of the injury in the AIS Manual will not coincide exactly. Occasionally, an injury will not be reference in the manual at all. In order to limit confusion, the following policy is established for recording and scoring injuries on **Form M.**

A. **RECORD AIS MANUAL INJURY DESCRIPTIONS ON FORM M.** The accuracy of AIS coding relies upon your judgment that the description of an injury found in the AIS Manual provides sufficient description of the injury described in the medical record. *Example:*

Medical Record Description	AIS Manual and Form M Description
Gunshot Wound to Liver	Liver Laceration, unspecified/AIS/4
Massive Brain Swelling	Cerebrum/Cerebellum, Brain Swelling/AIS/3
Frontal Contusion	Cerebrum Contusion/AIS/3

Bilateral Femur Shaft Fractures	Femur Fracture, shaft (left)/AIS/3 Femur Fracture, shaft (right)/AIS/3
Note:	The AIS would recognize a bilateral fracture as two separate injuries; therefore each should be recorded.

B. If an injury cannot be located in the AIS Manual, the Medical Record Description of the injury should be recorded on **Form M** and assigned a score of AIS 9.

An AIS 9 score will indicate that the severity of the injury is unknown. When assigning AIS 9 scores, it is important that you transcribe the exact medical record description of the injury onto **Form M** to facilitate unbiased decision making about AIS 9 scores.

Frequent AIS Scoring Mistakes

DO NOT record the patient as Brain Dead on admission. Use the appropriate level of consciousness descriptions or anatomical lesion descriptions found in the head injury section.

DO NOT take it upon yourself to subjectively elevate an AIS score found in the manual just because you know the patient died.

DO NOT invent AIS codes or reassign AIS codes because you cannot find an injury description or because you do not agree with the code assigned to an injury. such actions only defeat the purpose of having a standard injury severity coding manual.

Except for head injury, DO NOT record outcomes of injuries as injuries. For example, intra-abdominal hemorrhage is an outcome of laceration or rupture of some particular structure. Be aware, however that the severity of an injury will increase if certain outcomes are noted. For example, Lung Contusion AIS 3 vs. Lung Contusion with bilateral hemothorax AIS 4. In the Head Injury Section, level and length of unconsciousness are given specific AIS scores without reference to any particular anatomical lesion.

DO NOT code the lacerations associated with open fractures as separate injuries.

DO NOT code injuries sustained in previous traumatic episodes.

DO NOT count as injuries wounds that occur during surgery.

DO NOT record the same injury more than once because it is described more than once in the medical record.

Other AIS Scoring Tips

A bullet or knife wound which passes through an extremity, but does not injure any nerves, vessels, tendons, or bones, should be described in the external section and assigned a severity code of AIS 2.

When there is uncertainty about the location of MINOR multiple abrasions, contusions, and lacerations to the body surface, they should be aggregated regardless of their location and assigned an AIS score of 1.

An AIS 6 should be used ONLY for injuries specifically coded AIS 6 in the manual, and not because the victim died.

The AIS codes INDIVIDUAL injuries only. Injuries to bilateral body parts are coded as two separate injuries; e.g., fractured left tibia and fractured right tibia. While the term bilateral is used to describe hemothorax or pneumothorax with certain chest injuries, it should be emphasized that the results, which are not coded, are present bilaterally, but that the injury per se is still a single injury.

For all head injured patients, the level of consciousness at admission should be noted and scored. If level of consciousness at admission is not know, the overall length of unconsciousness should be scored on each patient. Read over the instructions in the AIS Manual (pp 30-32) for clarification on these items.

Be sure to score lacerations, abrasions, and contusions that do not involve deeper anatomical structures in the EXTERNAL skin/muscles subsection of Form M.

TRIS Code

Tris Scores will be assigned by an outside observer (? who). Not to be coded by Data Collector.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

NEUROLOGICAL EVALUATION

TO BE COMPLETED BY STUDY M.D.
WITH THE ASSISTANCE OF THE NURSE CLINICIAN

FORM N
(Mar 88)

	Pretreat			
1N. Date				
1N$. Time				
2N. Visit Type:				
1 Hospital admission; 2 ICU admission; 3 In hospital ICU; 4 Discharge from ICU; 5 In hospital, not ICU; 6 Hospital discharge; 8 Death; 12 Other; 13 Follow–up; O Randomization				
3N. Observer (Hospital keeps list of codes) (0–99)				
4N. Height (cm) (120–240)* U Unknown				
5N. Weight (kg) (30–200 kg)* U Unknown				

*Height and weight, if obtainable, are to be collected on ICU admission, and weight repeated whenever possible.

Eyes

6N. Best Eye Opening (Choose one)				
1 None; 2 To pain; 3 To sound; 4 Spontaneous; 5 Patched/tarsorrhaphy; 6 Injured/swollen; 7 Barbiturates, narcotics, or pharmacologic paralysis; U Other untestable				
7N. Right Pupil Response				
0 No reaction; 1 Reaction; 2 Sluggish; U Unknown				
8N. Right Pupil Size(1–9mm) U Unknown				
9N. Right Pupil Shape				
1 Round; 2 Elliptical; 3 Other; U Unknown				
10N. Left Pupil Response				
0 No reaction; 1 Reaction; 2 Sluggish; U Unknown				
11N. Left Pupil Size(1–9mm) U Unknown				
12N. Left Pupil Shape				
1 Round; 2 Elliptical; 3 Other; U Unknown				
13N. Right Corneal				
0 None; 1 Present; U Untestable				
14N. Left Corneal				
0 None; 1 Present; U Untestable				
15N. Right Oculocephalics*				
0 None; 1 Normal; 2 Abnormal; U Untestable; A Patient Awake				
16N. Left Oculocephalics*				
0 None; 1 Normal; 2 Abnormal; U Untestable; A Patient Awake				
17N. Right Oculovestibulars*				
0 None; 1 Normal; 2 Abnormal; U Untestable; A Patient Awake				
18N. Left Oculovestibulars*				
0 None; 1 Normal; 2 Abnormal; U Untestable; A Patient Awake				

*Enter A=not applicable, if patient is awake

	Pretreat			
Date				
Time				

19N. Best Verbal Response (Choose one)

1 None
2 Unintelligible sounds
3 Inappropriate words
4 Confused
5 Oriented
6 Intubation/tracheostomy
7 Oral/facial injury
8 Aphasia/dysarthria
9 Barbiturates, narcotics, or pharmacologic paralysis
U Other untestable

Motor Response

20N. Best *Right Arm* Motor Response (Choose one)

1 None
2 Extensor
3 Abnormal flexion
4 Withdrawal
5 Localizes
6 Obeys commands
7 Limb injury/immobilization
8 Spinal cord injury
9 Barbiturates, narcotics, or pharmacologic paralysis
U Other untestable

21N. Right Arm Weakness

0 No
1 Yes
U Untestable

22N. Best *Right Leg* Motor Response (Choose one)

1 None
2 Extensor
3 Abnormal flexion
4 Withdrawal
5 Localizes
6 Obeys commands
7 Limb injury/immobilization
8 Spinal cord injury
9 Barbiturates, narcotics, or pharmacologic paralysis
U Other untestable

23N. Right Leg Weakness

0 No
1 Yes
U Untestable

24N. Best *Left Arm* Motor Response (Choose one)

1 None
2 Extensor
3 Abnormal flexion
4 Withdrawal
5 Localizes
6 Obeys commands
7 Limb injury/immobilization
8 Spinal cord injury
9 Barbiturates, narcotics, or pharmacologic paralysis
U Other untestable

25N. Left Arm Weakness

0 No
1 Yes
U Untestable

26N. Best *Left Leg* Motor Response (Choose one)

1 None
2 Extensor
3 Abnormal flexion
4 Withdrawal
5 Localizes
6 Obeys commands
7 Limb injury/immobilization
8 Spinal cord injury
9 Barbiturates, narcotics, or pharmacologic paralysis
U Other untestable

27N. Left Leg Weakness

0 No
1 Yes
U Untestable

28N. Seizure Type (Choose one)

0 None
1 Generalized
2 Partial simple
3 Partial complex
4 Partial with secondary generalization
5 Suspected
6 Type unknown
U Unknown

	Pretreat				
Date					
Time					
Description of Coma*					
29N. Time in Coma (Number of Days)**					
30N. Date Patient Considered To No Longer Be In Coma					
31N. Accuracy of Date Patient Considered To No Longer Be in Coma 0 Date correct 1 Day guessed 2 Day and month guessed 3 Day, month, and year guessed 4 Patient discharged in vegetative state					

*Complete only once, in the appropriate date and time column or at discharge.

**Code A if patient expired. If patient discharged in vegetative state, enter number of days since onset of coma, and complete 31N=4.

Declaration of Brain Death*

310N. Date ___ ____ ___ (Day Mo Yr) 310N$. Time _____ : _____

*Complete only if applicable, otherwise leave blank.

General Complications

Codes: 0 No 1 Yes U Unknown

32N. Pulmonary (excluding pneumonia)				
33N. Cardiovascular				
34N. Peripheral Vascular				
35N. Gastrointestinal				
36N. Renal				
37N. Hepatic				
38N. Electrolyte				
39N. Coagulopathy				
40N. SIADH				
41N. Diabetes insipidus				
410N. Nonsurgical CSF Leak				
42N. Nonsurgical Meningitis				
420N. Non-iatrogenic Abscess				
43N. Non-iatrogenic Ventriculitis				
430N. Non-iatrogenic Wound Infection				
440N. Wound Dehiscence				
44N. Pneumonia				
45N. Septicemia				
46N. Other (Text limit 10 words)				

Complications of Treatment (Definitive Surgery or Diagnostic Procedures)

Iatrogenic Intracranial Complications

47N. Intracerebral Hemorrhage				
48N. Intraventricular Hemorrhage				
49N. Subdural Hemorrhage				
50N. Epidural Hemorrhage				
51N. Cerebrospinal Fluid Leak				
53N. Ventriculitis				
54N. Meningitis				
55N. Abscess				
56N. Wound Infection				
57N. Other (Text limit 10 words)				

Complications of Treatment (Definitive Surgery or Diagnostic Procedures) Continued

	Pretreat				
Date					
Time					
Iatrogenic Complications (Not Intracranial)					
58N. Pneumothorax					
59N. Urinary Infection					
590N. Vascular Catheter Sepsis					
60N. Esophageal Intubation (leading to hypoxia) (PaO_2<60)					
61N. Major Vessel Occlusion (requiring surgery)					
62N. Extubation					
63N. Other (Text limit 10 words)					
Diagnosis Complications					
64N. Undetected Operable Intracranial Mass					
65N. Spinal Fracture					
66N. Other (Text limit 10 words)					

Neurologic Status Summary

Modified Kurtzke Score (use attached coding guide, pages 5-6)

Systems					
67N. Pyramidal Functions (0-6 or U)					
68N. Cerebellar Functions (0-6 or U)					
69N. Brain Stem Functions (0-5 or U)					
70N. Sensory Functions (0-5 or U)					
71N. Visual (or optic) Functions (0-4 or U) (Right)					
72N. Visual (or optic) Functions (0-4 or U) (Left)					
73N. Cerebral (or mental) Functions (0-5 or U)					
74N. Other Functions (0,1,U)					
75N. Expanded Disability Status Scale (0.0-10.0)					
76N. Ambulation Index (0-9)					

Physical Examination (Day 1, 7, and Discharge)

0 Normal 1 Abnormal

77N. General Appearance					
78N. Skin					
79N. Ears, Nose, Throat					
80N. Neck (including thyroid)					
81N. Heart					
82N. Chest (including lungs)					
83N. Abdomen					
84N. Genitourinary					
85N. Musculoskeletal					
86N. Lymphatic					

Medications (Enter Dosage in Units Specified)

Codes: 0 None G Given, dosage unknown U Unknown

Diuretics					
87N. Mannitol (grams) (0.0–300.0)					
88N. Furosemide (mg) (Lasix) (0.0–300.0)					
89N. Other (Text limit 10 words)					
Steroids					
90N. Dexamethasone (mg)(Decadron) (0–50)					
91N. Methylprednisolone (mg)(Solu–medrol)(0–500)					
92N. Other (Text limit 10 words)					

	Pretreat			
Date				
Time				
Anticonvulsants				
93N. Phenytoin Sodium (mg) (Dilantin) (0–1500)				
94N. Phenobarbital (mg) (0–1500)				
95N. Diazepam (mg) (Valium) (0.0–50.0)				
96N. Other (Text limit 10 words)				
Paralytic Agents				
97N. Pancuronium bromide (mg) Pavulon) (0.0–95.0)				
98N. Succinylcholine (mg) (Anectine) (0–1200)				
99N. Tubocurarine (mg) (Curare) (0–200)				
100N. Other (Text limit 10 words)				
Antihypertensives				
101N. Methyldopa (mg)(Aldomet)(0–1000)				
102N. Hydralazine (mg)(Apresoline()0.0–150.0)				
103N. Propranolol (mg)(Inderal)(0.0–40.0)				
104N. Nitroprusside (Nipride) 0 No 1 Yes U Unknown				
105N. Trimethaphan (Arfonad) 0 No 1 Yes U Unknown				
106N. Other (Text limit 10 words)				
Narcotics				
107N. Morphine Sulfate (mg)(0.0–200.0)				
108N. Meperidine HCL (mg)(0.0–1500.0)				
109N. Codeine (mg)(0.0–250.0)				
110N. Other (Text limit 10 words)				
Barbiturates				
111N. Sodium Pentobarbital (mg)(Nembutal)(0.0–3000.0)				
112N. Other (Text limit 10 words)				
Vasopressors				
113N. Dopamine HCl (Intropin) 0 No 1 Yes U Unknown				
114N. Dobutamine HCl (Dobutrex) 0 No 1 Yes U Unknown				
115N. Xylocaine (mg)(Lidocaine)(0–2000)				
116N. Other Medications (Text limit 10 words)				
117N. Nafcillin 0 No 1 Yes U Unknown				
118N. Chloramphenicol 0 No 1 Yes U Unknown				
119N. Cefazolin (Ancef) 0 No 1 Yes U Unknown				
120N. Ceftriaxone (Rocephin) 0 No 1 Yes U Unknown				
121N. Other (Text limit 10 words)				
122N$. *Study Drug Given* (Specify time)				

	Pretreat			
Date				
Time				
123N. Comments (Text limit 50 words)				
1231N.				
1232N.				
1233N.				

FUNCTIONAL SYSTEMS (FS)

Pyramidal Functions
0. Normal
1. Abnormal signs without disability
2. Minimal disability
3. Mild or moderate paraparesis or hemiparesis; severe monoparesis
4. Marked paraparesis or hemiparesis; moderate quadri paresis; or monoplegia
5. Paraplegia, hemiplegia, or marked quadriparesis
6. Quadriplegia
U Unknown

Cerebellar Functions
0. Normal
1. Abnormal signs without disability
2. Mild ataxia
3. Moderate truncal or limb ataxia
4. Severe ataxia, all limbs
5. Unable to perform coordinated movements due to ataxia
6. Undetermined because of pyramidal weakness
U Unknown

Brain Stem Functions
0. Normal
1. Signs only
2. Moderate nystagmus or other mild disability
3. Severe nystagmus, marked extraocular weakness, or moderate disability of other cranial nerves
4. Marked dysarthria or other marked disability
5. Inability to swallow or speak
U Unknown

Sensory Functions (revised 1982)
0. Normal
1. Mild decrease in touch or pain or position sense, and/or moderate decrease in vibration in one or two limbs
2. Moderate decrease in touch or pain or position sense, and/or essentially lost vibration in one or two limbs
3. Marked decrease in touch or pain or loss of proprioception, alone or combined, in one or two limbs
4. Loss (essentially) of sensation in one or two limbs; or moderate decrease in touch or pain and/or loss of proprioception for most of the body below the head
5. Sensation essentially lost below the head
U Unknown

Visual (or Optic) Functions
0. Normal
1. Decreased visual acuity
2. Blind
3. Quadrantanopsia
4. Hemianopsia
U Unknown

Cerebral (or Mental) Functions
0. Normal
1. Mood alteration only (does not affect DDS score)
2. Mild decrease in mentation
3. Moderate decrease in mentation
4. Marked decrease in mentation (chronic brain syndrome, moderate)
5. Dementia or chronic brain syndrome, severe or incompetent
U Unknown

Other Functions
0. None
1. Any other neurologic findings attributed to head injury
U Unknown

Expanded Disability Status Scale

0=Normal neurologic exam (all grade 0 in functional systems [FS]; cerebral grade 1 acceptable)

1.0=No disability, minimal signs in one FS (i.e., grade 1, excluding cerebral grade 1)

1.5=No disability minimal signs in more than one FS (more than one grade 1, excluding cerebral grade 1)

2.0=Minimal disability in one FS (one FS grade 2, others 0 or 1)

2.5=Minimal disability in two FS (two FS grade 2, other 0 or 1)

3.0=Moderate disability in one FS (one FS grade 3, others 0 or 1), or mild disability in three or four FS (three/four FS grade 2, others 0 or 1), although fully ambulatory

3.5=Fully ambulatory but with moderate disability in one FS (one grade 3) and one or two FS grade 2; or two FS grade 3; or five FS grade 2 (others 0 or 1)

4.0=Fully ambulatory without aid, self–sufficient, up and about some 12 hours a day despite relatively severe disability consisting of one FS grade 4 (others 0 or 1), or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 500 meters

4.5=Fully ambulatory without aid, up and about much of the day, able to work full day, may otherwise have some limitation of full activity or require minimal assistance; characterized by relatively severe disability, usually consisting of one FS grade 4 (others 0 or 1), or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest for some 300 meters

5.0=Ambulatory without aid or rest for about 200 meters; disability severe enough to impair full daily activities (e.g., to work full day without special provisions) (usual FS equivalents are one grade 5 alone, other 0 or 1; or combinations of lesser grades, usually exceeding specifications for step 4.0)

5.5=Ambulatory without aid or rest for about 100 meters; disability severe enough to preclude full daily activities (usual FS equivalents are one grade 5 alone, others 0 or 1; or combinations of lesser grades, usually exceeding those for step 4.0)

6.0=Intermittent or unilateral constant assistance (cane, crutch, or brace) required to walk about 100 meters, with or without resting (usual FS equivalents are combinations with more than two FS grade 3+)

6.5=Constant bilateral assistance (canes, crutches or braces) required to walk about 20 meters without resting (usual FS equivalents are combinations with more than two FS grade 3+)

7.0=Unable to walk beyond about 5 meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day (usual FS equivalents are combinations with more than one FS grade 4+; very rarely, pyramidal grade 5 alone)

7.5=Unable to take more than a few steps; restricted to wheelchair; may need aid in transfer; wheels self but cannot carry on in standard wheelchair a full day; may require motorized wheelchair (usual FS equivalents are combinations with more than one FS grade 4+)

8.0=Essentially restricted to bed or chair or perambulated in wheelchair, but may be out of bed itself much of the day; retains many self–care functions; generally has effective use of arms (usual FS equivalents are combinations, generally grade 4+ in several systems)

9.0=Helpless bed patient; can communicate and eat (usually FS equivalents are combinations, most grade 4+)

9.5=Totally helpless bed patient; unable to communicate effectively or eat/swallow (usual FS equivalents are combinations, almost all grade 4+)

10.=Death

Ambulation Index

0 Asymptomatic; fully active

1 Walks normally, but reports fatigue that interferes with athletic or other demanding activities

2 Abnormal gait or episodic imbalance; gait disorder is noticed by family and friends; able to walk 25 feet (8 meters) in 10 seconds or less

3 Walks independently; able to walk 25 feet in 20 seconds or less

4 Requires unilateral support (cane or single crutch)

5 Requires bilateral support (canes, crutches, or walker) and walks 25 feet in 20 seconds or less; or requires unilateral support, but needs more than 20 seconds to walk 25 feet

6 Requires bilateral support and more than 20 seconds to walk 25 feet (may use wheelchair)

7 Walking limited to several steps with bilateral support; unable to walk 25 feet (may use wheelchair)

8 Restricted to wheelchair; able to transfer self independently

9 Restricted to wheelchair; unable to transfer self independently

FORM N

NEUROLOGICAL EVALUATION

To Be Completed by Nurse Clinician
in Consultation with PI or Trauma Fellow

This form is to be completed on the first evaluation by the neurosurgeon. Thereafter, it is completed on a daily basis during morning rounds by the neurosurgeon, while the patient is in the ICU. It may also be used to record a significant change in the patient's neurologic status at any time during the patient course. After discharge from the ICU, the form should be completed on a twice weekly basis. Should the patient remain in the APHIP hospital longer than one (1) month, data collection may be halted at the discretion of the neurosurgeon and final entry made at discharge from the hospital.

1N. DATE. Enter dd/mmm/yr.

1N$. TIME. Record actual time of examination.

2N. VISIT TYPE. Hospital admission refers to the first neurological evaluation by the neurosurgeon.

3N. The OBSERVER is the physician who performs the examination of the patient. Hospital keeps list of codes. (0-20)

4N-5N. HEIGHT AND WEIGHT. Should be entered on ICU admission and weight repeated whenever possible. Height, enter 120-240 cm; weight, enter 30-200 kg; **U=Unknown.**

Eyes

6N. BEST EYE OPENING. See Glasgow Coma Scale, Table 1. Use an *"untestable"* answer for eyes which are patched, injured, swollen, or for patients who have had tarsorrhaphy or treatment with barbiturates, narcotics, or paralytic agents. The GCS score will be calculated for a person with one or more untestable values with **Eyes=1.1**, enter 1-7.

7N,10N. PUPIL RESPONSE. Patients whose eyes are severely injured or closed by swelling may be entered as *Untestable=U.*

0=No Reaction **2=Sluggish**
1=Reaction **U=Unknown**

8N,11N. PUPIL SIZE. Enter in mm. (1-9) If >9, enter 9; **U=Unknown**

9N,12N. PUPIL SHAPE. Record:

1=Round **3=Other**
2=Elliptical **U=Unknown**

13N-14N. CORNEALS. Record:

0=None **1=Present** **U=Untestable**

15N-16N. OCULOCEPHALICS.

0=None	U=Untestable
1=Normal	A=Not Applicable
2=Abnormal	if patient is awake

17N-18N. OCULOVESTIBULARS.

0=None	U=Untestable
1=Normal	A=Not Applicable
2=Abnormal	if patient is awake

Verbal Response

19N. BEST VERBAL RESPONSE. See Glasgow Coma Scale, Table 1. Use an *"untestable" answer for the best verbal response* for all patients who are intubated, trached, or who have oral/facial injuries, aphasia, dysarthria, or who have been treated with barbiturates, narcotics, or paralytic agents. If patient in barbiturate coma or paralyzed, enter [9] instead of [6]. Enter 1-9, **U=Other Untestable.**

The Glasgow Coma Scale score will be calculated for a person with one or more untestable values equal to 1.1. each.

Motor Response

20N,22N, 24N,26N. BEST MOTOR RESPONSE. See Glasgow Coma Scale, Table 1. The motor responses for the Neurologic Exam are separated into four categories, corresponding to the four limbs. In order to calculate the motor response for the Glasgow Coma Scale score, the computer will choose the response of the arm with the best function, ignoring untestable limbs.

Use an *"untestable"* answer for motor response for patients with limb injuries and/or immobilization, spinal cord injuries, or who have been treated with barbiturates, narcotics, or paralytic agents. If all limbs are untestable, the GCS will be calculated with **motor score=1.1.** See Table 1.

All *untestable* GCS will be computed 3.3.

Enter 1-9, **U=Other Untestable**

21N,23N, 25N,27N. WEAKNESS. Record if weakness if present in each limb.

0=No 1=Yes U=Untestable

28N. Rate SEIZURE TYPE. If patient is paralyzed or in barbiturate coma, code unknown unless there is EEG evidence of seizures, then code type unknown.

0=None	4=Partial with Secondary Generalization
1=Generalized	5=Suspected
2=Partial Simple	6=Type Unknown
3=Partial Complex	U=Unknown

Description of Coma*

29N. TIME IN COMA. Coma duration is the time from injury until the patient begins to follow commands consistently. The end of coma is the first day the patient is able to follow commands; however, he must do so for at least two days in a row. For patients comatose longer than 24 hours, the day of injury is considered day 1 and the day the patient begins to follow commands consistently is not included in the calculation. For patients comatose less than 24 hours, coma duration is the number of hours they did not follow commands divided by 24 (round to the nearest tenth). Enter 0.0-300.0, **U=Unknown, A=Not Applicable if patient dies.** If patient discharged in vegetative state, enter number of days since onset of coma and enter 4 in 31N.

30N. DATE patient was considered to no longer be in coma by physician. Enter dd/mmm/yr. Leave blank if patient expires without emerging from coma, or if patient discharged in vegetative state.

31N. ACCURACY of date patient considered to no longer be in coma.

0=Date Correct
1=Day Guessed
2=Day and Month Guessed
3=Day, Month and Year Guessed
4=Discharged in a Vegetative State

*Note: Complete only once on day patient considered to no longer be in coma, at hospital discharge, or death.

Declaration of Brain Death

310N. DATE. Enter date patient determined to be brain dead, if applicable; otherwise leave blank.

310N$. TIME. Enter time patient determined to be brain dead, if applicable; otherwise leave blank.

Complications **Codes: 0=No 1=Yes U=Unknown**

General Complications. Categorized as *"General Complications"* on the *"Neurological Exam"*. These are complications related to an untoward clinical course. Code **Yes** on the first day the complication is diagnosed and continue until the condition is resolved.

General Complications Definitions

32N. PULMONARY. Includes such diagnoses as acute respiratory distress syndrome, atelectasis, pleural effusion, pulmonary embolus, pneumothorax, pulmonary edema, and respiratory failure. The essentials of diagnosis are positive radiographic findings and/or abnormal arterial blood gases, including PaO_2 <60 and/or $PaCO_2$ >45mmg Hg. Includes lung abscess and empyema. Pneumonia is a separate category. Do not code here unless one of the above conditions also applies.

33N. CARDIOVASCULAR. Includes cardiac arrhythmias, congestive heart failure, myocardial ischemia. Systolic hypotension below 90mm Hg, or systolic hypertension above 160mm Hg if it persists for at least 30 minutes and requires treatment. This applies to normotensive patients. In known hypertensive patients, variation of blood pressures greater than 40mm Hg which requires adjustment of the treatment is considered a complication.

34N. PERIPHERAL VASCULAR. Deep venous thrombosis of an extremity and/or pelvic organ which requires therapeutic intervention; i.e., bedrest, heat, anti-inflammatory agents, anticoagulants, filter.

35N. GASTROINTESTINAL. GI hemorrhage requiring transfusion. Also, gastric perforation and secondary pancreatitis are included under this category.

36N. RENAL. Include acute renal failure which is determined by creatinine over 2.5 and dehydration ruled out.

37N. HEPATIC. Include liver failure, hepatitis, cholangitis, and hepatic renal syndrome. The diagnosis can be established by determination of serum SGPT greater than 30 international units and total serum bilirubin greater than 2.5 mm/dl.

38N. ELECTROLYTE. To include any electrolyte imbalance that causes symptomatology or requires specific treatment.

39N. COAGULOPATHY. This complication is determined by a platelet count of less than 80,000 per cubic mm, PT more reliable than 16 seconds, PTT more reliable than 35-40 seconds.

40N. SIADH. Essentials of diagnosis should include: hyponatremia not secondary to overhydration (Na<130); urine osmolality to exceed serum osmolality.

41N. DIABETES INSIPIDUS. Urine output over 200 ml/hr for 24 hours not responding to fluid restriction, or if patient requires a treatment with pitressin. Urine specific gravity less than 1.005, urine osmolality less than ½ of plasma.

410N. NONSURGICAL CSF LEAK.

42N. NONSURGICAL MENINGITIS. Diagnosed by a positive culture or in the absence of a positive culture, one of the following:

a. >50% polys on CSF cell count; minimum 50 cells counted.
b. CSF sugar <15.

420N. NON-IATROGENIC ABSCESS.

43N. NON-IATROGENIC VENTRICULITIS. Diagnosis by a positive culture or in the absence of a positive culture, one of the following:

a. >50% polys on CSF cell count; minimum 50 cells counted.
b. CSF sugar <15.

430N. NON-IATROGENIC WOUND INFECTION.

44N. PNEUMONIA. This diagnosis is made by the presence of infiltration on the chest x-ray and/or positive sputum for organisms on the gram stain specimen or culture.

Lung abscesses and empyemas are coded under *"Pulmonary Complications"*.

440N. WOUND DEHISCENCE.

45N. SEPTICEMIA. Documented by positive blood culture associated with clinical evidence of sepsis, such as hyperthermia, hypotension, etc.

46N. OTHER. Text 10 word limit.

Complications of Treatment. These are coded on the *"Neurologic Evaluation"* and refer to those complications which specifically relate to management of the patient and are iatrogenic in nature. Code **Yes** on the first day the complication is diagnosed by a physician, and continue until the condition has resolved.

Iatrogenic Complications: Intracranial

47N. INTRACEREBRAL HEMORRHAGE. Refers to the reaccumulation of intracerebral hemorrhage in the operative site. Any new hemorrhage remote from the surgical field is not considered a complication.

48N. INTRAVENTRICULAR HEMORRHAGE. Refers to secondary bleeding in the ventricular system following an intracranial procedure, either definitive surgery or diagnostic procedure. Diagnosis is made by CT scan.

49N. SUBDURAL HEMORRHAGE. Refers to the development of recurrent subdural hematoma after primary operation for definitive treatment.

50N. EPIDURAL HEMORRHAGE. Refers to the development of recurrent epidural hematoma following operative procedure.

51N. CEREBROSPINAL FLUID LEAK. CSF leak from a surgical incision. Otorrhea or rhinorrhea is not a surgical complication unless the procedure is performed on the base of the skull.

53N. POSTSURGICAL VENTRICULITIS. Diagnosed by a positive culture or in the absence of a positive culture, one of the following:

a. 50% polys on CSF cell count; minimum 50 cells counted;
b. CSF sugar <15.

54N. POSTSURGICAL MENINGITIS. Diagnosed by a positive culture or in the absence of a positive culture, one of the following:

a. 50% polys on CSF cell count; minimum 50 cells counted;
b. CSF sugar <15.

55N. ABSCESS. Documented by needle aspiration, surgical exploration, or autopsy. The location of the abscess must be anatomically related to the previous cranial procedure.

56N. WOUND INFECTION. Include such entities as osteomyelitis of bone flap, subgaleal infection, and epidural or subdural empyema secondary to cranial procedure.

57N. OTHER. Text 10 word limit.

Iatrogenic Complications: Not Intracranial

58N. PNEUMOTHORAX. This complication must have developed as the result of instrumentation for diagnostic or therapeutic purposes.

59N. URINARY INFECTION.

590N. VASCULAR CATHETER SEPSIS. Urinary tract infection of over 100,000 organisms (should develop after catheterization).

60N. ESOPHAGEAL INTUBATION. Documented erroneous intubation of esophagus resulting in hypoxia (PaO_2 <60mm Hg)

61N. MAJOR VESSEL OCCLUSION. An ischemic phenomenon in the distribution of any major vessel from instrumentation of the same vessel, such as arteriography or inadvertent ligation of the vessel.

62N. EXTUBATION. Inadvertent removal of endotracheal tube by either the patient or staff at a time when continued intubation is required.

63N. OTHER. Text 10 word limit.

Diagnosis Complications

64N. UNDETECTED OPERABLE INTRACRANIAL MASS. Refers to the lesions of surgical importance which are not detected within a reasonable period of time. The delay may be due to clinical judgment, or inaccurate interpretation of diagnostic studies.

65N. SPINAL FRACTURE. Refers to the failure to identify a fracture of bony spinal column, with or without neurological deficit associated with closed head injury in whom evidence obtained and other symptoms and signs might be masked.

66N. OTHER. Text 10 word limit.

NOTE: For those patients receiving weekly neurologic evaluations, the exam recorded reflects the status of the patient at the specific time noted. Complications, however, are cumulative and Yes to a specific complication indicates an occurrence between the last entry and the present one.

Neurologic Status Summary

Modified Kurtzke Score

67N. PYRAMIDAL FUNCTIONS. Enter 0-6 or U.

0=Normal
1=Abnormal signs without disability
2=Minimal disability
3=Mild or moderate paraparesis or hemiparesis; severe monoparesis
4=Marked paraparesis or hemiparesis; moderate quadri-paresis; or monoplegia
5=Paraplegia, hemiplegia, or marked quadriparesis
6=Quadriplegia
U=Unknown

68N. CEREBELLAR FUNCTIONS. Enter 0-6 or U.

0=Normal
1=Abnormal signs without disability
2=Mild ataxia
3=Moderate truncal or limb ataxia
4=Severe ataxia, all limbs
5=Unable to perform coordinated movements due to ataxia
6=Undetermined because of pyramidal weakness
U=Unknown

69N. BRAIN STEM FUNCTIONS. Enter 0-5 or U.

0=Normal
1=Signs only
2=Moderate nystagmus or other mild disability
3=Severe nystagmus, marked extraocular weakness, or moderate disability of other cranial nerves
4=Marked dysarthria or other marked disability
5=Inability to swallow or speak
U=Unknown

70N. SENSORY FUNCTIONS. Enter 0-5 or U.

0=Normal
1=Mild decrease in touch or pain or position sense, and/or moderate decrease in vibration in one or two limbs
2=Moderate decrease in touch or pain or position sense, and/or essentially lost vibration in one or two limbs
3=Marked decrease in touch or pain or loss of proprioception, alone or com bined, in one or two limbs
4=Loss (essentially) of sensation in one or two limbs; or moderate decrease in touch or pain and/or loss of proprioception for most of the body below the head
5=Sensation essentially lost below the head
U=Unknown

71N. VISUAL (OR OPTIC) FUNCTIONS (RIGHT). Enter 0-4 or U.

0=Normal
1=Decreased visual acuity
2=Blind
3=Quadrantanopsia
4=Hemianopsia
U=Unknown

72N. VISUAL (OR OPTIC) FUNCTIONS (LEFT). Enter 0-4 or U.

0=Normal
1=Decreased visual acuity
2=Blind
3=Quadrantanopsia
4=Hemianopsia
U=Unknown

73N. CEREBRAL (OR MENTAL) FUNCTIONS. Enter 0-5 or U.

0=Normal
1=Mood alteration only (does not affect DDS score)
2=Mild decrease in mentation
3=Moderate decrease in mentation
4=Marked decrease in mentation (chronic brain syndrome, moderate)
5=Dementia or chronic brain syndrome, severe or incompetent
U=Unknown

74N. OTHER FUNCTIONS.

0=None
U=Unknown
1=Any other neurologic findings attributed to head injury

75N. EXPANDED DISABILITY STATUS SCALE. Enter 0-10.

0=Normal neurologic exam (all grade 0 in functional systems [FS]; cerebral grade 1 acceptable)
1.0=No disability, minimal signs in one FS (i.e., grade 1, excluding cerebral grade 1)
1.5=No disability minimal signs in more than one FS (more than one grade 1, excluding cerebral grade 1)
2.0=Minimal disability in one FS (one FS grade 2, others 0 or 1)
2.5=Minimal disability in two FS (two FS grade 2, other 0 or 1)
3.0=Moderate disability in one FS (one FS grade 3, others 0 or 1), or mild disability in three or four FS (three/four FS grade 2, others 0 or 1), although fully ambulatory
3.5=Fully ambulatory but with moderate disability in one FS (one grade 3) and one or two FS grade 2; or two FS grade 3; or five FS grade 2 (others 0 or 1)
4.0=Fully ambulatory without aid, self-sufficient, up and about some 12 hours a day despite relatively severe disability consisting of one FS grade 4 (others 0 or 1), or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 500 meters
4.5=Fully ambulatory without aid, up and about much of the day, able to work full day, may otherwise have some limitation of full activity or require minimal assistance; characterized by relatively severe disability, usually consisting of one FS grade 4 (others 0 or 1), or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest for some 300 meters

5.0=Ambulatory without aid or rest for about 200 meters; disability severe enough to impair full daily activities (e.g., to work full day without special provisions) (usual FS equivalents are one grade 5 alone, other 0 or 1; or combinations of lesser grades, usually exceeding specifications for step 4.0)
5.5=Ambulatory without aid or rest for about 100 meters; disability severe enough to preclude full daily activities (usual FS equivalents are one grade 5 alone, others 0 or 1; or combinations of lesser grades, usually exceeding those for step 4.0)
6.0=Intermittent or unilateral constant assistance (cane, crutch, or brace) required to walk about 100 meters, with or without resting (usual FS equivalents are combinations with more than two FS grade 3+)
6.5=Constant bilateral assistance (canes, crutches or braces) required to walk about 20 meters without resting (usual FS equivalents are combinations with more than two FS grade 3+)
7.0=Unable to walk beyond about 5 meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day (usual FS equivalents are combinations with more than one FS grade 4+; very rarely, pyramidal grade 5 alone)
7.5=Unable to take more than a few steps; restricted to wheelchair; may need aid in transfer; wheels self but cannot carry on in standard wheelchair a full day; may require motorized wheelchair (usual FS equivalents are combinations with more than one FS grade 4+)
8.0=Essentially restricted to bed or chair or perambulated in wheelchair, but may be out of bed itself much of the day; retains many self-care functions; generally has effective use of arms (usual FS equivalents are combinations, generally grade 4+ in several systems)
9.0=Helpless bed patient; can communicate and eat (usually FS equivalents are combinations, most grade 4+)
9.5=Totally helpless bed patient; unable to communicate effectively or eat/swallow (usual FS equivalents are combinations, almost all grade 4+)
10.=Death

76N. AMBULATION INDEX. Enter 0-9.

0=Asymptomatic; fully active
1=Walks normally, but reports fatigue that interferes with athletic or other demanding activities
2=Abnormal gait or episodic imbalance; gait disorder is noticed by family and friends; able to walk 25 feet (8 meters) in 10 seconds or less
3=Walks independently; able to walk 25 feet in 20 seconds or less
4=Requires unilateral support (cane or single crutch)
5=Requires bilateral support (canes, crutches, or walker) and walks 25 feet in 20 seconds or less; or requires unilateral support, but needs more than 20 seconds to walk 25 feet
6=Requires bilateral support and more than 20 seconds to walk 25 feet (may use wheelchair)
7=Walking limited to several steps with bilateral support; unable to walk 25 feet (may use wheelchair)
8=Restricted to wheelchair; able to transfer self independently
9=Restricted to wheelchair; unable to transfer self independently

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

INTRACRANIAL PRESSURE MONITORING FORM O

TO BE COMPLETED BY NURSE CLINICIAN IN CONSULTATION WITH PI OR TRAUMA FELLOW (Mar 88)

		0059	0159	0259	0359	0459	0559	0659	0759	0859	0959	1059	1159	1259	1359	1459	1559	1659	1759	1859	1959	2059	2159	2259	2359
10	Date																								
10$	Time																								
20	Place of Evaluation 1=ER 3=OR 5=RecRm 2=CT 4=ICU																								
30	Observer (Hospital keeps list of codes) (0–99)																								
40	Hourly recorded mean ICP* Enter –8–100 >100 enter 101 U=Unknown																								
50	Hourly recorded mean Arterial Pressure Enter 0–300 U=Unknown																								
60	Highest mean ICP observed during the hour* Enter –8–100 >100 enter 101 U=Unknown																								
70	Lowest mean ICP observed during the hour* Enter –8–100 >100 enter 101 U=Unknown																								
80	Monitoring Device :Subdural 2=Intraventricular =Epidural 4=Intraparenchymal :Subarachnoid U=Unknown																								
8100	ICP Device Type 1=Catheter 3=Fiberoptic 2=Bolt																								
8200	ICP Trace Loss 0=No 1=Yes																								

Therapy Intensity Level (TxIL) (0=No; 1=Yes; U=Unknown)

		TIL Wt	0059	0159	0259	0359	0459	0559	0659	0759	0859	0959	1059	1159	1259	1359	1459	1559	1659	1759	1859	1959	2059	2159	2259	2359
400	Barbiturates																									
410	Mannitol >1gm/kg/hr	6																								
420	Mannitol ≤1gm/kg/hr	3																								
430	Ventricular Drainage continuous or >4x/hr	2																								
440	Ventricular Drainage ≤4x/hr	1																								
450	Intensive Hyperventilation PCO2 <30	2																								
460	Mild Hyperventilation PCO2 ≥30 and <40	1																								
470	Paralysis	1																								
480	Sedation	1																								
490	No Therapy	0																								
510	Hourly Total TIL** (0–12)																									

300$ Time ICP monitoring initiated (24 hr clock): ____ ____:____ ____ (complete only once on the date monitoring initiated)

310 Date ICP monitoring discontinued: ____ ____/____ ____ ____/____ ____ 310$ Time ICP monitoring D/C (24 hr clock): ____ ____:____ ____

D/C=Discontinued

320 Date GUT determined: ____ ____/____ ____ ____/____ ____ 320$ GUT enter time (24 hr clock): ____ ____:____ ____

*Refers to the hour preceding the time at the top of the column.

**Barbiturates are to be included in the study on patients uncontrolled at TIL of 12; use of barbiturates gives an automatic score of 15.

FORM O

INTRACRANIAL PRESSURE MONITORING

To Be Completed by Nurse Clinician
in Consultation with PI or Trauma Fellow

To be initiated as soon as intracranial pressure measurements become available. Opening pressures are recorded on the surgical treatment form. Thereafter, hourly high and low recordings will be coded on the ICP Form.

1O. DATE. Unlike the other forms, one page covers a single 24 hour period. DO NOT use more than one date.

1O$. TIME. All entries are made at 59 minutes after the hour and refer to the hour preceding the time at top of the column.

2O. PLACE OF EVALUATION.

1=Emergency Room	4=ICU
2=CT Scan	5=Recovery Room
3=Operating Room	

3O. OBSERVER. Hospital keeps list of codes. Enter 0-20

4O. HOURLY RECORDED MEAN ICP. Record mean ICP each hour (enter value closest in time to the end of the hour). Enter 3-100. For ICP >100, enter 101; U=Unknown.

5O. HOURLY RECORDED MEAN ARTERIAL PRESSURE. Record mean arterial pressure coincident to ICP recorded in 4O. Enter 0-200

6O. HIGHEST MEAN ICP OBSERVED DURING THE HOUR. Enter 3-100. For ICP >100, enter 101; U=Unknown.

7O. LOWEST MEAN ICP OBSERVED DURING THE HOUR. Enter 3-100. For ICP >100, enter 101; U=Unknown.

8O. MONITORING DEVICE. For patients with more than one ICP monitor, indicate which is used for pressure recorded during that hour.

1=Ventriculostomy	3=Other
2=Bolt	U=Unknown

Therapy Intensity Level

The level of therapy necessary to control ICP is summarized every four hours. Record all therapies used during the four-hour interval. Code any of the agents listed regardless of their intent to treat ICP. The *"total dose"* of Mannitol refers to the cumulative amount during the four hours. Each level provides an *"other"* category and space to specify the individual therapy.

When an alternative therapy is used, it is the responsibility of the Principal Investigator initiating to obtain intercenter agreement of assignment of therapy level.

40O.

41O.

42O.

43O.

44O.

45O.

46O.

47O.

48O.

49O.

51O.

30O. **Time ICP Monitoring Initiated.** Indicate time when actual ICP recording was begun.

31O. **TIME ICP MONITORING DISCONTINUED.** Indicate the time that the monitoring device was removed. In the case of a patient who subsequently expires with a monitor in place, use time of brain death or absence of vital signs.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

MRI SCAN

(Optional)

TO BE COMPLETED BY THE RADIOLOGIST OR STUDY M.D.

FORM R

(MAR 88)

1R.	DATE				
1R$.	TIME				
2R.	OBSERVER (Hospital keeps list of codes) (0–20)				
210R.	FORM COMPLETION CODE: 0 Completed; 1 MRI Not Done; 2 MRI Done, Form Not Completed				
220R.	IF MRI DONE, FORM NOT COMPLETED (Specify)				
3R.	VISIT TYPE: 1=Hospital admission; 2=ICU admission; 3=In hospital ICU; 4=Discharge from ICU; 5=In hospital, not ICU; 6=Hospital discharge; 7=Follow–up; 8=Death; 9=Recovery room; 12=Other				
310R.	SCAN STATUS: 0=New Scan; 1=Recode; 2=Re–entry of original data; 3=Unable to read; MRI obtained, scan missing; 4=Neuroradiology report				
4R.	EXAM RESULT: 0=Normal; 1=Abnormal				
5R.	QUALITY OF MRI SCAN: 4=Readable 5=Unreadable U=Unknown				
510R.	COMPLETENESS OF SCAN: 0=Complete 1=Incomplete U=Unknown				
7R.	SCAN TYPE: 1=T_1 weighted; 2=T_2 weighted; 3=Balanced; 4=Unknown				
810R.	LEFT LATERAL VENTRICLE: 0=Normal 1=Enlarged 2=Small 3=Absent U=Unknown				
820R.	RIGHT LATERAL VENTRICLE: 0=Normal 1=Enlarged 2=Small 3=Absent U=Unknown				
9R.	VENTRICULAR BRAIN RATIO* (1–35.0) 1=Ventricles too small to measure U=Unknown				
10R.	SYMMETRY OF VENTRICULAR SYSTEM: Code=1 if frontal horns and body asymmetric in any cut 0=Symmetric 1=Asymmetric U=Unknown				
11R.	MESENCEPHALIC CISTERNS: 0=Absent or compressed (may be unilateral) 1=Present U=Unknown				
12R.	INTRAVENTRICULAR BLOOD: 0=No 1=Yes 2=Layering U=Unknown				
13R.	MIDLINE STRUCTURES(Choose One): 0=Normal; 1=Left to right supratentorial shift; 2=Right to left supratentorial shift U=Unknown				
14R.	SHIFT SIZE (mm): Measure the largest extent of shift of any midline structure (0–35) U=Unknown				
15R.	POSTERIOR FOSSA (Choose One): 0=Normal; 1=Left to right infratentorial shift; 2=Right to left infratentorial shift; 3=Not visible U=Unknown				
16R.	DIFFUSE BRAIN ATROPHY: 0=No 1=Yes U=Unknown				
17R.	EXTRACEREBRAL AIR: 0=No 1=Yes U=Unknown				
18R.	INTRAPARENCHYMAL AIR: 0=No 1=Yes U=Unknown				
19R.	INTRAVENTRICULAR AIR: 0=No 1=Yes U=Unknown				
20R.	SUBARACHNOID HEMORRHAGE: 0=No 1=Yes U=Unknown				

Note: When other codes are not appropriate due to insufficient information, poor scan, not enough cuts, etc., use code for unknown.

*VBR's should be measured on those patients surviving at discharge. Measure on the first scan and on the scans closest to 30 days and six months post–injury; otherwise code unknown.

Side Codes	Site Codes			Foreign Body Codes
0=None	0=None	6=Thalamus	13=Posterior Fossa	0=None
1=Right	1=Frontal	7=Cerebellum	U=Unknown	1=Bone
2=Left	2=Temporal	9=Corpus Callosum	N=Nonconfluent	2=Metal
3=Midline	3=Parietal	10=Pons		3=Bone and Metal
6=Bilateral	4=Occipital	11=Midbrain		4=Other (specify in commands)
U=Unknown	5=Basal Ganglia	12=Medulla		U=Unknown

Lesions are measured if the volume of the total lesion is ≥ 10cc. The total lesion mass volume includes both the hyperintense and the associated hypointense components. The total volume of the mass must be ≥ either component. Measure volumes by cursing the area of the lesion component on each slice, and stack the slices. The hypointense component is determined by measuring the volume of the total lesion and subtracting the hyperintense component. Components of lesions less than 10cc total will be coded as 0 (absent) or X (1–9cc).

All junctional lesion sites are coded with multiple numbers (i.e., frontal parietal=1,3).

Lesion identification will remain constant throughout all scans; i.e., Lesion A, or Lesion 1, etc.

N is added to site codes if lesion becomes nonconfluent.

	EXTRACEREBRAL LESIONS				
21R.	Lesion A				
	Side				
2110R.	Site(s) (Code 0, 1, 2, 3, 4, and/or 13)				
2120R.	Vol Hyperintense Component (0–600 cc)(code 0 or X if total lesion <10cc)				
2130R.	Vol Hypointense Component (0–600 cc)(code 0 or X if total lesion <10cc)				
22R.	Lesion B				
	Side				
2210R.	Site(s) (Code 0, 1, 2, 3, 4, and/or 13)				
2220R.	Vol Hyperintense Component (0–600 cc)(code 0 or X if total lesion <10cc)				
2230R.	Vol Hypointense Component (0–600 cc)(code 0 or X if total lesion <10cc)				
23R.	Lesion C				
	Side				
2310R.	Site(s) (Code 0, 1, 2, 3, 4, and/or 13)				
2320R.	Vol Hyperintense Component (0–600 cc)(code 0 or X if total lesion <10cc)				
2330R.	Vol Hypointense Component (0–600 cc)(code 0 or X if total lesion <10cc)				
24R.	Lesion D				
	Side				
2410R.	Site(s) (Code 0, 1, 2, 3, 4, and/or 13)				
2420R.	Vol Hyperintense Component (0–600 cc)(code 0 or X if total lesion <10cc)				
2430R.	Vol Hypointense Component (0–600 cc)(code 0 or X if total lesion <10cc)				
	INTRACEREBRAL LESIONS (Enter by order of size)				
25R.	Lesion 1				
	Side				
2510R.	Site(s)				
2520R.	Foreign Body				
2530R.	Vol Hyperintense Component (cc)(code 0 or X if total lesion <10cc)				
2540R.	Vol Associated Hypointense Component(Edema)(cc)(code 0 or X if lesion <10cc)				
26R.	Lesion 2				
	Side				
2610R.	Site(s)				
2620R.	Foreign Body				
2630R.	Vol Hyperintense Component (cc)(code 0 or X if total lesion <10cc)				
2640R.	Vol Associated Hypointense Component(Edema)(cc)(code 0 or X if lesion <10cc)				
27R.	Lesion 3				
	Side				
2710R.	Site(s)				
2720R.	Foreign Body				
2730R.	Vol Hyperintense Component (cc)(code 0 or X if total lesion <10cc)				
2740R.	Vol Associated Hypointense Component(Edema)(cc)(code 0 or X if lesion <10cc)				

Side Codes	Site Codes			Foreign Body Codes
0=None	0=None	6=Thalamus	13=Posterior Fossa	0=None
1=Right	1=Frontal	7=Cerebellum	U=Unknown	1=Bone
2=Left	2=Temporal	9=Corpus Callosum	N=Nonconfluent	2=Metal
3=Midline	3=Parietal	10=Pons		3=Bone and Metal
6=Bilateral	4=Occipital	11=Midbrain		4=Other (specify in commands)
U=Unknown	5=Basal Ganglia	12=Medulla		U=Unknown

28R.	Lesion 4				
	Side				
2810R.	Site(s)				
2820R.	Foreign Body				
2830R.	Vol Hyperintense Component (cc)(code 0 or X if total lesion <10cc)				
2840R.	Vol Associated Hypointense Component(Edema)(cc)(code 0 or X if lesion <10cc)				
29R.	Lesion 5				
	Side				
2910R.	Site(s)				
2920R.	Foreign Body				
2930R.	Vol Hyperintense Component (cc)(code 0 or X if total lesion <10cc)				
2940R.	Vol Associated Hypointense Component(Edema)(cc)(code 0 or X if lesion <10cc)				
30R.	Lesion 6				
	Side				
3010R.	Site(s)				
3020R.	Foreign Body				
3030R.	Vol Hyperintense Component (cc)(code 0 or X if total lesion <10cc)				
3040R.	Vol Associated Hypointense Component(Edema)(cc)(code 0 or X if lesion <10cc)				
31R.	Lesion 7				
	Side				
3110R.	Site(s)				
3120R.	Foreign Body				
3130R.	Vol Hyperintense Component (cc)(code 0 or X if total lesion <10cc)				
3140R.	Vol Associated Hypointense Component(Edema)(cc)(code 0 or X if lesion <10cc)				
32R.	Lesion 8				
	Side				
3210R.	Site(s)				
3220R.	Foreign Body				
3230R.	Vol Hyperintense Component (cc)(code 0 or X if total lesion <10cc)				
3240R.	Vol Associated Hypointense Component(Edema)(cc)(code 0 or X if lesion <10cc)				
33R.	Lesion 9				
	Side				
3310R.	Site(s)				
3320R.	Foreign Body				
3330R.	Vol Hyperintense Component (cc)(code 0 or X if total lesion <10cc)				
3340R.	Vol Associated Hypointense Component(Edema)(cc)(code 0 or X if lesion <10cc)				
34R.	Lesion 10				
	Side				
3410R.	Site(s)				
3420R.	Foreign Body				
3430R.	Vol Hyperintense Component (cc)(code 0 or X if total lesion <10cc)				
3440R.	Vol Associated Hypointense Component(Edema)(cc)(code 0 or X if lesion <10cc)				
35R.	Device Used To Measure Lesions 0=No longer measured 1=Planimeter 2=Computer 3=Grid				

68R. Comments (Text limit 50 words)

6810R. _____

6820R. _____

6830R. _____

FORM R

MRI SCAN

This form is to be completed by the neurosurgeon treating the patient or the designated study radiologist. Record the date and time that the scan was performed.

1R. DATE. Enter dd/mmm/yr.

1R$. TIME. Record time of CT scan.

2R. VISIT TYPE. Record most appropriate code.

1=Hospital Admission	6=Hospital Discharge
2=ICU Admission	7=Follow-Up
3=In-Hospital ICU	8=Death
4=Discharge from ICU	9=Recovery Room
5=In Hospital, not ICU	12=Other

3R. OBSERVER. Hospital keeps list of codes. Enter 1-20.

310R. Scan Status.

4R. EXAM RESULT. Code as **normal** only if it is a totally normal scan; otherwise, code **abnormal**. Disregard skull fractures unless indriven bone fragments present.

5R. QUALITY OF SCAN. 1=Good 2=Fair 3=Technically Unsatisfactory

510R. COMPLETENESS OF SCAN.

7R. CONTRAST. Code 1=Yes if contrast material was used. 0=No U=Unknown

810R.

820R.

9R. VENTRICULAR BRAIN RATIO. Using the CT slice showing the ventricles at their largest extent (through the body of the lateral ventricles), curse the perimeter of the lateral ventricles and the inner table of the skull. Divide the ventricular area by the intracranial area and multiply by 100 to yield a ventricle-brain percent ratio (VBR). The procedure should be repeated three times, by the same examiner, and the average score entered as the VBR. If the ventricles are too small to measure, enter an arbitrary value of 1. U=Unknown; Enter 1.0-35.0

10R. SYMMETRY. 0=Symmetric 1=Asymmetric U=Unknown

11R. MESENCEPHALIC CISTERNS. 0=Absent or Compressed (may be unilateral) 1=Present U=Unknown

12R. INTRAVENTRICULAR BLOOD. 0=No 1=Yes U=Unknown

13R. MIDLINE STRUCTURES.

0=Normal
1=Left to Right Supratentorial Shift
2=Right to Left Supratentorial Shift
U=Unknown

14R. SHIFT SIZE. Record in millimeters using conversion factor appropriate for your scanner. U=Unknown, Enter 0-35.

15R. POSTERIOR FOSSA. O=Normal
1=Left to Right Shift
2=Right to Left Shift
3=Not Visible
U=Unknown

16R.	DIFFUSE BRAIN ATROPHY.	0=No	1=Yes	U=Unknown
17R.	EXTRACEREBRAL AIR.	0=No	1=Yes	U=Unknown
18R.	INTRAPARENCHYMAL AIR.	0=No	1=Yes	U=Unknown
19R.	INTRAVENTRICULAR AIR.	0=No	1=Yes	U=Unknown
20R.	SUBARACHNOID HEMORRHAGE.	0=No	1=Yes	U=Unknown

Measurable Extracerebral Lesions

Use this section to code those extracerebral lesions which are >15 cc in volume.

Site Codes: 0=None
1=Right Hemisphere
2=Left Hemisphere
3=Midline (interhemispheric)
4=Right Posterior Fossa
5=Left Posterior Fossa
6=Bilateral
U=Unknown

21R,24R. SITE(s). Choose the code which most appropriately describes the location of the lesion. Your may enter more than one number if necessary.

22R,25R. VOLUME OF HIGH OR MIXED DENSITY ZONE. Curse the perimeter of the high or mixed density lesion on each slice. Using the thickness of the slice and the area cursed, stack the slices to give volume in cc's.

Measurable Intracerebral Mass

Use this section to describe intracerebral lesions >15 cc in volume.

Side Codes: 0=None
1=Right
2=Left
3=Midline
U=Unknown
6=Bilateral

28R,32R. SIDE. Choose code which corresponds to the side location of the lesion.
36R,40R.

Site Codes:	0=None	4=Occipital	8=Corpus Callosum
	1=Frontal	5=Basal Ganglia	9=Pons
	2=Temporal	6=Thalamus	10=Midbrain
	3=Parietal	7=Cerebellum	11=Medulla
			U=Unknown

27R,29R. SITE AND VOLUME. Coding explained above under Measurable Extracerebral Lesions.
331,33R.
35R,37R.
39R,41R.

2910R. VOLUME OF EDEMATOUS ZONE. Curse the perimeter of the corresponding ede
3310R. matous zone on each slice. Compute total volume and subtract the high
3710R. or mixed density volume to obtain the volume of the edematous zone.
4110R.

4120R. DEVICE USED TO MEASURE.

Large Intracerebral Infarct

Use this section to code large intracerebral infarcts which are defined as *"a large area of decreased density in the distribution of one or more arterial territories"*.

Side Codes:	0=None	2=Left	U=Unknown
	1=Right	3=Midline	

44R,46R. SIDE. Choose code which corresponds to the side location of the lesion.

Site Codes:	0=None	4=Occipital	8=Corpus Callosum
	1=Frontal	5=Basal Ganglia	9=Pons
	2=Temporal	6=Thalamus	10=Midbrain
	3=Parietal	7=Cerebellum	11=Medulla
			U=Unknown

43R,44R$ SITE AND VOLUME. Coding explained above under Measurable Extracerebral Lesions.
45R,45R$

4410R. VOLUME OF EDEMATOUS ZONE. Coding explained above under Measurable
4610R. Intracerebral Mass.

Small Lesions and Foreign Bodies

Use this section to code lesions (extracerebral and intracerebral) which are <15 cc in volume. Use this section to code the location of a foreign body (i.e., bullet for gunshot wounds).

Codes:	0=None	3=High Density	9=Bone
	1=Low Density	4=Mixed Density (Mottled)	10=Bone and Metal
	2=Isodense	8=Foreign Body Metal	U=Unknown

47R. **LEFT.** Enter appropriate code.

48R. **RIGHT.** Enter appropriate code.

49R. **MIDLINE.** Enter appropriate code.

50R. **LEFT POSTERIOR FOSSA.** Enter appropriate code.

51R. **RIGHT POSTERIOR FOSSA.** Enter appropriate code.

52R. **LEFT FRONTAL.** Enter appropriate code.

53R. **LEFT TEMPORAL.** Enter appropriate code.

54R. **LEFT PARIETAL.** Enter appropriate code.

55R. **LEFT OCCIPITAL.** Enter appropriate code.

56R. **LEFT CEREBELLUM.** Enter appropriate code.

57R. **LEFT BASAL GANGLIA.** Enter appropriate code.

58R. **LEFT THALAMUS.** Enter appropriate code.

59R. **RIGHT FRONTAL.** Enter appropriate code.

60R. **RIGHT TEMPORAL.** Enter appropriate code.

61R. **RIGHT PARIETAL.** Enter appropriate code.

62R. **RIGHT OCCIPITAL.** Enter appropriate code.

63R. **RIGHT CEREBELLUM.** Enter appropriate code.

64R. **RIGHT BASAL GANGLIA.** Enter appropriate code.

65R. **RIGHT THALAMUS.** Enter appropriate code.

66R. **CORPUS CALLOSUM.** Enter appropriate code.

6610R. **PONS.** Enter appropriate code.

6620R. **MIDBRAIN.** Enter appropriate code.

6630R. **MEDULLA.** Enter appropriate code.

68R. **COMMENTS.** Text 70 character limit.

ARMY PENETRATING HEAD INJURY PROJECT

Patient Study Number_____

SURGICAL TREATMENT

TO BE COMPLETED BY STUDY M.D.

FORM S

(JUN 88)

	Operation Number (i.e., 1,2,3, etc.)			
1S.	Date			
1S$.	Time			
110S.	Hours Postinjury			
2S.	Observer (Hospital keeps list of codes)(0–99)			
210S.	Form Completion Code: 0 Completed Not Completed Because: 1 Not Relevant 2 Other			
220S.	If Other (specify)			
3S.	Place of Procedure 1 Prehospital 5 Recovery Room 2 ER 6 Radiology 3 OR 7 Other 4 ICU			

Codes: Items 510S through 730S 0 No
1 Yes

	Missile or Indriven Bone Fragments Involved			
410S.	Skull only			
411S.	Skull plus dura (brain intact)			
412S.	Skull, dura, and brain			
420S.	Frontal sinus			
421S.	Ethmoid sinus			
422S.	Sphenoid sinus			
423S.	Mastoid sinus			
430S.	Sagittal sinus			
431S.	Torcula			
432S.	Transverse sinus			
440S.	Ventricle			
	Indriven Bone Fragments Identified on Preoperative			
510S.	Roentgenograms			
520S.	CT scans			
530S.	Both			
	Indriven Bone Fragments Identified on Postoperative			
610S.	Roentgenograms			
620S.	CT scans			
630S.	Both			

Operation Number (i.e., 1,2,3, etc.)			
Date			
Time			

Hematoma Evacuation

Codes: Items 9S through 1430S

Site:	0 None	**Side:**	0 None	**Code:**	0 Not done	4	Craniotomy
	1 Entry		1 Left		1 Twist drill	6	Other
	2 Opposite		2 Right		2 Burr hole	U	Unknown
			3 Bilateral		3 Craniectomy		

Estimated Size: enter in cc's (0–600); enter 0 if procedure not done

	Evacuation of Epidural Hematoma				
7S.		Side			
710S.		Site			
720S.		Code			
730S.		Estimated Size			
	Evacuation of Subdural Hematoma				
8S.		Side			
810S.	Acute (<24 hrs)	Site			
820S.		Code			
830S.		Estimated Size			
9S.		Side			
910S.	Subacute (24-72 hrs)	Site			
920S.		Code			
930S.		Estimated Size			
10S.		Side			
1010S.	Chronic (>72 hrs)	Site			
1020S.		Code			
1030S.		Estimated Size			
	Evacuation of Intracerebral Hematoma				
11S.		Side			
1110S.		Site			
1120S.		Code			
1130S.		Estimated Size			
	Evacuation of Intraventricular Hematoma				
12S.		Side			
1210S.		Site			
1220S.		Code			
1230S.		Estimated Size			
	Evacuation of Cerebellar Hematoma				
13S.		Side			
1310S.		Site			
1320S.		Code			
1330S.		Estimated Size			

Debridement

	Operation Number (i.e., 1,2,3, etc.)			
	Date			
	Time			
14S.	Skin Debridement Only 0 No 1 Yes			
15S.	Skin Debridement Plus Minimal Superficial Debridement Only (skull opening not surgically enlarged) 0 No 1 Yes			
16S.	Craniectomy and Surgical Debridement 0 No 1 Yes			
17S.	Craniotomy and Surgical Debridement 0 No 1 Yes			
	Surgical Procedures			
1810S.	Frontal Sinus 1 Exenterated 3 Galeal flap oversewn, 4 Plug with muscle 2 Nasofrontal duct opened frontal sinus 5 Plug with other			
1820S.	Ethmoid Sinus (If yes, explain in 42S) 0 No 1 Yes			
1830S.	Sphenoid Sinus (If yes, explain in 42S) 0 No 1 Yes			
1840S.	Mastoid Sinus (If yes, explain in 42S) 0 No 1 Yes			
	Major Venous Structures			
1910S.	Reconstructed with Vein Graft 0 Not reconstructed 1 Yes, with shunt 2 Yes, without shunt			
1920S.	Tamponaded Vein Laceration 0 No 1 Yes			
1930S.	Major Venous Structure Ligated or Occluded 0 No 1 Yes 2 Not applicable, no venous structure injury			
1940S.	Did Major Venous Structure Appear to Conduct Blood After Above 0 No 1 Yes			
	Major Artery Structures Lacerated or Occluded by Codes: Items 20S–2090S 0 Not Involved 1 Missile 2 Surgery 3 Other			
20S.	Internal Carotid Artery			
2010S.	Middle Cerebral Artery M1			
2020S.	Distal Branches MCA			
2030S.	Anterior Cerebral Artery A1			
2040S.	Anterior Cerebral Artery A2			
2050S.	Distal Branches ACA			
2060S.	Posterior Cerebral Artery P1			
2070S.	Posterior Cerebral Artery P2			
2080S.	Distal Branches PCA			
2090S.	Other			
2091S.	If Other, specify (Text limit 10 words)			
21S.	Was Post Debridement Dura? 1 Closed, water tight 2 Closed with a few sutures 3 Allowed to remain open			
22S.	Was Brain Loose After Debridement? 0 No 1 Yes			
2210S.	If Not, What Was Done? (Text limit 10 words)			
23S.	Operative Complications 0 No (If no, go to 3010S) 1 Yes			

Complications

	Operation Number (i.e., 1,2,3, etc.)			
	Date			
	Time			
24S.	Hypotension (Cause) (Systolic ≤ 90 mmHg during surgery) 0 None 2 Anesthetic 1 Excessive bleeding 3 Other			
2410S.	If Other, specify (Text limit 10 words)			
2420S.	Preoperative Blood Pressure — Systolic			
2421S.	Diastolic			
2430S.	Lowest Operative Blood Pressure — Systolic			
2431S.	Diastolic			
2440S.	Length of Hypotension (min) (0–1440)			
25S.	Hypoxia (Cause) (Text limit 10 words)			
2510S.	Preoperative pO_2 (0–600)			
2520S.	Lowest Operative pO_2 (0–600)			
2530S.	Length of Hypoxia (min) (0–1440)			
26S.	Hypercarbia (Cause) (Text limit 10 words)			
2610S.	Preoperative pCO_2 (0–200)			
2620S.	Highest Operative pCO_2 (0–200)			
2630S.	Length of Hypercarbia (min) (0–1440)			

Other Operative Complications

27S.	Other Operative Complications 0 No 1 Yes			
2710S.	If Yes, describe (Text limit 10 words)			
28S.	Other Anesthetic Complications 0 No 1 Yes			
2810S.	If Yes, describe (Text limit 10 words)			
29S.	Anesthetic Used During Debridement (Text limit 10 words)			
30S.	Length of Time (Min)			
3010S.	Admission to CT scan			
3020S.	CT scan to surgery			
3030S.	Surgical Procedure			

Postoperative Complications

Operation Number (i.e., 1,2,3, etc.)			
Date			
Time			
31S. Wound Infection 0 No 1 Yes			
32S. CSF Leak 0 No 1 Yes			
3210S. If Yes 1 Through wound 2 Via air sinus 3 Both			
33S. Abscess 0 None 2 Subdural 1 Epidural 3 Brain			
34S. Meningitis 0 No 1 Yes			
35S. Osteomyelitis of Skull 0 No 1 Yes			
36S. Infected Bone Flap 0 No 1 Yes			
37S. Retained Bone Fragments 0 No 1 Yes			

Surgical Procedures Other Than Primary Debridement

38S. ICP Monitoring Device Site 0 None 3 Intraventricular U Unknown 1 Epidural 4 Intraparenchymal 2 Subdural 5 Subarachnoid			
39S. ICP Device Type 1 Catheter 3 Fiberoptic 2 Bolt 4 Other			
40S. Side of Monitoring Device 1 Right 2 Left			
41S. Opening Pressure (8–100)			

Codes for 42S:

0 None	6 ORIF	11 Brain abscess evacuation
1 Elevated depressed fracture	7 Craniofacial repair	12 Other abscess evacuation
2 Remove bone flap (infection)	8 Laparotomy	13 Shunt
3 Remove bone flap (swelling)	9 Thoracotomy	14 Organ donation
4 Tracheostomy	10 Spine operation	15 Other
5 Chest tubes		

42S. Surgical Procedure (Enter under appropriate date column)			

43S. Narrative (Text Limit 100 words)

4310S.

4320S.

4330S.

4340S.

FORM S

SURGICAL TREATMENT

This form is to be completed by the neurosurgeon as the procedures are done.

1S-1S$. DATE AND TIME. Enter date and time surgery begins (do not use anesthesia induction time).

2S. OBSERVER. Hospital keeps list of codes. Enter 0-20.

3S. PLACE OF PROCEDURE. Where the procedure is performed.

1=Prehospital	4=ICU	7=Other
2=ER	5=Recovery Room	
3=OR	6=Radiology	

Evacuation of Hematomas

Enter the site and type of procedure used to evacuate the specific type of hematoma.

Site Code: 0=None
1=Entry
2=Opposite

Side Code: 0=None 2=Right
1=Left 3=Bilateral

Code: 0=Not Done 3=Craniectomy U=Unknown
1=Twist Drill 4=Craniotomy
2=Burr Hole 6=Other

7S-730S. EVACUATION OF EPIDURAL HEMATOMA. Enter side and site codes and estimated size.

8S-830S. EVACUATION OF SUBDURAL HEMATOMA. Acute, <24 hours. Enter side and site codes and estimated size.

9S-930S. EVACUATION OF SUBDURAL HEMATOMA. Subacute, 24-72 hours. Enter side and site codes and estimated size.

10S-1030S. EVACUATION OF SUBDURAL HEMATOMA. Chronic, >72 hours. Enter side and site codes and estimated size.

11S-1130S. EVACUATION OF INTRACEREBRAL HEMATOMA. Enter side and site codes and estimated size.

12S-1230S. EVACUATION OF INTRAVENTRICULAR HEMATOMA. Enter side and site codes and estimated size.

13S-1330S. EVACUATION OF CEREBELLAR HEMATOMA. Enter side and site codes and estimated size.

42S. **SURGICAL PROCEDURES.** Use codes to indicate other surgical procedures done either on same date or on another date. If performed on an occasion other than the primary cranial surgery, code on a separate column with appropriate date. More than one code may be entered on one date.

Codes for 42S:

0=None
1=Elevated Depressed Fracture
2=Remove Bone Flap (Infection)
3=Remove Bone Flap (Swelling)
4=Tracheostomy
5=Chest Tubes
6=ORIF
7=Craniofacial Repair
8=Laparotomy
9=Thoracotomy
10=Spine Operation
11=Brain Abscess Evacuation
12=Other Abscess Evacuation
13=Shunt
14=Organ Donation
15=Other

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

ICU FORM

TO BE COMPLETED BY NURSE CLINICIAN OR STUDY M.D.

DISCONTINUE AT SEVEN (7) DAYS

FORM U

(Mar 88)

1U. Date						
1U$. Time	0759	1559	2359	0759	1559	2359
2U. Observer (Hospital keeps list of codes)(0–99)						
210U. Form Completion Code: 0 Completed Not Completed Because: 1 Not Relevant 2 Other						
220U. If Other (specify)						
3U. Visit Type: 2 ICU admission 8 Death 3 In hospital ICU 9 Recovery Room 4 Discharge from ICU						
Intracranial Pressure						
4U. ICP Monitored 0 No 3 Yes, Bolt 1 Yes, Ventriculostomy 4 Other 2 Yes, Camino U Unknown						
410U. Reason ICP Not Monitored A Not applicable; ICP monitored 3 Coagulopathy 4 Other 1 Not clinically indicated 5 Discontinued 2 GCS >8 U Unknown						
Vital Signs						
7U. Blood Pressure-High Systolic (0–300)						
8U. U Unknown Diastolic** (0–200)						
9U. Blood Pressure-Low Systolic (0–300)						
10U. U Unknown Diastolic** (0–200)						
11U. Pulse Rate-High U Unknown (0–250)						
12U. Pulse Rate-Low U Unknown (0–250)						
13U. Temperature °C-High U Unknown (33.0–42.0)						
14U. Temperature °C-Low U Unknown (33.0–42.0)						
Pupillary Response						
15U. Right Pupil Response 0 No reaction 2 Sluggish 1 Reaction U Unknown						
16U. Right Pupil Size(1–9mm) U Unknown						
17U. Right Pupil Shape 1 Round 3 Other 2 Elliptical U Unknown						
18U. Left Pupil Response 0 No reaction 2 Sluggish 1 Reaction U Unknown						
19U. Left Pupil Size(1–9mm) U Unknown						
20U. Left Pupil Shape 1 Round 3 Other 2 Elliptical U Unknown						

**Palpable blood pressure: Diastolic is U

	Date						
	Time	0759	1559	2359	0759	1559	2359
Best Glasgow Coma Scale							
21U.	Best Eye Opening (Choose one) 1 None 2 To pain 3 To sound 4 Spontaneous 5 Patched/tarsorrhaphy 6 Injured/swollen 7 Barbiturates, narcotics, or pharmacologic paralysis U Other untestable						
22U.	Best Verbal Response (Choose one) 1 None 2 Unintelligible sounds 3 Inappropriate words 4 Confused 5 Oriented 6 Intubation/tracheostomy 7 Oral/facial injury 8 Aphasia/dysarthria 9 Barbiturates, narcotics, or pharmacologic paralysis U Other untestable						
23U.	Best Right Arm Motor Response (Choose one) 1 None 2 Extensor 3 Abnormal flexion 4 Withdrawal 5 Localizes 6 Obeys commands 7 Limb injury/immobilization 8 Spinal cord injury 9 Barbiturates, narcotics, or pharmacologic paralysis U Other untestable						
24U.	Best Right Leg Motor Response (Choose one) 1 None 2 Extensor 3 Abnormal flexion 4 Withdrawal 5 Localizes 6 Obeys commands 7 Limb injury/immobilization 8 Spinal cord injury 9 Barbiturates, narcotics, or pharmacologic paralysis U Other untestable						
25U.	Best Left Arm Motor Response (Choose one) 1 None 2 Extensor 3 Abnormal flexion 4 Withdrawal 5 Localizes 6 Obeys commands 7 Limb injury/immobilization 8 Spinal cord injury 9 Barbiturates, narcotics, or pharmacologic paralysis U Other untestable						
26U.	Best Left Leg Motor Response (Choose one) 1 None 2 Extensor 3 Abnormal flexion 4 Withdrawal 5 Localizes 6 Obeys commands 7 Limb injury/immobilization 8 Spinal cord injury 9 Barbiturates, narcotics, or pharmacologic paralysis U Other untestable						
42U.	Patient on Ventilator 0 No 1 Yes U Unknown						
43U.	Seizure Type (Choose one) 0 None 1 General 2 Focal 3 Suspected 4 Type unknown 5 Combination						
44U.	Number of Seizures (Choose one) 0 None 1 Single 2 Multiple 3 Status epilepticus U Unknown						

Date						
Time	0759	1559	2359	0759	1559	2359
Medications (Enter Dosage in Units Specified)						
Codes: 0 None G Given, dosage unknown U Unknown						
Diuretics						
45U. Mannitol (grams) (0.0–300.0)						
46U. Furosemide (mg) (Lasix) (0.0–300.0)						
47U. Other (Text limit 10 words)						
Steroids						
48U. Dexamethasone (mg)(Decadron) (0–50)						
49U. Methylprednisolone (mg)(Solu–medrol)(0–500)						
50U. Other (Text limit 10 words)						
Anticonvulsants						
51U. Phenytoin Sodium (mg) (Dilantin) (0–1500)						
52U. Phenobarbital (mg) (0–1500)						
53U. Diazepam (mg) (Valium) (0.0–50.0)						
54U. Other (Text limit 10 words)						
Paralytic Agents						
55U. Pancuronium bromide (mg) Pavulon) (0.0–95.0)						
56U. Succinylcholine (mg) (Anectine) (0–1200)						
57U. Tubocurarine (mg) (Curare) (0–200)						
58U. Other (Text limit 10 words)						
Antihypertensives						
59U. Methyldopa (mg)(Aldomet)(0–1000)						
60U. Hydralazine (mg)(Apresoline()0.0–150.0)						
61U. Propranolol (mg)(Inderal)(0.0–40.0)						
62U. Nitroprusside (Nipride)						
0 No 1 Yes U Unknown						
63U. Trimethaphan (Arfonad)						
0 No 1 Yes U Unknown						
64U. Other (Text limit 10 words)						
Narcotics						
65U. Morphine Sulfate (mg)(0.0–200.0)						
66U. Meperidine HCL (mg)(0.0–1500.0)						
67U. Codeine (mg)(0.0–250.0)						
68U. Other (Text limit 10 words)						
Barbiturates						
69U. Sodium Pentobarbital (mg)(Nembutal)(0.0–3000.0)						
70U. Other (Text limit 10 words)						
Vasopressors						
71U. Dopamine HCl (Intropin)						
0 No 1 Yes U Unknown						
72U. Dobutamine HCl (Dobutrex)						
0 No 1 Yes U Unknown						
73U. Xylocaine (mg)(Lidocaine)(0–2000)						
74U. Other (Text limit 10 words)						

	Date						
	Time	0759	1559	2359	0759	1559	2359
Antibiotics							
75U.	Nafcillin 0 No 1 Yes U Unknown						
76U.	Chloramphenicol 0 No 1 Yes U Unknown						
77U.	Cefazolin (Ancef) 0 No 1 Yes U Unknown						
78U.	Ceftriaxone (Rocephin) 0 No 1 Yes U Unknown						
79U.	Other (Text limit 10 words)						
791U.	Other Medications (Text limit 10 words)						
80U$.	*Study Drug Given* (Specify time)						
Laboratory							
2L.	Initial pH of Blood (6.00–9.00) (Code only once)						
3L.	Initial Blood Gas PO_2 (0–600) (Code only once)						
4L.	Initial Blood Gas PCO_2 (0–200) (Code only once)						
5L.	Worst pH of Blood* (lowest) (6.00–9.00)						
6L.	Worst Blood Gas PO_2* (lowest) (0–600)						
7L.	Worst Blood Gas PCO_2* (highest) (0–200) *Need not be from the same sample.						
8L.	Delivered Oxygen Concentration(%)(0–100)						
9L.	Hemoglobin (5.0–20.0)						
910L.	Hematocrit (lowest) (5–60) (gm%)						
920L.	Red Blood Cells (2–8)(Millions)						
10L.	White Blood Count (1000–20,000) (least optimal value; low or high)						
101L.	Platelets (lowest) (1,000–800,000)						
102L.	Granulocytes (%) (0–100)						
103L.	Lymphocytes (%) (0–100)						
11L.	PT (highest) (5.0–30.0 sec)						
12L.	PT Corresponding Control (8.0–15.0 sec)						
13L.	PTT (longest) (20.0–200.0 sec)						
14L.	PTT Corresponding Control (20.0–40.0 sec)						
15L.	Fibrinogen Split Products (0.0–30.0 mcg%)						
16L.	Thrombin Time (0–10 sec)						
17L.	Na(least optimal value furthest from 140)(90–190 meq/L)						
18L.	K (least optimal value furthest from 4.0) (1.5–8.0 meq/L)						
19L.	Chloride (50–150 meq/L)						
20L.	Glucose (0.0–500.0) (highest) (mg%)						
201L.	Glucose (0.0–500.0) (lowest) (mg%)						
21L.	BUN (0–100 mg%)						
22L.	Creatinine (0–5 mg%)						
23L.	Calcium (5–15 mg%)						
24L.	Inorganic Phosphorus (0–10 mg%)						
25L.	Total Protein (0–10 mg%)						
26L.	Bilirubin (0–5 mg%)						
27L.	Uric Acid (0–20 mg%)						
28L.	Alkaline Phosphatase (0–1000 u/L)						
29L.	LDH (0–1000 u/L)						

Note: For serum glucose and serum osmolality: If only one value available for the shift, enter the number for both highest and lowest.

	Date						
	Time	0759	1559	2359	0759	1559	2359
30L	SGOT (0–1000 u/L)						
31L	SGPT (0–500 u/L)						
32L	Serum Osmolality (highest) (least optimal value furthest from 285)(200–400)						
320L	Serum Osmolality (lowest) (least optimal value furthest from 285)(200–400)						
33L	Urine Protein (0–4+)						
330L	White Cells (0.0–1000.0 mg%)						
34L	CSF Protein (0.0–1000.0 mg%)						
340L	White Cells (0.0–1000.0 mg%)						
341L	RBC (0.0–5000.0 mg%)						

FORM U

ICU

To Be Completed by Nurse Clinician
in Consultation with PI or Trauma Fellow

This form is to be filled in once every eight (8) hours (each shift). To facilitate retrieval, regular shift data will be entered at 0759, 1559, and 2359. If the patient has an ICP catheter or bolt in place, data is collected until the device is removed. If the patient does not have an ICP monitoring device, data is collected for seven days. If the patient with a monitoring device has it removed within the initial seven-day period, data is still collected for a total of seven days. Termination of ICU collection occurs when the patient is discharged from the ICU, or seven days after admission, unless ICP monitoring continues. Regardless, ICU data collection should cease after one month.

It should be noted that before any parameters are entered, standardizations of monitoring should be met. These include:

a. Systemic arterial pressure transducer should be placed at heart level.

b. ICP transducer should be at the level of the ventricles.

c. Head of bed (HOB) should be elevated 30°.

1U. DATE. Enter dd/mmm/yr.

1U$. TIME. All entries are made at the end of the shift at 0759, 1559, and 2359.

2U. OBSERVER. Hospital keeps list of codes, enter 0-99. NOTE: Because of the turnover in nursing personnel over the course of the study, each center may choose to enter the code of the data bank nurse collecting the data.

3U. VISIT TYPE. Enter:

2=ICU Admission
3=In Hospital ICU
4=Discharge from ICU
8=Death
9=Recovery Room

4U. Indicate if ICP was *monitored* during that shift.

0=No
1=Yes, ventriculostomy
2=Yes, camino
3=Yes, bolt
4=Other
U-Unknown

PLEASE NOTE: During data entry, 5U, 6U, 8 hour high and low ICP items will appear on the screen. These items are for San Diego community hospitals only. All other centers should ignore these items.

Vital Signs

7U. BLOOD PRESSURE HIGH*: SYSTOLIC. Enter 0-300, U=Unknown

8U. DIASTOLIC. Enter 0-200, U=Unknown

9U. BLOOD PRESSURE LOW*: SYSTOLIC. Enter 0-300, U=Unknown

10U. DIASTOLIC. Enter 0-200, U=Unknown

*Palpable Blood Pressure: Diastolic=U

11U. PULSE RATE: HIGH. Enter 0-250, U=Unknown

12U. PULSE RATE: LOW. Enter 0-250, U=Unknown

13U. TEMPERATURE: HIGH. Enter 33-42.0, U=Unknown

14U. TEMPERATURE: LOW. Enter 33-42.0, U=Unknown

NOTE: Temperature <33, enter 33; temperature >42.0, enter 42.0

Pupillary Response

15U,18U. Note PUPILLARY REACTIVITY.

0=No Reaction	2=Sluggish
1=Reaction	U=Unknown

16U,19U. Note the SIZE OF EACH PUPIL in mm. Enter 1-9. Pupils >9, enter 9; U=Unknown.

17U,20U. Note SHAPE OF PUPIL.

1=Round	3=Other
2=Elliptical	U=Unknown

Best Glasgow Coma Scale

Enter EYES, MOTOR, and VERBAL responses as defined in Table 1, the computer will choose Best Motor Response and calculate the Glasgow Coma Score.

21U. BEST EYE OPENING. See Table 1. Enter 1-7, U=Unknown.

22U. BEST VERBAL RESPONSE. See Table 1. Enter 1-9, U=Unknown. NOTE. If patient is under pharmacologic paralysis or barbiturate coma, enter 9, even though the patient is obviously intubated.

23U,26U. BEST MOTOR RESPONSE. See Table 1. The overall GCS is calculated by the computer based on the best motor response of the arms. If any component of the GCS is entered as pharmacologic paralysis or barbiturate coma, all components must be coded the same. Enter 1-9, U=Other Untestable.

42U. PATIENT ON VENTILATOR. Enter [1] if patient is on a ventilator or [0] if not. If the patient is on intermittent mandatory ventilation (IMV) or intermittent demand ventilation (IDV), enter [1]. If the patient is on blow-by or T-piece, enter [0].

43U. SEIZURE TYPE THIS SHIFT. If the patient is paralyzed or in barbiturate coma, code unknown, less there is EEG evidence of seizures, then code [4] type unknown.

0=None	3=Suspected
1=General	4=Type Unknown
2=Focal	5=Combination

44U. NUMBER OF SEIZURES THIS SHIFT. If the patient is paralyzed or in barbiturate coma, code unknown.

0=None	3=Status Epilepticus
1=Single	U=Unknown
2=Multiple	

Medications

Enter all listed medications (and any pertinent others) which are given during each eight (8) hour shift. Enter total dose given for each shift (must use indicated unit of measurement); enter [0] for none. If dosage is not known, enter [G] (=Given) to indicate that a particular medication has at least been given. If unknown whether medication has been given, enter [U].

Diuretics

45U. MANNITOL (grams). Enter 0.0-300.0.

46U. FUROSEMIDE (mg) Lasix. Enter 0.0-300.0.

47U. OTHER. Enter drug and dosage. Text 10 word limit.

Steroids

48U. DEXAMETHASONE (mg) Decadron. Enter 0-50.

49U. METHYLPREDNISOLONE (mg) Solu-Medrol. Enter 0-500.

50U. OTHER. Enter drug and dosage. Text 10 word limit.

Anticonvulsants

51U. PHENYTOIN SODIUM (mg) Dilantin. Enter 0-1500.

52U. PHENOBARBITAL (mg). Enter 0-1500.

53U. DIAZEPAM (mg) Valium. Enter 0.0-50.0

54U. OTHER. Enter drug and dosage. Text 10 word limit.

Paralytic Agents

55U. PANCURONIUM BROMIDE (mg) (Pavulon). Enter 0.0-95.0.

56U. SUCCINYLCHOLINE (mg) Apresoline. Enter 0-1200.

57U. TUBOCURARINE (mg) Curare. Enter 0-200.

58U. OTHER. Enter drug and dosage. Text 10 word limit.

Antihypertensives

59U. METHYLDOPA (mg) Aldomet. Enter 0-1000.

60U. HYDRALAZINE (mg) Apresoline. Enter 0.0-150.0.

61U. PROPRANOLOL (mg) Inderal. Enter 0.0-40.0.

62U. NITROPRUSSIDE Nipride. 0=No 1=Yes U=Unknown

63U. TRIMETHAPHAN Arfonad. 0=No 1=Yes U=Unknown

64U. OTHER. Enter drug and dosage. Text 10 word limit.

Narcotics

65U. MORPHINE SULFATE (mg) Enter 0.0-200.0.

66U. MEPERIDINE HCL (mg) Enter 0.0-1500.0.

67U. CODEINE (mg) Enter 0.0-250.0.

68U. OTHER. Enter drug and dosage. Text 10 word limit.

Barbiturates

69U. SODIUM PENTOBARBITAL (mg) Nembutal. Enter 0.0-3000.0.

70U. OTHER. Enter drug and dosage. Text 10 word limit.

Vasopressors

71U. DOPAMINE HCI Intropin. 0=No 1=Yes U=Unknown

72U. DOBUTAMINE HCI Dobutrex. 0=No 1=Yes U=Unknown

73U. XYLOCAINE (mg) Lidocaine. Enter 0-2000.

74U. OTHER. Enter drug and dosage. Text 10 word limit.

Antibiotics

75U. NAFCILLIN.

76U. Chloramphenicol.

77U. Cefazolin. (Ancef)

78U. Ceftriaxone. (Rocephin)

79U. OTHER. Enter drugs and dosage (include vitamins, nutritional supplements, etc.). Text 10 word limit.

791U. OTHER MEDICATIONS. Include vitamins, nutritional supplements, etc.

80U$. STUDY DRUG GIVEN. Specify time if given this shift; otherwise, enter 0.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

CHRONOLOGY OF EVENTS

TO BE COMPLETED BY NURSE CLINICIAN

FORM V

(Mar 88)

1V. Date of Injury

__ __ Day ____ Mo __ __ Yr

2V. Observer (Hospital keeps list of codes)(0–99)

_____

210V. Form Completion Code

0 Completed
1 Not Completed

220V. If Not Completed, specify

_____

4V. Number Hospitals Patient Brought to Since Accident and Prior to APHIP Hospital Admission

1 None, APHIP hospital is first
2 One
3 Two
4 Three
5 Four or more
U Unknown

5V. Date of Arrival at APHIP Hospital

__ __ Day ____ Mo __ __ Yr

5V$. Time of Arrival at APHIP Hospital

_____:_____

6V. Date of Arrival at First Hospital

__ __ Day ____ Mo __ __ Yr

6V$. Time of Arrival at First Hospital

_____:_____

7V. Date of Arrival at Second Hospital

__ __ Day ____ Mo __ __ Yr

7V$. Time of Arrival at Second Hospital

_____:_____

8V. Date of Arrival at Third Hospital

__ __ Day ____ Mo __ __ Yr

8V$. Time of Arrival at Third Hospital

_____:_____

DETAILS OF PATIENT ADMISSION/TRANSFER

9V. Patient Admitted/Transferred to APHIP Hospital

1 Direct from scene of accident
2 From home (not scene of accident)
3 From non-hospital provider
4-75 Individual hospital codes_____
U Unknown

10V. Transport Mode to APHIP Hospital

1 Self
2 Relative/friend
3 Ambulance
4 Helicopter/plane
5 Police (not ambulance)
6 Other
U Unknown

1010V. If Other, specify_____

11V. Transport Mode to First Hospital

1 Self
2 Relative/friend
3 Ambulance
4 Helicopter/plane
5 Police (not ambulance)
6 Other
U Unknown
A First hospital is APHIP hospital

1110V. If Other, specify_____

12V. Training of Transporter to APHIP Hospital

1 None
2 Police/fireman (if less than EMT)
3 EMT 1 (Basic EMS)
4 EMT 2 (Advanced EMS)
5 Nurse
6 Physician
7 Other
U Unknown

1210V. If Other (specify)_____

13V. Training of Transporter to First Hospital

1 None
2 Police/fireman (if less than EMT)
3 EMT 1 (Basic EMS)
4 EMT 2 (Advanced EMS)
5 Nurse
6 Physician
7 Other
U Unknown
A First hospital is APHIP Hospital

1310V. If Other, specify_____

14V. Miles From Scene of Accident to APHIP Hospital (Use a Straight Line Estimate)

_____
(0-500; if >500, enter 500)
U Unknown

Accident Characteristics

15V. Mechanism of Injury (Choose One)
- 1 Bullet
- 2 Shotgun
- 3 Missile fragment
- 4 Other
- U Unknown

1510V. If Other, specify_____

16V. Place of Injury
- 1 Home
- 2 Work
- 3 Street/Highway
- 4 Recreational area
- 5 Other
- U Unknown

1610V. If Other, specify_____

Predisposing Conditions

17V. Alcohol
- 0 No
- 1 Yes
- 2 Suspected, unless otherwise specified
- U Unknown

18V. Ethanol Level in mg%(0-0.8%)_____

19V. Nonprescribed Drugs
- 0 No (Negative Toxic Screen)
- 1 Yes (Verified by Laboratory)
- 2 Suspected, unless otherwise specified
- U Unknown

20V. Loss of Consciousness Postinjury
- 0 No
- 1 Yes

2010V. If Yes, Onset of Loss of Consciousness
- 1 Immediate post-injury
- 2 Delayed post-injury(>5min)
- 3 No loss of consciousness
- U Unknown

2020V. Duration of Loss of Consciousness (estimated GCS<8)
- 0 None
- 1 Yes, momentary
- 2 1-15 minutes
- 3 15 minutes - 1 hour
- 4 1-6 hours
- 5 >6 hours
- U Unknown

2030V. Lucid Interval Prior to Coma
- 1 In coma since wounding
- 2 Lucid interval followed by coma
- 3 Never in coma
- U Unknown

2031V. If 2, estimate duration of lucid interval

_____

21V. Work Related
- 0 No
- 1 Yes
- U Unknown

22V. Suicide Attempt
- 0 No
- 1 Yes
- 2 Suspected
- U Unknown

23V. Child Abuse
- 0 No
- 1 Yes
- 2 Suspected
- U Unknown

24V. Spouse Abuse
- 0 No
- 1 Yes
- 2 Suspected
- U Unknown

25V. Incarcerated
- 0 No
- 1 Yes
- U Unknown

26V. Wounding Location_____

27V. HIV Screen
- 1 Positive
- 2 Negative
- 3 Not done

28V. NARRATIVE OF WOUNDING DETAILS (Text limit 150 words)_____

2810V. _____

2820V. _____

2830V. _____

2840V. _____

2850V. _____

2860V. _____

2870V. _____

2880V. _____

FORM V

CHRONOLOGY OF EVENTS

To Be Completed by Nurse Clinician

1V. DATE. Enter date of injury: dd/mmm/yr.

2V. OBSERVER. Hospital keeps list of codes. Enter 0-20.

4V. NUMBER OF HOSPITALS patients was taken to since accident and prior to admission to APHIP hospital. It is important to enter as many of these time factors as are known in order to enable the computer to determine transport times. If there are referring hospitals, enter time and date of arrival at the ER of each. Since times reported may vary, an average of those reported by different observers is recommended, unless the data collector has reason to have greater confidence in a single observer. Enter 0-4; U=Unknown

5V-5V$. DATE AND TIME OF ARRIVAL TO APHIP HOSPITAL.

6V-6V$. DATE AND TIME OF ARRIVAL TO FIRST HOSPITAL. Use if the patient was transferred to one or more hospitals before being transferred to APHIP hospital. If APHIP hospital is the first hospital, enter date and time in 5V-5V$ only; otherwise leave blank.

7V-8V$. DATE AND TIME OF ARRIVAL TO SECOND AND THIRD HOSPITAL. Use if patient transferred to two or more hospitals before being transferred to APHIP hospital; otherwise leave blank.

Details of Patient Admission/Transfer

9V. ADMISSION/TRANSFER TO APHIP HOSPITAL. If patient is admitted directly to the APHIP hospital from the scene of the accident, enter [1]. If home is the scene of the accident, also enter [1]. However, if the patient has returned home and/or if some period of time has elapsed from the time of injury before medical care is sought, then enter [2].

If patient has been seen in a doctor's office, industrial or school nurse's office, detoxification center, jail, military base where no hospital is available, outpatient clinic, etc. (nonhospital providers), prior to being admitted to the APHIP hospital, enter [3]. If the patient is transferred from another hospital, enter the code [4-75] for that institution as defined in Appendix III (Regional Information Section). In the event of more than one referring hospital, enter the one which referred the patient to the APHIP hospital.

10V. TRANSPORT MODE TO APHIP HOSPITAL. If the patient drives himself or walks into the APHIP hospital, enter [1]. If the patient is brought to the hospital by a relative, friend or passerby, enter [2]. If the patient is transported by ambulance (non-medic, private, police, or fire), enter [3]; by helicopter or plane, enter [4]; by police (not ambulance), enter [5]. If transported by other means, specify the mode and code [6]. If unknown, code [U].

11V. TRANSPORT MODE TO FIRST HOSPITAL. Defined above in 10V. If APHIP hospital is first hospital enter [A].

13V. TRANSPORTER TRAINING TO APHIP HOSPITAL. Since the level of training of various paramedical personnel varies in different areas of the country, it is necessary to be specific regarding the level of training of transporters. If police and/or firemen has less than EMT 1 training (i.e., basic first aid), then enter [1]. Most private ambulance drivers are trained as EMT 1 and should be entered as [2]. However, paramedics usually have advanced EMS training (EMT2) and therefore should be entered as [3]. Should transporters have different levels of training, as a nurse and physician accompanying the patient is helicopter rescue, then enter that person with the highest level of training.

4=Nurse **5=Physician**
U=Unknown

14V. TRANSPORTER TRAINING TO FIRST HOSPITAL. Defined above in 13V. However, if the APHIP hospital is the first hospital the patient is taken to, enter [A]; **U=Unknown.**

16V. MILES FROM SCENE TO APHIP HOSPITAL. Straight line estimate. Use your map and ruler to measure distance from scene of accident to hospital and convert it to miles. If there is no address for scene, but the accident took place in your city, an average distance may be used (has to be decided upon by each center individually). Enter 0-500; if >500, enter 500. **Unknown mileage=U.**

21V. PLACE OF INJURY.

Codes: **1=Home** **5=Hospital**
2=Work **6=Other**
3=Street/Highway **U=Unknown**
4=Recreational area

Predisposing Conditions

22V. ALCOHOL. Indicate *"yes"* if alcohol was confirmed at least 100 mg% (.1G% or more) on laboratory testing, if the breath smells of alcohol, or if reliable sources report the patient had been intoxicated prior to the injury. Indicate *"suspected"* if there are reports that the patient had been drinking alcohol in the 12-hour period prior to injury, or for blood alcohol levels less than 100 mg%. Indicate *"no"* if there are no reports from any source of alcohol use within 12 hours prior to injury. If unknown, enter [U].

23V. ETHANOL LEVEL. Record earliest reported ETOH level in mg%, enter 0-500 (0.1 GM%=100 mg/dl=100 mg%). If unknown, enter [U]. If 22V **0=Alcohol**, enter **A=not applicable.**

24V. DRUGS. *"Drug"* is intended to refer to any pharmacological agent taken orally, or parenterally, or smoked, or insufflated that was not prescribed by a physician. Include sedatives, narcotics, neuroleptics, amphetamines, street drugs, antipsychotics, even marijuana. Exclude such things as antibiotics, antacids, or others which are not known to alter consciousness in any way, even if these were taken with suicidal intent. Indicate *"yes"* if a drug blood level is confirmed or if a reliable source reports having seen the drug taken

within 12 hours prior to injury. Indicate *"suspected"* if drug levels are not done or are not confirmatory; but, if drugs were found on or with the patient, or he was reported by reliable sources to be acting like he had taken drugs prior to injury. Indicate *"no"* if there is no suspicion of illicit drug use. If unknown, enter [U].

CONTRIBUTING FACTORS

26V. WORK RELATED. If the injury was work related, enter [1]; if suspected, enter [2]; 0=No; if unknown, enter [U].

27V. SUICIDE ATTEMPT. If police have determined the injury to be a suicide attempt, enter [1]; if suspected, enter [2]; 0=No; if unknown, enter [U].

28V. CHILD ABUSE. If police or protective services have determined the injury to be child abuse, enter [2]; if suspected, enter [2]; 0=No; if unknown, enter [U].

29V. SPOUSE ABUSE. If the police or witnesses have determined that the injury was inflicted by the patient's spouse, enter [2]. If family members or other responsible persons indicate a strong suspicion, enter [2]; 0=No; if unknown, enter [U].

30V. INCARCERATED. Enter [1] for a person serving a court ordered sentence in a correctional facility at the time of injury; 0=No.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

WOUND BALLISTICS FORM

TO BE COMPLETED BY THE NURSE CLINICIAN

FORM W

(MAR 88)

1W. Date ___ ___ ___
Day Mo Yr

1W$. Time _____:____

2W. Observer (Hospital keeps list of codes)(0–99)

_____

210W. Form Completion Code
Not Completed Because:
0 Completed
1 Not Relevant
2 Other

220W. If Other, specify_____

3W. Penetrating Missile
1 Bullet (Answer questions 4W–710W)
2 Shotgun pellets (Answer questions 8W–110W)
3 Shotgun slug (Answer questions 8W–110W)
4 Metallic fragment (Answer questions 12W–14W)
5 Other
U Unknown

310W. If Other, specify_____

BULLET

4W. Type of Gun
1 Rifle
2 Handgun
3 Other
U Unknown

410W. If Other, specify_____

5W. Type of Bullet
1 5.56 mm (M–16, AR15)
2 7.63 mm (AK 47)
3 7.62 mm (M–14)(M1)
4 9 mm
5 306
6 30-30
7 Other
8 22 cal short
9 22 cal long
10 22 cal undetermined
11 32 cal
12 38 cal
13 (45 cal)
14 357 magnum
15 Other
16 Large, type unknown
17 Small, type unknown
A Not applicable

510W. If Other, specify_____

6W. Accuracy of Information for Caliber of Bullet
1 Caliber is definitely known
2 Caliber is probably known
U Unknown

7W. Source of Information for Caliber of Bullet
1 Skull roentgenograms
2 Police report without definite possession of gun/bullets
3 Other report (e.g., from ambulance drivers)
4 Other evidence (e.g., person doing shooting known to carry certain type of gun)
5 Other
A Not applicable (caliber is not probably known, or missile is not a bullet)
U Unknown

710W. If Other, explain_____

SHOTGUN PELLET OR SLUG

8W. Shotgun Gauge
1 10 gauge
2 12 gauge
3 16 gauge
4 20 gauge
5 28 gauge
6 410 gauge
U Unknown

9W. Type of Shotgun Pellet or Slug
1 Known
U Unknown

910W. If Known, describe (i.e., birdshot, buckshot, slug)

_____

10W. Accuracy of Information for Shotgun Pellet or Slug
1 Definitely known
2 Probably known
U Unknown

11W. Source of Information for Shotgun Pellet or Slug
1 Skull roentgenograms
2 Police report without definite possession of gun/bullets
3 Other report (e.g., from ambulance drivers)
4 Other evidence (e.g., person doing shooting known to carry certain type of gun)
5 Other
A Not applicable (pellet gauge is not probably known)
U Unknown

110W. If Other, explain_____

METALLIC FRAGMENT(s)

12W. Number of Fragments_____

13W. Source of Fragment(s)
- 1 Grenade
- 2 Shell fragment
- 3 Pellets
- 4 Homemade explosive device
- 5 Other explosive device
- 6 Other missile (e.g., iron bar hurled by explosion, rock)
- A Not applicable, not a fragment
- U Unknown

130W. If Other Explosive, identify_____

131W. If Other Missile, identify_____

14W. Accuracy of Information for Source of Fragment
- 1 Definitely known
- 2 Probably known
- U Unknown

15W. Exclusive of metallic trail, did bullet fragment?
- 0 No
- 1 Yes
- A Not applicable, not a bullet
- U Unknown

16W. If bullet fragmented, how many pieces evident on skull films?
- 0 None, bullet did not fragment
- 1 Two
- 2 Three to four
- 3 Five to six
- 4 Seven to eight
- 5 Nine to ten
- 6 >Ten
- A Not applicable, bullet did not fragment, or not a bullet
- U Unknown

17W. Weight of Missile Penetrating Brain
- 1 Enter in grams (____-____)
- U Unknown

18W. Weight of Similar Bullets/Pellets/Fragments Found at Scene
- 1 Enter in grams (____-____)
- U Unknown

19W. Distance of Gun or Explosive Device From Victim
- 1 Zero to one meter
- 2 One to four meters
- 3 Four to 10 meters
- 4 Ten to 20 meters
- 5 > 20 meters
- 6 Unknown

20W. Distance of Gun or Explosive Device above
- 1 Definitely known
- 2 Estimated
- U Unknown

21W. Number of Separate Brain Wounds
- 1 One
- 2 Two
- 3 Three
- U Unknown

22W. Farthest Extent of Head Wounds
- 1 Scalp only
- 2 Scalp and skull
- 3 Scalp, skull, dura
- 4 Scalp, skull, dura, brain
- 5 Tangential high velocity

23W. Powder Burns
- 0 No
- 1 Yes
- U Unknown

24W. Brain Damage from
- 1 Missile (penetrating/perforating wound, plus indriven bone)
- 2 Bone fragments alone (tangential wound)
- U Unknown

Site Codes:
1 Frontal
2 Parietal
3 Occipital
4 Temporal
5 Posterior Fossa
6 Brain Stem, base of brain
U Unknown

Side Codes:
1 Right
2 Left
3 Bilateral

25W. Brain Entry Site (enter all that apply)

_____

26W. Brain Entry Side (enter code)

_____

27W. Final Position of Bullet or Exit Wound, Site (enter all that apply)

_____

28W. Final Position of Bullet or Exit Wound, Side (enter code)

_____

29W. Did missile ricochet off inner table of skull before assuming final position?
0 No
1 Yes
2 Probably Yes
U Unknown

30W. Did missile exit?
0 No
1 Yes
U Unknown

31W. Brain Exit Site (enter all that apply)

_____

32W. Brain Exit Side (enter code)

_____

33W. How was 29W-35W determined?
1 CT/MRI
2 Skull films
3 Physical examination
U Unknown

34W. Associated Air Sinus Injury
0 No
1 Frontal
2 Ethmoid
3 Sphenoid
4 Mastoid

35W. Associated Major Venous Injury
0 No
1 Sagittal sinus
2 Sigmoid sinus
3 Vein of galen

36W. Associated Major Arterial Injury
0 No
1 Internal carotid
2 Middle cerebral
3 Anterior cerebral
4 Posterior cerebral
5 Vertebral
6 Basilar

37W. Associated Cerebral Ventricular Wound
0 No
1 Yes

38W. CSF Leak
0 No
1 From missile entry/ exit wound
2 Nose
3 Ear
4 Other
U Unknown

380W. If Other, specify_____

39W. Intracranial Indriven Bone Fragments Seen on Initial Plain Skull Films
0 No
1 Yes

40W. Intracranial Indriven Bone Fragments Seen on Initial CT/MRI Scan
0 No
1 Yes (CT Scan)
2 Yes (MRI Scan)

41W. Intracranial Bone Fragments Evident on Skull Films Postoperatively or at Death
0 No
1 Yes
U Unknown

42W. Retained Intracranial Bone Fragments Evident on CT Postoperatively or at Death
0 No
1 Yes
U Unknown

43W. Was any reoperation undertaken specifically to remove indriven retained bone fragments?
0 No
1 Yes
U Unknown

FORM W

WOUND BALLISTICS

3W. Denote type of missile causing brain wound. Brain damage is related to missile energy. If bullet type and distance are known, missile mass and velocity can be determined and energy calculated: $E=\frac{1}{2}mv^2$.

If 3W answered [1] bullet, the following data are relevant for ballistics:

4W - 71W

If 3W answered [2] shotgun or [3] shotgun slug, the following data are relevant for ballistics:

8W - 110W

If 3W answered [4] metallic fragment, the following data are relevant for ballistics:

12W - 14W

15W-16W. Note bullet fragmentation is important because this may greatly increase brain damage.

24W. Separates brain damage caused by missile entry into brain from brain damage caused by indriven bone alone.

25W-27W. Most patients will have <u>one</u> brain wound. Do not count scalp wounds which do not enter cranium as a brain wound.

Site Codes. This will refer to entrance/exit sites determined from CT Scan whenever possible. If this is not possible, skull films or physical examination will be used. Source for site data will be indicated 33W.

34W-37W. Indicates major categories of complicated brain wounds.

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

COMPLICATIONS SUMMARY*

FORM X (MAR 88)

To Be Completed by Nurse Clinician in Consultation With Study M.D.

*To be completed once, at hospital discharge or death.

1X. Date

__ ___ __
Day Mo Yr

1X$. Time _____:_____

2X. Visit Type
6 Hospital discharge
8 Death

3X. Observer (Hospital keeps list of codes)(0–99)

_____

Severity Scale (Use for 4X–23X) Codes:

0	No complication	3	Serious complication, not life threatening
1	Mild complication	4	Severe complication, life threatening
2	Moderate complication	5	Critical complication, life threatening (cause of death)
		U	Unknown

Severity scale must be 3, 4, or 5 in a category for complication to be a factor influencing morbidity or death.

Neurosurgical

4X. Delayed Hematoma

5X. Posttraumatic Hydrocephalus

6X. Meningitis/Ventriculitis

7X. Seizures

8X. Brain Abscess

9X. CSF Leak (Surgical)

90X. CSF Leak (Nonsurgical)

10X. Wound Infection

105X. SIADH

110X. Diabetes Insipidus

Pulmonary

11X. Infection

12X. Embolus

13X. Insufficiency

Cardiovascular

14X. Shock

145X. Hypertension

15X. MI, CHF, Arrhythmias

Genito-Urinary

150X. Urinary Tract Infection

Other

16X. Peripheral Vascular

17X. Renal

18X. Hepatic

19X. Gastrointestinal

20X. Coagulopathy

21X. Electrolyte

22X. Septicemia

225X. Wound Dehiscence
(Specify location)_____

23X. Other (Text limit 10 words)

FORM X

COMPLICATION SUMMARY

To Be Completed by Nurse Clinician
in Consultation with PI or Trauma Fellow
at Discharge or Death

It is intended to summarize the complications experienced during the patient's clinical course and to determine their influence on outcome. Definitions for the complications are the same as those used for the *Neurologic Evaluation* form, page _____ of this manual. The complications are rated on the severity scale, which follows, to indicate their impact on the patient's clinical course. The occurrence of all complications coded here must be indicated on the *"Complications"* section of the *Neurological Evaluation.*

Severity Scale

Codes:	0=No Complication	3=Serious Complication, Not Life Threatening
	1=Mild Complication	4=Severe Complication, Life Threatening
	2=Moderate Complication	5=Critical Complication, Life Threatening (cause of death)

Severity scale must be 3, 4, or 5 in a category for complication to be a factor influencing morbidity or death.

1X. DATE. Enter date of patient's discharge or death.

1X$. TIME. Enter time of patient's discharge or death.

2X. VISIT TYPE. 6=Hospital Discharge 8=Death

3X. OBSERVER. Hospital keeps list of codes. Enter 0-20.

Neurosurgical

4X. DELAYED HEMATOMA. Enter appropriate code.

5X. POST-TRAUMATIC HYDROCEPHALUS. Enter appropriate code.

6X. MENINGITIS/VENTRICULITIS. Enter appropriate code.

7X. SEIZURES. Enter appropriate code.

8X. BRAIN ABSCESS. Enter appropriate code.

9X. CSF LEAK. Enter appropriate code.

10X. WOUND INFECTION. Enter appropriate code.

105X. SIADH (Syndrome of Inappropriate ADH). Enter appropriate code.

Pulmonary

11X. INFECTION. Enter appropriate code.

12X. EMBOLUS. Enter appropriate code.

13X. INSUFFICIENCY. Enter appropriate code.

Cardiovascular

14X. SHOCK. Enter appropriate code.

145X. HYPERTENSION. Enter appropriate code.

15X. MI, CHF, ARRHYTHMIAS. Enter appropriate code.

Other

16X. PERIPHERAL VASCULAR. Enter appropriate code.

17X. RENAL. Enter appropriate code.

18X. HEPATIC. Enter appropriate code.

19X. GASTROINTESTINAL. Enter appropriate code.

20X. COAGULOPATHY. Enter appropriate code.

21X. ELECTROLYTE. Enter appropriate code.

22X. SEPTICEMIA. Enter appropriate code.

225X. WOUND DEHISCENCE. Enter appropriate code.

23X. OTHER. Text 50 character limit.

ARMY PENETRATING HEAD INJURY PROJECT

NEUROPSYCHOLOGY TEST BATTERY

ACUTE STAGE BATTERY

MAY 1988

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

NEUROPSYCHOLOGICAL ASSESSMENT

ACUTE STAGE BATTERY

FORM Y

(MAR 88)

1Y. Date

__ __ Day ___ Mo __ Yr

1Y$. Start Time

_____:_____

110Y$. Finish Time

_____:_____

2Y. Examiner (0-20)_____

3Y. Test Session_____

Codes for 3Y

1	Day 1*	**6**	Day 9
2	Day 2	**7**	3 Mos
3	Day 3	**8**	6 Mos
4	Day 5	**9**	1 Yr
5	Day 7	**10**	2 Yrs

*GCS Motor=6 for 24 hours

Patient Initials _____

Sex _____

Age _____

Handedness _____

Years of Schooling _____

Examiner Initials _____

310Y. Form Completion Code_____

0 Fully Completed

Not Completed Because:

1 Patient vegetative or severe confusion state
2 Patient refused testing
3 Patient refused form (including refusing part way through)
4 Discontinued by examiner due to patient condition (illness, fatigue)
5 Examiner error

RELIABILITY CODES

1.0 Standard procedure, reliable results
2.0 Irregular procedure, reliability affected minor
3.0 Irregular procedure, unreliable
4.0 Patient attempted, but abilities excused
5.0 Patient attempted, but refused to finish
6.0 Patient refused
7.0 Not administered

IMPAIRMENT CODE AFTER THE DECIMAL

.1 Vision
.2 Hearing
.3 Right hand
.4 Left hand
.5 Language comprehension
.6 Oral expression
.7 Extreme fatigue
.8 Agitated
.9 Confusional state
.99 Nonpreferred hand

GALVESTON ORIENTATION AND AMNESIA TEST (GOAT)

1. What is your name?_____ 4Y. _____(0/-2)

   When were your born?_____ 5Y. _____(0/-4)

   Where do you live?_____ 6Y. _____(0/-4)

2. Where are you now? (City)_____ 7Y. _____(0/-5)

   (Hospital)_____ _____ 8Y. _____(0/-5)
   (name of hospital not necessary)

3. On what date were you admitted to this hospital?_____ 9Y. _____(0/-5)

   _____

   How did you get here?_____ 10Y. _____(0/-5)

4. What is the first event you can remember *after* the injury?_____ 11Y. _____(0/-5)

   _____

   Can you describe in detail (e.g., date, time, companions) the first event you recall *after* the injury? 12Y. _____(0/-5)

   _____

5. Can you describe the last event you recall *before* the accident?_____ 13Y. _____(0/-5)

   _____

   Can you describe in detail (e.g., date, time, companions) the first event you recall *before* the injury? 14Y. _____(0/-5)

   _____

6. What time is it now?_____ 15Y. _____(0/-5)
   (−1 for each ½ hour removed from correct time to a maximum of −5)

7. What day of the week is it?_____ 16Y. _____(0/-5)
   (−1 for each day removed from correct one)

8. What day of the month is it?_____ 17Y. _____(0/-5)
   (−1 for each day removed from correct date to a maximum of −5)

9. What is the month?_____ 18Y. _____(0/-15)
   (−5 for each month removed from correct one to a maximum of −15)

10. What is the year?_____ 19Y. _____(0/-30)
    (−10 for each year removed from correct one to a maximum of −30)

Total Error Points _____

Total Goat Score 20Y. _____

Medical Record Number _____
Date _____
Examiner's Initials _____

FORM Y

GALVESTON ORIENTATION AND AMNESIA TEST (GOAT)

Estimate of anterograde amnesia. 21Y. _____(1-6)

(1) ≤ 15 min
(2) 15 min to 1 hr
(3) 1-24 hours
(4) 1-7 days
(5) 8 days to 1 mo
(6) >1 mo

Estimate of retrograde amnesia. 22Y. _____(1-6)

(1) ≤ 15 min
(2) 15 min to 1 hr
(3) 1-24 hours
(4) 1-7 days
(5) 8 days to 1 mo
(6) >1 mo

Administration: 1=Standard; 2=Modified 23Y. _____(1-2)

Number of multiple choice questions given 230Y. _____(0-20)

GOAT Reliability Code 24Y. _____•_____

240Y. COMMENTS:

REACTION TIME/RESPONSE REVERSAL

Simple Reaction Time

Foreperiod=light; 1 or 3 secs delay, random
Stimulus=red light

Foreperiod Delay	RT msec
1"	P1._____
3"	P2._____
1"	P3._____
	/replacements*
1"	1._____/_____
1"	2._____/_____
3"	3._____/_____
1"	4._____/_____
3"	5._____/_____
3"	6._____/_____
3"	7._____/_____
1"	8._____/_____
3"	9._____/_____
1"	10._____/_____
1"	11._____/_____
3"	12._____/_____

Response Reversal

	Imitation		Reversal
1	P1._____	1	P4._____
2	P2._____	2	P5._____
1	P3._____	2	P6._____
1	1._____	1	13._____
2	2._____	2	14._____
2	3._____	2	15._____
1	4._____	1	16._____
1	5._____	2	17._____
1	6._____	2	18._____
2	7._____	1	19._____
2	8._____	1	20._____
1	9._____	2	21._____
2	10._____	1	22._____
1	11._____	2	23._____
2	12._____	1	24._____

241Y. Hand
0 Left **1** Right _____ (0-1)

25Y. Total anticipations* (<150 msec)_____ (0-12)

26Y. Total misses* (>2000 msec)_____ (0-12)

27Y. Total hits _____ (0-12)

28Y. Median RT (hits) _____ (151-1999)

29Y. Reliability ____.____

30Y. Imitation errors _____ (0-12)

31Y. Reversal errors _____ (0-12)

32Y. Reliability ____.____

*rerun all trials of RT <150 msec, >2000 following trial 12. Do not exceed 5 reruns.

AUDITORY NUMBER SEARCH

DETECTION OF "2's" AND "5's"
ISI=1.0 seconds

Practice Trials			Test Trials			
Trial Number	Number	Response	Trial Number	Number	Response	
P1	9	_____	1	3		_____
P2	2	_____	2	4		_____
P3	1	_____	3	2		_____
P4	5	_____	4	8		_____
P5	8	_____	5	5		_____
			6	4		_____
			7	9		_____
			8	8		_____
			9	5		_____
			10	4		_____
			11	4		_____
			12	2		_____
			13	8		_____
			14	1		_____
			15	1		_____
			16	3		_____
			17	8		_____
			18	5		_____
			19	8		_____
			20	1		_____
			21	3		_____
			22	8		_____
			23	2		_____
			24	9		_____
			25	1		_____
			26	2		_____
			27	8		_____
			28	9		_____
			29	6		_____
			30	5		_____
			31	8		_____
			32	9		_____
			33	8		_____
			34	1		_____
			35	5		_____
			36	4		_____
			37	8		_____
			38	6		_____
			39	2		_____
			40	9		_____

33Y. Total hits _____ (0-10)

34Y. Total false alarms _____ (0-30)

35Y. Reliability code ____•____

36Y. Response mode ____•____

SCORE SHEET

VISUAL NUMBER SEARCH

SEARCH FOR "2" AND "5"

37Y. Hand _____(0–1)
0 Left
1 Right

38Y. Total Time _____secs (5–180)

	HITS	COMMISSIONS
39Y. Upper left	_____(0–8)	44Y. _____(0–24)
40Y. Lower left	_____(0–8)	45Y. _____(0–24)
41Y. Upper right	_____(0–8)	46Y. _____(0–24)
42Y. Lower right	_____(0–8)	47Y. _____(0–24)
43Y. Total	_____(0–32)	48Y. _____(0–96)

Reliability Code 49Y. ____•___

SCORE SHEET

MAZE LEARNING

MAZE A: EASY

50Y. Hand _____(0–1)
0 Left
1 Right

51Y$. Total Time _____secs (0–120)

		BLIND ALLEYS	WALL TOUCHES/CROSSES*	WALL CROSSES/LOST**
52Y.	Left	_____(0–99)	55Y. _____(0–99)	58Y. _____(0–99)
53Y.	Right	_____(0–99)	56Y. _____(0–99)	59Y. _____(0–99)
54Y.	Total	_____(0–99)	57Y. _____(0–99)	60Y. _____(0–99)

Reliability Code 61Y. ____•___

MAZE B: HARD

62Y. Total Time_____secs (0–240)

		BLIND ALLEYS	WALL TOUCHES/CROSSES*	WALL CROSSES/LOST**
63Y.	Left	_____(0–99)	66Y. _____(0–99)	69Y. _____(0–99)
64Y.	Right	_____(0–99)	67Y. _____(0–99)	70Y. _____(0–99)
65Y.	Total	_____(0–99)	68Y. _____(0–99)	71Y. _____(0–99)

Reliability Code 72Y. ____•___

* Motor errors; subject spontaneously corrects.

** Patient crosses wall and continues on new path, requiring tester intervention.

INSTRUCTIONS

ACUTE STAGE BATTERY

GOAT: STANDARD ADMINISTRATION

Questions

1. Assign 2 error points if patient fails to state first and last names correctly; 4 points if patient fails to state date of birth correctly; 4 points are scored if patient fails to state the town of his residence (street address is unnecessary).

2. If the patient is unable to state the town he is in at the time of the assessment, 5 points are scored; 5 additional points are deducted if the patient fails to state that he is in the hospital, although mentioning the name of the hospital is unnecessary.

3. Five (5) error points are given if the patient is unable to recall the date of admission; 5 additional points are deducted if the patient fails to describe accurately the mode of transportation to the hospital.

4. Five (5) error points are given when the patient is unable to recall the first event after injury (e.g., waking up in hospital room); patients who cannot recall an event after the injury would have 5 additional error points deducted because of failure to present details of such an event. Those patients who describe a verifiable, or at least plausible, posttraumatic event but are unable to provide details, would accrue 5 error points on this question.

5. Criteria for scoring responses are similar to those used in question 4; 5 error points are deducted for vague recall of an event prior to the injury (e.g., driving a car shortly before the accident), whereas 5 additional points are deducted for total failure to recall any retrograde event.

6. Score 1 error point for each half hour that the patient's response deviates from the correct time, up to a maximum of -5.

7. Assign 1 error point for each day that the patient's response is removed from the correct day of the week (max=3 or 6).

8. Score 1 error point for each day of the month that the patient's response deviates from the correct date, to a maximum of -5.

9. Five (5) error points are deducted for each month that the patient's response is removed from the correct month, to a maximum of 15.

10. Ten (10) error points are deducted for each year that the patient's response deviates from the correct one, to a maximum of -30.

Computation of GOAT Score

Enter the total error points accrued for the ten items in the lower right hand corner of the test form (Figure 1). The GOAT score equals 100 minus total error points.

MODIFIED ADMINISTRATION: MULTIPLE CHOICE

Indications

Patients unable to respond verbally who are capable of following instructions and signaling their response (e.g., by pointing) may be given a modified version of the GOAT.

Instructions

Present three alternatives in addition to the correct choice, both visually (on an index card) and orally. Point to each choice on the index card as you present it orally. Ask the patient to nod his head or lift a finger when you mention the correct choice. This modified procedure can be used for all questions on the GOAT except questions 4 and 5, which require elaboration. The three response alternatives for each question should be arranged vertically in large print on an index card. The examiner should develop multiple sets of response alternatives for serially testing patients who are unable to verbalize because of aphasia, intubation, or other reasons.

1. On question 1 an index card should be presented which includes three fictitious names and the patient's name, followed by an index card which shows four dates, including the patient's date of birth, and, finally, a third index card which includes four citiees within your state, including the city in which the patient lives.

2. Similarly, question 2 would include three cities within your state, in addition to the city in which your center is located. A separate card would be used to present three places (e.g., school, factory, store) in addition to "hospital" for the second part of question 2.

3. An index card presenting three alternative dates and the date of admission would be presented for the first half of question 3, whereas a second card would show three alternative methods of emergency evacuation in addition to the method of evacuation used for the patient.

4. Multiple choice testing is not feasible for questions 4 and 5.

5. The three alternatives for questions 6-10 would include different times of day (question 6), days of the week (question 7), date (question 8), month (question 9), and year (question 10).

Scoring

Error points will be deducted for each question similar to the procedure used in the standard administration of the GOAT. The total error points are recorded on the form. The total number of error points is deducted from 80, reflecting omission of questions 4 and 5. Accordingly, resolution of posttraumatic amnesia corresponds to a residual GOAT score of at least 60 on the multiple choice administration.

INSTRUCTIONS

ACUTE STAGE BATTERY

SIMPLE REACTION TIME/RESPONSE REVERSAL

As best as possible, the patient should be comfortably placed in an upright position with the keyboard/stimulus unit on a table directly in front of him/her. Ideally the main reaction time unit should be placed on another table, ensuring that the control panel is not visible to the subject. The test environment should be made as dark as possible.

Simple Reaction Time

> *"In this task, we will determine how quickly you can react to the presence of a light. Your job will be to press this button* (point to the central key) *as quickly as you can whenever you see a RED light appear in this window* (point to the light source)."

Place the index finger of the subject's preferred or best responding hand on the response key.

> *"First, I will say 'READY' and you will see this light come on* (point to the warning light). *This light is to alert you to get ready to push the button. After a short delay, the RED light will appear here* (point to the window below the warning light). *Your job is to push the button as fast as you can as soon as you see the RED light. Remember, do not press until the RED light appears."*

Present the three practice trials to ensure that the subject understands the task.

> *"Okay, very good. Now let's do it some more. Remember, do not press the button until the RED light appears."* Begin each trial by saying *"ready".*

Deliver the 12 trials using the prescribed sequence of foreperiod durations indicated on the score sheet. It is extremely important that you add a random number of clicks when resetting the CUE DURATION knob for each trial so that the subject cannot anticipate the next setting.

Record the RT (or indicate MISS) for each trial. Trials with response times of more than 2000 msecs (late or no response) or less than 150 msecs (anticipations) must be rerun (replaced). However, the total number of replacement trials should not exceed five (5). Remember to RESET the digital display after recording the RT (in msecs) for each trial.

Response Reversal

Remove RT equipment. *"Now I want you to do what I do. When I tap once* (demonstrate - fist, knuckles down), *you tap once. When I tap twice* (demonstrate), *you tap twice. Okay, let's try it."* Give three practice trials. Record and correct any error. *"Good, let's try some more."* Present 12 trials. Initiate each trial as soon as subject has completed his/her response to the preceding trial.

"Now, let's try something different. When I tap once, you tap twice. When I tap twice, you tap once. Give three practice trials. Correct any errors. Administer the 12 experimental trials as indicated above. Record all reversal errors.

INSTRUCTIONS

ACUTE STAGE BATTERY

AUDITORY SEARCH TASK

Detection of "2" and "5" ISI=1.0 sec

"I would like you to listen to this tape very carefully. You will hear a voice saying some numbers and I would like you to raise your finger (preferred hand) *every time you hear the number two, and also every time you hear the number five. Remember, raise your finger only if you hear the number two or the number five. Listen very carefully because the numbers will go by pretty fast. You will need to bring your finger up and down quickly, so that it is clear which number you are responding to. Let's give it a try."* Administer the five practice trials. Attempt to correct ambiguous response patterns (e.g., responding too slowly, not bringing finger down).

Note: If the patient cannot raise a finger, every attempt should be made to have the patient respond in another appropriate (scorable) manner (e.g., orally, head movement, whole arm movement, etc.).

INSTRUCTIONS

ACUTE STAGE BATTERY

VISUAL SEARCH TASK

Search For "2" and "5"

"In this task you will be given a sheet of paper with numbers written all over it. Every time you see the number 2 or the number 5 on the paper, I want you to simply draw a line right through it. Be sure to look at the whole paper carefully. Work quickly, but do not skip any 2's or 5's. Remember, draw a line through every number 2 and 5 BUT only through those numbers. Do not mark any other number. Mark only the 2's and 5's."

Give the subject a pencil. Then position the paper directly in front of the subject and begin timing. Allow a maximum of 180 secs to complete the task. Be sure to record the time to completion.

INSTRUCTIONS

ACUTE STAGE BATTERY

MAZE LEARNING

MAZE A: Easy

Take the pencil from the subject. Position Maze A directly in front of the subject.

> *"This is a drawing of a maze* (point to a space between lines). *This is the PATH and these black lines are SOLID WALLS. Your task will be to stay on the road and draw a line from this START position to this FINISH position as quickly as you can. You are not allowed to pass through any of the walls. You should also be very careful to keep your pencil on the road. Try not to bump into any of the walls. Once you begin, you must not lift your pencil from the paper."*

Give the subject a pencil, place him at the START position, and begin timing. If the subject crosses through a line and does not spontaneously self-correct, return his pencil to last correct position and remind him/her that he cannot cross through the walls.

MAZE B: Hard

> *"Very good. Now I will give you another one to do that has many more paths on it. Remember, work as quickly as you can, but do not touch or cross through any of the walls and do not lift your pencil from the page."*

Place Maze B in front of the subject. Position his/her pencil at the START position and begin timing.

ARMY PENETRATING HEAD INJURY PROJECT

NEUROPSYCHOLOGY TEST BATTERY

STANDARD BATTERY

MAY 1988

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

NEUROPSYCHOLOGICAL ASSESSMENT

STANDARD BATTERY

FORM Q

(MAR 88)

1Q. Date

__ __ Day ___ Mo __ Yr

110Q. Start Time

_____:_____

120Q. Finish Time

_____:_____

2Q. Observer (0-20)_____

3Q. Test Session_____

Codes for 3Q
1=Baseline
2=3 Mos
3=6 Mos
4=1 Yr
5=2 Yrs

Patient Initials _____

Sex _____

Age _____

Handedness _____

Years of Schooling _____

Examiner Initials _____

310Q. Form Completion Code_____

0=Fully Completed
Not Completed Because:
1=Patient vegetative or severe confusion state
2=Patient refused testing
3=Patient refused form (including refusing part way through)
4=Discontinued by examiner due to patient condition (illness, fatigue)
5=Examiner error

RELIABILITY CODES

1.0=Standard procedure, reliable results
2.0=Irregular procedure, reliability affected minor
3.0=Irregular procedure, unreliable
4.0=Patient attempted, but abilities excused
5.0=Patient attempted, but refused to finish
6.0=Patient refused
7.0=Not administered

IMPAIRMENT CODE AFTER THE DECIMAL

.1=Vision
.2=Hearing
.3=Right hand
.4=Left hand
.5=Language comprehension
.6=Oral expression
.7=Extreme fatigue
.8=Agitated
.9=Confusional state
.99=Nonpreferred hand

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

PROBLEM CHECK LIST

FORM Q

(MAR 88)

Since your injury (or last exam), have you had difficulty:	Comments	No/Yes (0,1)
Wakefulness/Concentration		
1. Getting to sleep		4Q._____
2. Awaken often		5Q._____
3. Tire easily, fatigue		6Q._____
4. Concentrating		7Q._____
Somatic		
1. Headache		8Q._____
2. Other pain (specify)		9Q._____
Motor ("Unaffected" Limbs)		
1. Slowness		10Q._____
2. Clumsy, uncoordinated		11Q._____
3. Manipulating small objects (buttons)		12Q._____
Sensory		
1. Loss of vision, blind spots		13Q._____
2. Blurred vision		14Q._____
3. Double vision		5Q._____
4. Hearing loss		16Q._____
5. Ringing in ears		17Q._____
6. Tingling sensations		18Q._____
7. Numbness		19Q._____
8. Vertigo (spinning sensation)		20Q._____
9. Other dizziness (unsteadiness, faintness)		21Q._____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

PROBLEM CHECK LIST

FORM Q

(MAR 88)

Since your injury (or last exam), have you had difficulty:	Comments	No/Yes (0,1)
Recognition (not sensory)		
1. Recognizing familiar people, faces (relatives)		22Q.____
2. Recognizing common objects		23Q.____
3. Recognizing things in pictures, photographs, drawings		24Q.____
4. Objects looking distorted		25Q.____
5. Seeing strange things that are not there (hallucinations)		26Q.____
6. Hearing strange things that are not there (hallucinations)		27Q.____
7. Decreased sense of smell or smelling things that are not there (hallucinations)		28Q.____
8. Decreased sense of taste or tasting things that are not there (hallucinations)		29Q.____
9. Recognizing shape or texture of small objects (change in pocket)		30Q.____
Spatial		
1. Judging the location of things		31Q.____
2. Reaching for objects		32Q.____
3. Finding your way around the ward/hospital		33Q.____
4. Things moving around the room (not vertigo)		34Q.____
Language		
1. Slurring words		35Q.____
2. Understanding what others say		36Q.____
3. Finding words: tip-of-the-tongue		37Q.____
4. Reading		38Q.____
5. Writing		39Q.____
6. Spelling		40Q.____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

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PROBLEM CHECK LIST

FORM Q

(MAR 88)

PAGE OF

Since your injury (or last exam), have you had difficulty:

Comments

No/Yes (0,1)

Memory

1. Remembering day-to-day events (meals, visitors) _____ 41Q._____
2. Remembering facts you used to know (first president, capital of France) _____ 42Q._____
3. Remembering events from your past (schools, friends) _____ 43Q._____
4. Remembering how to do things (get dressed, eat, shave/make-up) _____ 44Q._____

Mood

1. Feel like crying, very sad _____ 45Q._____
2. Feel very anxious _____ 46Q._____
3. Feel very good _____ 47Q._____
4. Feel angry _____ 48Q._____
5. Feel that you cannot control your feelings _____ 49Q._____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

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HANDEDNESS QUESTIONNAIRE

FORM Q

(MAR 88)

PAGE OF

Instructions to Examiner: Ask the following questions and record responses.

		Right	Left
1. Which hand do you use for writing.		___	___
		Yes	**No**
2. Is this the hand you have always used for writing?		___	___
3. Are there any left-handers in your immediate, biological family?		___	___
4. If Yes, which family member(s)?	Mother	___	___
	Father	___	___
	Sister or Brother	___	___
	Other	___	___

5. Please print your name_____

6. Now write your signature_____

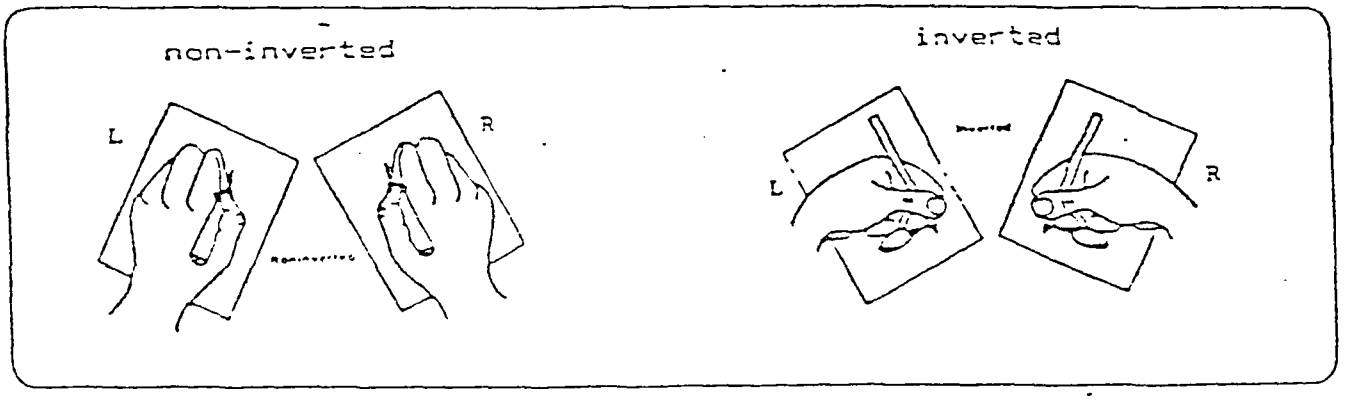
7. Now write *"the food in this hospital stinks"*.

_____

Watch writing style and check: Inverted ___

Noninverted ___

(Note: Most right handers use a non-inverted hand position for writing, and most left handers appear to prefer an inverted position.)



	Always Use L (1)	Usually Use L (2)	Both Equally (3)	Usually Use R (4)	Always Use R (5)
7. Which hand do you normally use to:					
a. Write a message	___	___	___	___	___
b. Draw a picture	___	___	___	___	___
c. Hold a toothbrush	___	___	___	___	___
d. Throw a ball	___	___	___	___	___
e. Use a pair of scissors	___	___	___	___	___

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

DIGIT SPAN (WAIS-R)

FORM Q

(MAR 88)

Discontinue after failure on BOTH TRIALS of any item.
Administer BOTH TRIALS of each item, even after subject passes first trial.

DIGITS FORWARD (Span)		PASS—FAIL (1, 0)	SCORE 2, 1 or 0
1. (3)	5 — 8 — 2 6 — 9 — 4		
2. (4)	6 — 4 — 3 — 9 7 — 2 — 8 — 6		
3. (5)	4 — 2 — 7 — 3 — 1 7 — 5 — 8 — 3 — 6		
4. (6)	6 — 1 — 9 — 4 — 7 — 3 3 — 9 — 2 — 4 — 8 — 7		
5. (7)	5 — 9 — 1 — 7 — 4 — 2 — 8 4 — 1 — 7 — 9 — 3 — 8 — 6		
6. (8)	5 — 8 — 1 — 9 — 2 — 6 — 4 — 7 3 — 8 — 2 — 9 — 5 — 1 — 7 — 4		
7. (9)	2 — 7 — 5 — 8 — 6 — 2 — 5 — 8 — 4 7 — 1 — 3 — 9 — 4 — 2 — 5 — 6 — 8		

Total Forward Max=14 _____

DIGITS BACKWARD Administer DIGITS BACKWARD even if subject scores 0 on DIGITS FORWARD		PASS—FAIL (1, 0)	SCORE 2, 1 or 0
1. (2)	2 — 4 5 — 8		
2. (3)	6 — 2 — 9 4 — 1 — 5		
3. (4)	3 — 2 — 7 — 9 4 — 9 — 6 — 8		
4. (5)	1 — 5 — 2 — 8 — 6 6 — 1 — 8 — 4 — 3		
5. (6)	5 — 3 — 9 — 4 — 1 — 8 7 — 2 — 4 — 8 — 5 — 6		
6. (7)	8 — 1 — 2 — 9 — 3 — 6 — 5 4 — 7 — 3 — 9 — 1 — 2 — 8		
7. (8)	9 — 4 — 3 — 7 — 6 — 2 — 5 — 8 7 — 2 — 8 — 1 — 9 — 6 — 5 — 3		

Total Backward Max=14 _____

_____	+	_____	=	_____
Forward		Backward		(Max=28)

1. Scale score (age corrected): _____
2. Maximum number digits forward (span): _____ (0-9)
3. Maximum number digits backward: _____ (0-8)
4. Reliability: _____ • _____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

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DIGIT SUPRASPAN

FORM Q

(MAR 88)

PAGE OF

INSTRUCTIONS: Begin with span +1. Present one digit/second and ask patient to recall series in same order after you finish. Record patient's recall under *Response*. Proceed to next longest series after one perfect recall. Stop when the patient fails five consecutive trials of the same length. Circle the longest length series recalled perfectly. See full instructions for scoring.

	SEQUENCE	RESPONSE	CORRECT	LENGTH
1.	9-5-3			3
2.	9-5-3			3
3.	9-5-3			3
4.	9-5-3			3
5.	9-5-3			3
1.	5-4-1-8			4
2.	5-4-1-8			4
3.	5-4-1-8			4
4.	5-4-1-8			4
5.	5-4-1-8			4
1.	7-3-1-5-6			5
2.	7-3-1-5-6			5
3.	7-3-1-5-6			5
4.	7-3-1-5-6			5
5.	7-3-1-5-6			5
1.	4-8-6-3-1-9			6
2.	4-8-6-3-1-9			6
3.	4-8-6-3-1-9			6
4.	4-8-6-3-1-9			6
5.	4-8-6-3-1-9			6
1.	6-3-1-9-7-2-5			7
2.	6-3-1-9-7-2-5			7
3.	6-3-1-9-7-2-5			7
4.	6-3-1-9-7-2-5			7
5.	6-3-1-9-7-2-5			7

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

DIGIT SUPRASPAN

FORM Q

(MAR 88)

PAGE OF

	SEQUENCE	RESPONSE	CORRECT	LENGTH
1.	2-8-5-3-7-9-4-2			8
2.	2-8-5-3-7-9-4-2			8
3.	2-8-5-3-7-9-4-2			8
4.	2-8-5-3-7-9-4-2			8
5.	2-8-5-3-7-9-4-2			8
1.	1-7-4-8-2-5-7-8-1			9
2.	1-7-4-8-2-5-7-8-1			9
3.	1-7-4-8-2-5-7-8-1			9
4.	1-7-4-8-2-5-7-8-1			9
5.	1-7-4-8-2-5-7-8-1			9
1.	5-8-4-1-3-6-7-9-5-1			10
2.	5-8-4-1-3-6-7-9-5-1			10
3.	5-8-4-1-3-6-7-9-5-1			10
4.	5-8-4-1-3-6-7-9-5-1			10
5.	5-8-4-1-3-6-7-9-5-1			10
1.	4-2-8-5-1-9-7-2-8-3-1			11
2.	4-2-8-5-1-9-7-2-8-3-1			11
3.	4-2-8-5-1-9-7-2-8-3-1			11
4.	4-2-8-5-1-9-7-2-8-3-1			11
5.	4-2-8-5-1-9-7-2-8-3-1			11
1.	5-7-1-3-7-6-1-3-2-8-4-9			12
2.	5-7-1-3-7-6-1-3-2-8-4-9			12
3.	5-7-1-3-7-6-1-3-2-8-4-9			12
4.	5-7-1-3-7-6-1-3-2-8-4-9			12
5.	5-7-1-3-7-6-1-3-2-8-4-9			12
1.	1-3-8-6-7-1-2-4-8-5-3-9-2			13
2.	1-3-8-6-7-1-2-4-8-5-3-9-2			13
3.	1-3-8-6-7-1-2-4-8-5-3-9-2			13
4.	1-3-8-6-7-1-2-4-8-5-3-9-2			13
5.	1-3-8-6-7-1-2-4-8-5-3-9-2			13

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

DIGIT SUPRASPAN

FORM Q

(MAR 88)

	SEQUENCE	RESPONSE	CORRECT	LENGTH
1.	4-7-3-1-2-9-4-2-6-7-1-9-5-3			14
2.	4-7-3-1-2-9-4-2-6-7-1-9-5-3			14
3.	4-7-3-1-2-9-4-2-6-7-1-9-5-3			14
4.	4-7-3-1-2-9-4-2-6-7-1-9-5-3			14
5.	4-7-3-1-2-9-4-2-6-7-1-9-5-3			14
1.	3-9-4-1-8-7-5-2-4-7-5-3-6-9-2			15
2.	3-9-4-1-8-7-5-2-4-7-5-3-6-9-2			15
3.	3-9-4-1-8-7-5-2-4-7-5-3-6-9-2			15
4.	3-9-4-1-8-7-5-2-4-7-5-3-6-9-2			15
5.	3-9-4-1-8-7-5-2-4-7-5-3-6-9-2			15
1.	6-2-3-7-1-4-9-2-8-5-3-1-7-9-6-4			16
2.	6-2-3-7-1-4-9-2-8-5-3-1-7-9-6-4			16
3.	6-2-3-7-1-4-9-2-8-5-3-1-7-9-6-4			16
4.	6-2-3-7-1-4-9-2-8-5-3-1-7-9-6-4			16
5.	6-2-3-7-1-4-9-2-8-5-3-1-7-9-6-4			16
1.	7-6-1-9-6-8-3-5-2-4-6-9-8-4-1-3-7			17
2.	7-6-1-9-6-8-3-5-2-4-6-9-8-4-1-3-7			17
3.	7-6-1-9-6-8-3-5-2-4-6-9-8-4-1-3-7			17
4.	7-6-1-9-6-8-3-5-2-4-6-9-8-4-1-3-7			17
5.	7-6-1-9-6-8-3-5-2-4-6-9-8-4-1-3-7			17
1.	4-1-5-9-8-6-3-2-1-7-9-4-8-9-6-5-3-8			18
2.	4-1-5-9-8-6-3-2-1-7-9-4-8-9-6-5-3-8			18
3.	4-1-5-9-8-6-3-2-1-7-9-4-8-9-6-5-3-8			18
4.	4-1-5-9-8-6-3-2-1-7-9-4-8-9-6-5-3-8			18
5.	4-1-5-9-8-6-3-2-1-7-9-4-8-9-6-5-3-8			18
1.	9-6-3-8-2-5-1-7-2-3-4-8-1-6-5-9-3-4-1			19
2.	9-6-3-8-2-5-1-7-2-3-4-8-1-6-5-9-3-4-1			19
3.	9-6-3-8-2-5-1-7-2-3-4-8-1-6-5-9-3-4-1			19
4.	9-6-3-8-2-5-1-7-2-3-4-8-1-6-5-9-3-4-1			19
5.	9-6-3-8-2-5-1-7-2-3-4-8-1-6-5-9-3-4-1			19

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

DIGIT SUPRASPAN

FORM Q

(MAR 88)

PAGE OF

SEQUENCE	RESPONSE	CORRECT	LENGTH
1. 7-2-8-1-6-4-9-7-3-5-1-7-9-3-1-4-8-5-6-3			20
2. 7-2-8-1-6-4-9-7-3-5-1-7-9-3-1-4-8-5-6-3			20
3. 7-2-8-1-6-4-9-7-3-5-1-7-9-3-1-4-8-5-6-3			20
4. 7-2-8-1-6-4-9-7-3-5-1-7-9-3-1-4-8-5-6-3			20
5. 7-2-8-1-6-4-9-7-3-5-1-7-9-3-1-4-8-5-6-3			20

Span Achieved (2-20) _____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BLOCK SPAN: FORWARD

FORM Q

(MAR 88)

PAGE OF

I am going to tap some of these blocks with the eraser. First, watch carefully so you can tap the same blocks in the same order when I am through. (Discontinue after failure on BOTH TRIALS of any item. Administer BOTH TRIALS of each item, even after subject passes first trial.)

BLOCKS FORWARD (Span)		PASS—FAIL (1, 0)	SCORE 2, 1 or 0
1. (3)	5 — 8 — 2		
	6 — 9 — 4		
2. (4)	6 — 4 — 3 — 9		
	7 — 2 — 8 — 6		
3. (5)	4 — 2 — 7 — 3 — 1		
	7 — 5 — 8 — 3 — 6		
4. (6)	6 — 1 — 9 — 4 — 7 — 3		
	3 — 9 — 2 — 4 — 8 — 7		
5. (7)	5 — 9 — 1 — 7 — 4 — 2 — 8		
	4 — 1 — 7 — 9 — 3 — 8 — 6		
6. (8)	5 — 8 — 1 — 9 — 2 — 6 — 4 — 7		
	3 — 8 — 2 — 9 — 5 — 1 — 7 — 4		
7. (9)	2 — 7 — 5 — 8 — 6 — 2 — 5 — 8 — 4		
	7 — 1 — 3 — 9 — 4 — 2 — 5 — 6 — 8		

Total Forward (0-14): _____

Span (0-9): _____

Reliability: ____ • ____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BLOCK SUPRASPAN

FORM Q

(MAR 88)

PAGE OF

INSTRUCTIONS: Begin with span +1. Present one block/second and ask patient to repeat series in same order after you finish. Record patient's recall under *Response*. Proceed to next longest series after one perfect recall. Stop when the patient fails five consecutive trials of the same length. Circle the longest length series recalled perfectly. See full instructions for scoring.

	SEQUENCE	RESPONSE	CORRECT	LENGTH
1.	9-5-3			3
2.	9-5-3			3
3.	9-5-3			3
4.	9-5-3			3
5.	9-5-3			3
1.	5-4-1-8			4
2.	5-4-1-8			4
3.	5-4-1-8			4
4.	5-4-1-8			4
5.	5-4-1-8			4
1.	7-3-1-5-6			5
2.	7-3-1-5-6			5
3.	7-3-1-5-6			5
4.	7-3-1-5-6			5
5.	7-3-1-5-6			5
1.	4-8-6-3-1-9			6
2.	4-8-6-3-1-9			6
3.	4-8-6-3-1-9			6
4.	4-8-6-3-1-9			6
5.	4-8-6-3-1-9			6
1.	6-3-1-9-7-2-5			7
2.	6-3-1-9-7-2-5			7
3.	6-3-1-9-7-2-5			7
4.	6-3-1-9-7-2-5			7
5.	6-3-1-9-7-2-5			7

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BLOCK SUPRASPAN

FORM Q

(MAR 88)

	SEQUENCE	RESPONSE	CORRECT	LENGTH
1.	2-8-5-3-7-9-4-2			8
2.	2-8-5-3-7-9-4-2			8
3.	2-8-5-3-7-9-4-2			8
4.	2-8-5-3-7-9-4-2			8
5.	2-8-5-3-7-9-4-2			8
1.	1-7-4-8-2-5-7-8-1			9
2.	1-7-4-8-2-5-7-8-1			9
3.	1-7-4-8-2-5-7-8-1			9
4.	1-7-4-8-2-5-7-8-1			9
5.	1-7-4-8-2-5-7-8-1			9
1.	5-8-4-1-3-6-7-9-5-1			10
2.	5-8-4-1-3-6-7-9-5-1			10
3.	5-8-4-1-3-6-7-9-5-1			10
4.	5-8-4-1-3-6-7-9-5-1			10
5.	5-8-4-1-3-6-7-9-5-1			10
1.	4-2-8-5-1-9-7-2-8-3-1			11
2.	4-2-8-5-1-9-7-2-8-3-1			11
3.	4-2-8-5-1-9-7-2-8-3-1			11
4.	4-2-8-5-1-9-7-2-8-3-1			11
5.	4-2-8-5-1-9-7-2-8-3-1			11
1.	5-7-1-3-7-6-1-3-2-8-4-9			12
2.	5-7-1-3-7-6-1-3-2-8-4-9			12
3.	5-7-1-3-7-6-1-3-2-8-4-9			12
4.	5-7-1-3-7-6-1-3-2-8-4-9			12
5.	5-7-1-3-7-6-1-3-2-8-4-9			12
1.	1-3-8-6-7-1-2-4-8-5-3-9-2			13
2.	1-3-8-6-7-1-2-4-8-5-3-9-2			13
3.	1-3-8-6-7-1-2-4-8-5-3-9-2			13
4.	1-3-8-6-7-1-2-4-8-5-3-9-2			13
5.	1-3-8-6-7-1-2-4-8-5-3-9-2			13

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

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BLOCK SUPRASPAN

FORM Q

(MAR 88)

	SEQUENCE	RESPONSE	CORRECT	LENGTH
1.	4-7-3-1-2-9-4-2-6-7-1-9-5-3			14
2.	4-7-3-1-2-9-4-2-6-7-1-9-5-3			14
3.	4-7-3-1-2-9-4-2-6-7-1-9-5-3			14
4.	4-7-3-1-2-9-4-2-6-7-1-9-5-3			14
5.	4-7-3-1-2-9-4-2-6-7-1-9-5-3			14
1.	3-9-4-1-8-7-5-2-4-7-5-3-6-9-2			15
2.	3-9-4-1-8-7-5-2-4-7-5-3-6-9-2			15
3.	3-9-4-1-8-7-5-2-4-7-5-3-6-9-2			15
4.	3-9-4-1-8-7-5-2-4-7-5-3-6-9-2			15
5.	3-9-4-1-8-7-5-2-4-7-5-3-6-9-2			15
1.	6-2-3-7-1-4-9-2-8-5-3-1-7-9-6-4			16
2.	6-2-3-7-1-4-9-2-8-5-3-1-7-9-6-4			16
3.	6-2-3-7-1-4-9-2-8-5-3-1-7-9-6-4			16
4.	6-2-3-7-1-4-9-2-8-5-3-1-7-9-6-4			16
5.	6-2-3-7-1-4-9-2-8-5-3-1-7-9-6-4			16
1.	7-6-1-9-6-8-3-5-2-4-6-9-8-4-1-3-7			17
2.	7-6-1-9-6-8-3-5-2-4-6-9-8-4-1-3-7			17
3.	7-6-1-9-6-8-3-5-2-4-6-9-8-4-1-3-7			17
4.	7-6-1-9-6-8-3-5-2-4-6-9-8-4-1-3-7			17
5.	7-6-1-9-6-8-3-5-2-4-6-9-8-4-1-3-7			17
1.	4-1-5-9-8-6-3-2-1-7-9-4-8-9-6-5-3-8			18
2.	4-1-5-9-8-6-3-2-1-7-9-4-8-9-6-5-3-8			18
3.	4-1-5-9-8-6-3-2-1-7-9-4-8-9-6-5-3-8			18
4.	4-1-5-9-8-6-3-2-1-7-9-4-8-9-6-5-3-8			18
5.	4-1-5-9-8-6-3-2-1-7-9-4-8-9-6-5-3-8			18
1.	9-6-3-8-2-5-1-7-2-3-4-8-1-6-5-9-3-4-1			19
2.	9-6-3-8-2-5-1-7-2-3-4-8-1-6-5-9-3-4-1			19
3.	9-6-3-8-2-5-1-7-2-3-4-8-1-6-5-9-3-4-1			19
4.	9-6-3-8-2-5-1-7-2-3-4-8-1-6-5-9-3-4-1			19
5.	9-6-3-8-2-5-1-7-2-3-4-8-1-6-5-9-3-4-1			19

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BLOCK SUPRASPAN

FORM Q

(MAR 88)

PAGE __ OF __

	SEQUENCE	RESPONSE	CORRECT	LENGTH
1.	7-2-8-1-6-4-9-7-3-5-1-7-9-3-1-4-8-5-6-3			20
2.	7-2-8-1-6-4-9-7-3-5-1-7-9-3-1-4-8-5-6-3			20
3.	7-2-8-1-6-4-9-7-3-5-1-7-9-3-1-4-8-5-6-3			20
4.	7-2-8-1-6-4-9-7-3-5-1-7-9-3-1-4-8-5-6-3			20
5.	7-2-8-1-6-4-9-7-3-5-1-7-9-3-1-4-8-5-6-3			20

Span Achieved (2-20) _____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

DOUBLE SIMULTANEOUS STIMULATION

FORM Q

(MAR 88)

PAGE OF

Present a minimum of four trials for each unilateral and bilateral-simultaneous condition. Record number of errors (extinctions). See manual for instructions.

	UNILATERAL		BILATERAL-SIMULTANEOUS	
Tactile				
Left Hand/Right Hand	LH _____	RH _____	LH _____	RH _____
Left Face/Right Face	LF _____	RF _____	LF _____	RF _____
Left Hand/Left Face			LH _____	LF _____
Right Hand/Right Face			RH _____	RF _____
Left Hand/Right Face			LH _____	RF _____
Right Hand/Left Face			RH _____	LF _____
Auditory				
Left Ear/Right Ear	LE _____	RE _____	LE _____	RE _____
Visual				
Above Eye Level	LVF _____	RVF _____	LVF _____	RVF _____
Eye Level	LVF _____	RVF _____	LVF _____	RVF _____
Below Eye Level	LVF _____	RVF _____	LVF _____	RVF _____

Reliability _____•_____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

GROOVED PEGBOARD

FORM Q

(MAR 88)

PAGE OF

Right

Total Time (Sec.) (25–300) _____.____

Number Pegs Place (0–25) _____

Number Errors (drops) (0–50) _____

Reliability _____.____

Left

Total Time (Sec.) (25–300) _____.____

Number Pegs Place (0–25) _____

Number Errors (drops) (0–50) _____

Reliability _____.____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____
Date _____
Examiner's Initials _____

TOKEN TEST

FORM Q

(MAR 88)
PAGE OF

RESPONSE

		Score
1.	Point to a circle	0 1 2
2.	Point to a square	0 1 2
3.	Point to a black circle	0 1 2
4.	Point to a yellow square	0 1 2
5.	Point to the small white circle	0 1 2
6.	Point to the large yellow square	0 1 2
7.	Pick up the large green square and the large red square	0 1 2
8.	Pick up the small red circle and the small white circle	0 1 2
9.	Pick up the large white square and the small green circle	0 1 2
10.	Pick up the small yellow circle and the large black square	0 1 2
	(REMOVE THE SMALL TOKENS)	
11.	Pick up the white square and the green circle	0 1 2
12.	Touch the green square with the black circle	0 1 2
13.	Touch the white circle with the green square	0 1 2
14.	Touch all squares except the green one	0 1 2
15.	Touch the green square or the yellow circle	0 1 2
16.	Touch all circles except the yellow one	0 1 2
17.	Pick up the white circle and the red circle	0 1 2
18.	Pick up the green square or the white square	0 1 2
19.	Put the yellow square on the white circle	0 1 2
20.	Touch the black circle with the red square	0 1 2
21.	Pick up the black circle or the red square	0 1 2
22.	Put the white circle on the red square	0 1 2

Total Score _____
Reliability ____.____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BOSTON NAMING TEST I

FORM Q

(MAR 88)

	Correct	With Stimulus Cue		With Phonemic Cue	
		Correct	Incorrect	Correct	Incorrect
1. Bed (a piece of furniture)	___	___	___	___	___
2. Pencil (used for writing)	___	___	___	___	___
3. Whistle (used for blowing)	___	___	___	___	___
4. Comb (used for fixing hair)	___	___	___	___	___
5. Saw (used by a carpenter)	___	___	___	___	___
6. Helicopter (used for air travel)	___	___	___	___	___
7. Octopus (an ocean animal)	___	___	___	___	___
8. Hanger (found in a closet)	___	___	___	___	___
9. Camel (an animal)	___	___	___	___	___
10. Pretzel (something to eat)	___	___	___	___	___
11. Racquet (used for sports)	___	___	___	___	___
12. Volcano (a kind of mountain)	___	___	___	___	___
13. Dart (you throw it)	___	___	___	___	___
14. Globe (a kind of map)	___	___	___	___	___
15. Beaver (an animal)	___	___	___	___	___

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BOSTON NAMING TEST I

FORM Q

(MAR 88)

	Correct	With Stimulus Cue		With Phonemic Cue	
		Correct	Incorrect	Correct	Incorrect
16. Rhinoceros (an animal)	___	___	___	___	___
17. Igloo (type of house)	___	___	___	___	___
18. Dominoes (a game)	___	___	___	___	___
19. Escalator (you go up on it)	___	___	___	___	___
20. Hammock (you lie on it)	___	___	___	___	___
21. Pelican (a bird)	___	___	___	___	___
22. Pyramid (found in Egypt)	___	___	___	___	___
23. Unicorn (mythical animal)	___	___	___	___	___
24. Accordion (a musical instrument)	___	___	___	___	___
25. Asparagus (something to eat)	___	___	___	___	___
26. Latch (part of a door)	___	___	___	___	___
27. Scroll (a document)	___	___	___	___	___
28. Sphynx (it's found in Egypt)	___	___	___	___	___
29. Trellis (used in a garden)	___	___	___	___	___
30. Protractor (measures angles)	___	___	___	___	___
Total	___	___	___	___	___

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BOSTON NAMING TEST I

FORM Q

(MAR 88)

PAGE OF

Correct (correct plus correct with stimulus cue) _____

Errors Prior to Phonemic Cuing _____

No Response _____

Semantic-Within Category _____

Semantic-Category Label _____

Correct Description _____

Synonym _____

Phonemic Paraphasia _____

Perceptual _____

Other Real Words _____

Correct With Phonemic Cue _____

Reliability _____.___

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BOSTON NAMING TEST II

FORM Q

(MAR 88)

	Correct	With Stimulus Cue		With Phonemic Cue	
		Correct	Incorrect	Correct	Incorrect
1. Tree (something that grows outdoors)	___	___	___	___	___
2. House (a kind of building)	___	___	___	___	___
3. Scissors (used for cutting)	___	___	___	___	___
4. Flower (grows in a garden)	___	___	___	___	___
5. Toothbrush (used in the mouth)	___	___	___	___	___
6. Broom (used for cleaning)	___	___	___	___	___
7. Mushroom (something to eat)	___	___	___	___	___
8. Wheelchair (found in a hospital)	___	___	___	___	___
9. Mask (part of a costume)	___	___	___	___	___
10. Bench (used for sitting)	___	___	___	___	___
11. Snail (an animal)	___	___	___	___	___
12. Seahorse (an ocean animal)	___	___	___	___	___
13. Canoe (used in the water)	___	___	___	___	___
14. Wreath (a Christmas decoration)	___	___	___	___	___
15. Harmonica (musical instrument)	___	___	___	___	___

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BOSTON NAMING TEST II

FORM Q

(MAR 88)

PAGE OF

	Correct	With Stimulus Cue		With Phonemic Cue	
		Correct	Incorrect	Correct	Incorrect
16. Acorn (it comes from a tree)	___	___	___	___	___
17. Stilts (used to make you taller)	___	___	___	___	___
18. Cactus (something that grows)	___	___	___	___	___
19. Harp (a musical instrument)	___	___	___	___	___
20. Knocker (it's on a door)	___	___	___	___	___
21. Stethoscope (used by doctors and nurses)	___	___	___	___	___
22. Muzzle (used on dogs)	___	___	___	___	___
23. Funnel (used for pouring)	___	___	___	___	___
24. Noose (used for hanging)	___	___	___	___	___
25. Compass (for drawing)	___	___	___	___	___
26. Tripod (photographers or surveyors use it)	___	___	___	___	___
27. Tongs (a utensil)	___	___	___	___	___
28. Yoke (used on farm animals)	___	___	___	___	___
29. Palette (artists use it)	___	___	___	___	___
30. Abacus (it's used for counting)	___	___	___	___	___
Total	___	___	___	___	___

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BOSTON NAMING TEST II

FORM Q

(MAR 88)

PAGE OF

Correct (correct plus correct with stimulus cue) _____

Errors Prior to Phonemic Cuing _____

No Response _____

Semantic-Within Category _____

Semantic-Category Label _____

Correct Description _____

Synonym _____

Phonemic Paraphasia _____

Perceptual _____

Other Real Words _____

Correct With Phonemic Cue _____

Reliability _____.___

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____
Date _____
Examiner's Initials _____

LETTER FLUENCY I

FORM Q
(MAR 88)
PAGE OF

	C	F	L
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			
21.			
22.			
23.			
24.			
25.			

	"C"	"F"	"L"	TOTAL	+ADJ	Adjusted SCORE
Total Output	____	____	____	____		
Total Correct	____	____	____	____	____	____
Perseveration: Exact	____	____	____	____		
Perseveration: Stem	____	____	____	____		
Non-Words	____	____	____	____		
Other Letters	____	____	____	____		
Latency to First Word (sec)	____	____	____	____		

Reliability ____ • ____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

LETTER FLUENCY II

FORM Q

(MAR 88)

PAGE OF

	P	R	W
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			
21.			
22.			
23.			
24.			
25.			

	"P"	"R"	"W"	TOTAL	+ADJ	Adjusted SCORE
Total Output						
Total Correct						
Perseveration: Exact						
Perseveration: Stem						
Non-Words						
Other Letters						
Latency to First Word (sec)						

Reliability _____.___

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

CATEGORY FLUENCY

FORM Q

(MAR 88)

PAGE OF

	Animals	Furniture	Supermarket Items
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			
21.			
22.			
23.			
24.			
25.			

	Animals	Furniture	Supermarket Items
Total Output			
Total Correct			
Perseveration: Exact			
Perseveration: Stem			
Non-Words			
Other Categories			
Latency to First Word (sec)			

Reliability _____·____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BENTON FACIAL RECOGNITION TEST

FORM Q

(MAR 88)

Point to the single picture for number one and say, *"See this picture? Find another picture of this person down here.* (Gesture) *Tell me the number of that picture."* Check off correct responses. Circle incorrect responses.

At number 7 say, *"Now this person is shown three times down in these pictures.* (Gesture) *Tell me which three pictures are of the same person."*

Administer the short form only (1-13). If the subject cannot find three, make him/her guess which match. If the subject has a problem with numbers, have him/her point to the correct pictures.

SHORT FORM (SF)

Page Number	Correct Responses			Errors
1	(5) ____			1 2 3 4 5 6
2	(1) ____			1 2 3 4 5 6
3	(2) ____			1 2 3 4 5 6
4	(3) ____			1 2 3 4 5 6
5	(6) ____			1 2 3 4 5 6
6	(2) ____			1 2 3 4 5 6
7	(2) ____	(5) ____	(6) ____	1 3 4
8	(1) ____	(3) ____	(4) ____	2 5 6
9	(2) ____	(4) ____	(6) ____	1 3 5
10	(2) ____	(5) ____	(6) ____	1 3 4
11	(1) ____	(4) ____	(6) ____	2 3 5
12	(2) ____	(3) ____	(6) ____	1 4 5
13	(1) ____	(3) ____	(5) ____	2 4 6

Score Conversions

Short Form	Long Form
27	54
26	52
25	50
24	49
23	47
22	45
21	43
20	41
19	39
18	37
17	36
16	34
15	32
14	30
13	28
12	27
11	25

Score Corrections

Age	Education 6-11	Education 12+
16-54	0	0
55-64	3	1
65-74	4	2

SF Score _____

LF Score _____

Correction ____+____

Corrected Long Form Score _____

Reliability ____•____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____
Date _____
Examiner's Initials _____

CLOSURE TESTS

FORM Q
(MAR 88)
PAGE OF

STREET CLOSURE

On the following pages are pictures of objects. However, the pictures are not really complete. Please look at each one carefully and tell me what you think the object is. (Circle correct responses. Record incorrect or responses other than those indicated. If the subject does not know what the object is, give cue *"It is something man-made"* or *"It is something natural"*. Record response.)

	Correct (1, 0)	Answer	Response	Cue	Correct (1, 0)
P_1	_____	Man, Face	_____	N	_____
P_2	_____	Airplane, Plane	_____	M	_____
1	_____	Dog, Puppy	_____	N	_____
2	_____	Sailboat, Boat	_____	M	_____
3	_____	Cat, Kitten, Kitty	_____	N	_____
4	_____	Baby, Child, Boy	_____	N	_____
5	_____	Soldier, Japanese Soldier	_____	N	_____
6	_____	Train, Locomotive, Train Engine	_____	M	_____

ETS CLOSURE

(For the second set.) *The following items are similar, but a little harder than the ones you just saw. Here are a couple of examples that have been filled in to show you the complete object. The rest of the problems are like this, but your task is the same — to tell me what the object is.* (Administer as above.)

	Correct (1, 0)	Answer	Response	Cue	Correct (1, 0)
1	_____	Sailboat	_____	M	_____
2	_____	Hand	_____	N	_____
3	_____	Chicken	_____	N	_____
4	_____	Dog	_____	N	_____
5	_____	Lamp	_____	M	_____
6	_____	House	_____	M	_____
7	_____	Faucet	_____	M	_____
8	_____	Telephone	_____	M	_____

Street: Correct _____
Correct with Cue _____
Ets: Correct _____
Correct with Cue _____
Total: Correct _____
Correct with Cue _____
Reliability _____.____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

FIGURE ROTATION TEST

FORM Q

(MAR 88)

PAGE OF

On the following pages you will see boxes with two figures like this (point). *Sometimes the two figures will be exactly the same, except that one of them is placed on the page at a different angle or slid around. I will show you what I mean with these shapes here.* (Take two that are the same, position them to look like A1.) *These figures are exactly the same. If I slide this one around, it will look exactly like this one.* (Demonstrate)

Other times the two figures will be different. To make them look exactly the same, one of them would have to be flipped over and slid around. For example, this one (point to A3) *is different because I can't just slide the bottom one around* (demonstrate). *I would have to flip it over and slide it around to make them look the same. Now, are these two the same or different?* (Point to A2. If incorrect, demonstrate with the pieces. Do the same for A4-A6.)

Good. For the rest of the problems you will do the same thing. Tell me whether the two figures are the same or different. (Correct answers if necessary for B1-B6. Do not correct answers for 1-36.)

SAMPLES (Circle One)

A1.	S	A2.	S	A3.	D	A4.	D	A5.	S	A6.	D
B1.	S	B2.	D	B3.	S	B4.	S	B5.	D	B6.	D

Circle Errors (Check [✓] if Correct)

1.	D	13.	D	25.	S
2.	S	14.	D	26.	S
3.	S	15.	S	27.	D
4.	S	16.	D	28.	D
5.	D	17.	S	29.	S
6.	D	18.	D	30.	D
7.	S	19.	D	31.	S
8.	D	20.	S	32.	D
9.	D	21.	S	33.	D
10.	D	22.	D	34.	S
11.	S	23.	S	35.	S
12.	D	24.	S	36.	S

Total _____

Total Time _____min_____sec

Reliability Code _____•_____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BLOCK DESIGN (WAIS-R)

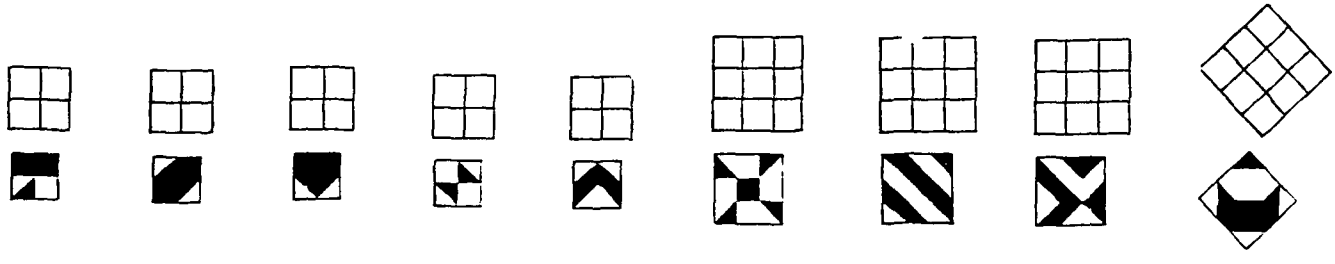
FORM Q

(MAR 88)

PAGE OF

Discontinue after three consecutive failures.

Design	Time	Pass-Fail	Score (Circle the appropriate score for each design.)
1. 60"	1		2
	2		0 1
2. 60"	1		2
	2		0 1
3. 60"			0 — 16-60: 4; 11-15: 5; 1-10: 6
4. 60"			0 — 16-60: 4; 11-15: 5; 1-10: 6
5. 60"			0 — 21-60: 4; 16-20: 5; 11-15: 6; 1-10: 7
6. 120"			0 — 36-120: 4; 26-35: 5; 21-25: 6; 1-20: 7
7. 120"			0 — 61-120: 4; 46-60: 5; 31-45: 6; 1-30: 7
8. 120"			0 — 76-120: 4; 56-75: 5; 41-55: 6; 1-40: 7
9. 120"			0 — 76-120: 4; 56-75: 5; 41-55: 6; 1-40: 7



Total (max=51) _____

Scaled Score (age corrected) _____

Reliability _____.____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

WARRINGTON RECOGNITION TEST

FORM Q

(MAR 88)

Administration Time_____

WORDS Correct Response		Score			Score
1	AID	_____	26	CAUGHT	_____
2	YOUNG	_____	27	TERM	_____
3	SAKE	_____	28	GAUGE	_____
4	DASH	_____	29	SOLD	_____
5	SOIL	_____	30	SHADE	_____
6	MILE	_____	31	NUT	_____
7	WINE	_____	32	SURE	_____
8	ART	_____	33	WIND	_____
9	REST	_____	34	TIRE	_____
10	RUSH	_____	35	DUE	_____
11	DIVE	_____	36	STUFF	_____
12	MAIN	_____	37	TREAT	_____
13	WILD	_____	38	SELL	_____
14	SINK	_____	39	MEAN	_____
15	HIT	_____	40	STRING	_____
16	RAW	_____	41	GRANT	_____
17	CAUSE	_____	42	PAUSE	_____
18	OUGHT	_____	43	OUT	_____
19	LAW	_____	44	WAGE	_____
20	SELF	_____	45	ACT	_____
21	SIDE	_____	46	DRAG	_____
22	BRAVE	_____	47	TASK	_____
23	BURN	_____	48	SHARE	_____
24	BARK	_____	49	DEEP	_____
25	FALL	_____	50	START	_____
				TOTAL	_____

FACES Correct Response	Score		Score
1A	_____	26B	_____
2B	_____	27A	_____
3B	_____	28B	_____
4B	_____	29B	_____
5A	_____	30A	_____
6A	_____	31A	_____
7A	_____	32B	_____
8B	_____	33A	_____
9A	_____	34A	_____
10B	_____	35B	_____
11A	_____	36B	_____
12A	_____	37B	_____
13A	_____	38A	_____
14B	_____	39A	_____
15B	_____	40B	_____
16B	_____	41A	_____
17B	_____	42A	_____
18A	_____	43A	_____
19B	_____	44B	_____
20B	_____	45B	_____
21B	_____	46A	_____
22A	_____	47B	_____
23B	_____	48A	_____
24B	_____	49B	_____
25A	_____	50A	_____
	TOTAL		_____

Reliability ____•____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

WARRINGTON RECOGNITION TEST

FORM Q

(MAR 88)

PAGE OF

Words	Raw Score	_____
	Percentile Score	_____
	Scaled Score	_____
Faces	Raw Score	_____
	Percentile Score	_____
	Scaled Score	_____
Discrepancy (lower of face and word)		_____
	Raw Score	_____
	Percentile Score	_____
	Reliability Code	____•____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

WARRINGTON DELAYED RECOGNITION

FORM Q

(MAR 88)

PAGE OF

Administration Time_____

WORDS

Correct Response		Score			Score
1	AID	_____	26	CAUGHT	_____
2	YOUNG	_____	27	TERM	_____
3	SAKE	_____	28	GAUGE	_____
4	DASH	_____	29	SOLD	_____
5	SOIL	_____	30	SHADE	_____
6	MILE	_____	31	NUT	_____
7	WINE	_____	32	SURE	_____
8	ART	_____	33	WIND	_____
9	REST	_____	34	TIRE	_____
10	RUSH	_____	35	DUE	_____
11	DIVE	_____	36	STUFF	_____
12	MAIN	_____	37	TREAT	_____
13	WILD	_____	38	SELL	_____
14	SINK	_____	39	MEAN	_____
15	HIT	_____	40	STRING	_____
16	RAW	_____	41	GRANT	_____
17	CAUSE	_____	42	PAUSE	_____
18	OUGHT	_____	43	OUT	_____
19	LAW	_____	44	WAGE	_____
20	SELF	_____	45	ACT	_____
21	SIDE	_____	46	DRAG	_____
22	BRAVE	_____	47	TASK	_____
23	BURN	_____	48	SHARE	_____
24	BARK	_____	49	DEEP	_____
25	FALL	_____	50	START	_____
				TOTAL	_____

FACES

Correct Response	Score		Score
1A	_____	26B	_____
2B	_____	27A	_____
3B	_____	28B	_____
4B	_____	29B	_____
5A	_____	30A	_____
6A	_____	31A	_____
7A	_____	32B	_____
8B	_____	33A	_____
9A	_____	34A	_____
10B	_____	35B	_____
11A	_____	36B	_____
12A	_____	37B	_____
13A	_____	38A	_____
14B	_____	39A	_____
15B	_____	40B	_____
16B	_____	41A	_____
17B	_____	42A	_____
18A	_____	43A	_____
19B	_____	44B	_____
20B	_____	45B	_____
21B	_____	46A	_____
22A	_____	47B	_____
23B	_____	48A	_____
24B	_____	49B	_____
25A	_____	50A	_____
		TOTAL	_____

Reliability ____•____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

WARRINGTON DELAYED RECOGNITION

FORM Q

(MAR 88)

PAGE OF

Words	Raw Score	_____
	Percentile Score	_____
	Scaled Score	_____
Faces	Raw Score	_____
	Percentile Score	_____
	Scaled Score	_____
Discrepancy (lower of face and word)		_____
	Raw Score	_____
	Percentile Score	_____
	Reliability Code	____•____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number ____________

Date ____________

Examiner's Initials ____________

WISCONSIN CARD SORTING TEST

FORM Q

(MAR 88)

PAGE ___ OF ___

TRIALS: C, F, N, C, F, N

C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O	C F N O	C F N O	C F N O	C F N O	C F N O
C F N O	C F N O					
[19]	[38]	[56]	[74]	[92]	[110]	[128]

Categories Achieved ____

Number of Trials ____

Trials to 3 Categories ____

Errors: Nonperseverative ________

Perseverations ________

Unique Responses ________

Reliability ____.___

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

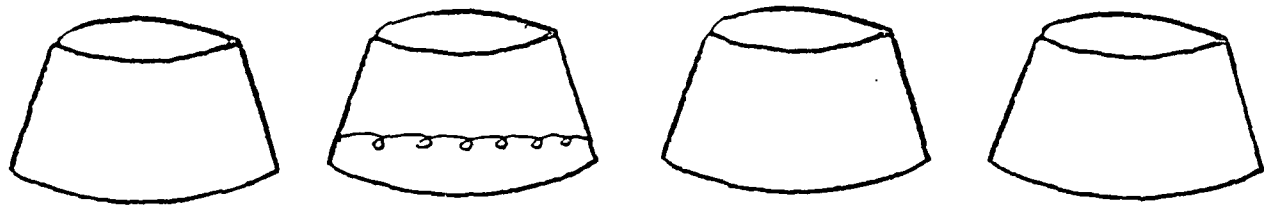
FORM Q

(MAR 88)

PAGE OF

DESIGN FLUENCY

"This is a test of your ability to think of as many different ways as possible to decorate an object. Look at the sample below. The first picture shows a plain lampshade. The second shows the same lampshade after a design has been added to it. Can you think of two more designs for the other two lampshades?"



"The decorations you put on objects in this test can be of any type, but each must be different. Also do not use letters or numbers in your designs. Random marks or scribbles will not be considered as designs. Each decoration can be as simple or as complicated as you choose. However, your score on this test will be the number of different designs you make. Therefore, it will not be to your advantage to spend too much time on any one design." Time 2 minutes for each page. Encourage subject to continue if he/she gives up before time is over.

Total Page 1 _____

Total Page 2 _____

Grand Total _____

Reliability ___.___

Medical Record Number _____

Date _____

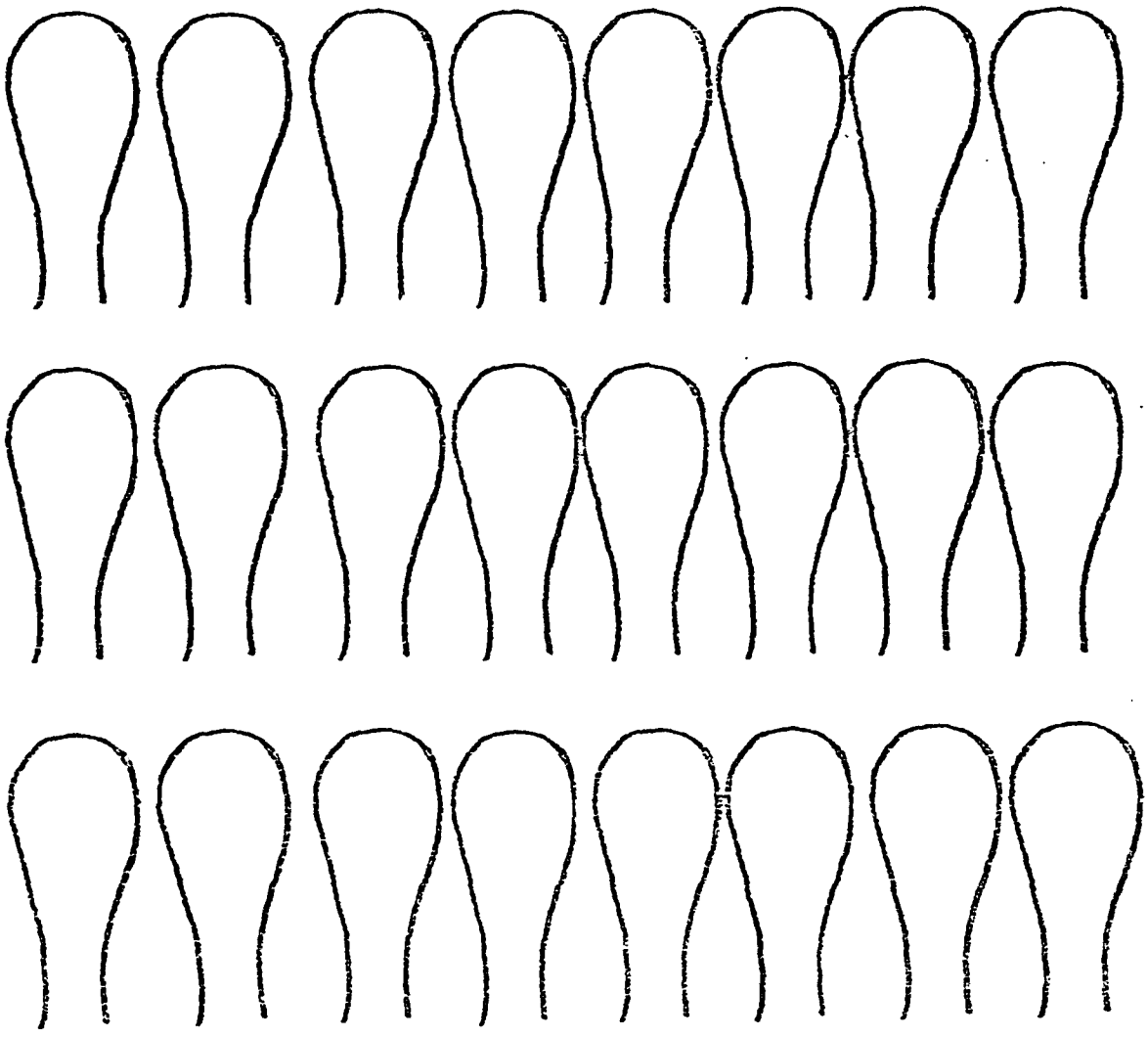
Examiner's Initials _____

FORM Q

(MAR 88)

DESIGN FLUENCY

Here are the outlines of some spoon handles. Decorate each of them differently.



ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

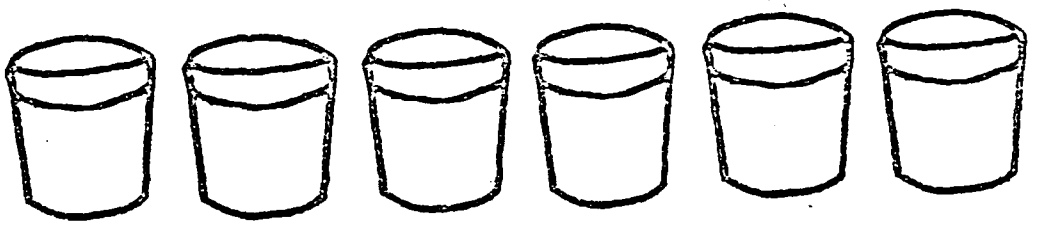
Examiner's Initials _____

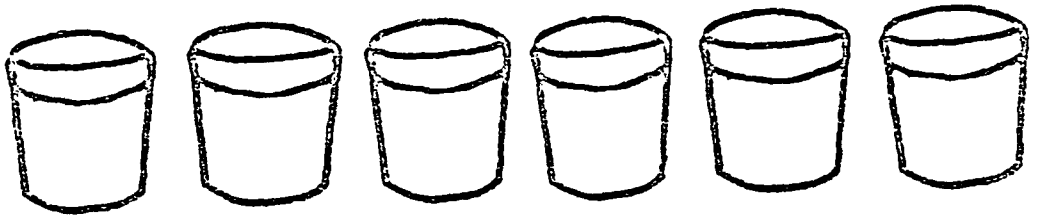
FORM Q

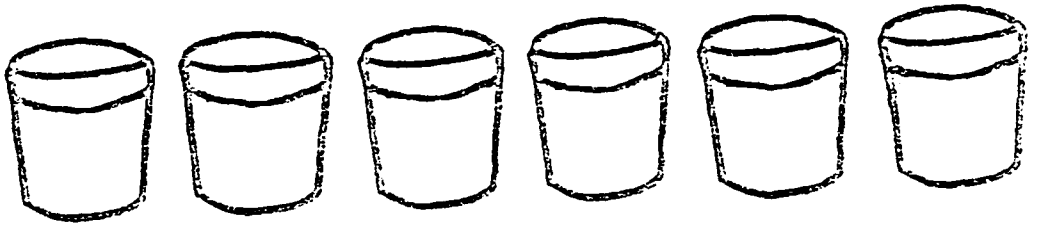
(MAR 88)

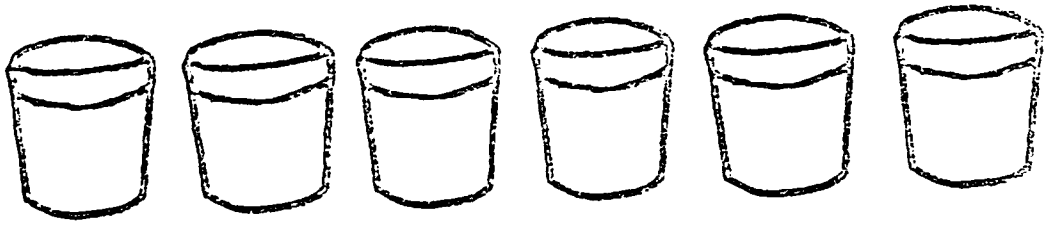
DESIGN FLUENCY

Here are the outlines of some flower pots. Decorate each of them differently.









ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BECK INVENTORY

FORM Q

(MAR 88)

On this questionnaire are groups of statements. Please read each group of statements carefully. Then pick out the one statement in each group which best describes the way you have been feeling the PAST WEEK, INCLUDING TODAY. Circle the number beside the statement you picked. If several statements seem to apply equally well, circle each one. Be sure to read all the statements in each group before making your choice.

1. 0 I do not feel sad.
   1 I feel sad.
   2 I am so sad all the time and I can's snap out of it.
   3 I am so sad or unhappy that I can't stand it.

2. 0 I am not particularly discouraged about the future.
   1 I feel discouraged about the future.
   2 I feel I have nothing to look forward to.
   3 I feel that the future is hopeless and that things cannot improve.

3. 0 I do not feel like a failure.
   1 I feel I have failed more than the average person.
   2 As I look back on my life, all I can see are a lot of failures.
   3 I feel I am a complete failure as a person.

4. 0 I get as much satisfaction out of things as I used to.
   1 I don't enjoy things the way I used to.
   2 I don't get real satisfaction out of anything anymore.
   3 I am dissatisfied or bored with everything.

5. 0 I don't feel particularly guilty.
   1 I feel guilty a good part of the time.
   2 I feel quite guilty all of the time.
   3 I feel guilty all of the time.

6. 0 I don't feel I am being punished.
   1 I feel I may be punished.
   2 I expect to be punished.
   3 I feel I am being punished.

7. 0 I don't feel disappointed in myself.
   1 I am disappointed in myself.
   2 I am disgusted with myself.
   3 I hate myself.

8. 0 I don't feel I am any worse off than anybody else.
   1 I am critical of myself for my weaknesses and mistakes.
   2 I blame myself all the time for my faults.
   3 I blame myself for everything bad that happens.

9. 0 I don't have any thoughts of killing myself.
   1 I have thoughts of killing myself, but I would not carry them out.
   2 I would like to kill myself.
   3 I would kill myself if I had the chance.

10. 0 I don't cry any more than usual.
1 I cry more now than I used to.
2 I cry all the time now.
3 I used to be able to cry, but now I can't cry even though I want to.

11. 0 I don't get irritated at all by things that used to irritate me.
1 I am no more irritated now than I ever am.
2 I get annoyed or irritated more easily than I used to.
3 I feel irritated all the time now.

12. 0 I have not lost interest in other people.
1 I am less interested in other people than I used to be.
2 I have lost most of my interest in other people.
3 I have lost all of my interest in other people.

13. 0 I make decisions about as well as I ever could.
1 I put off making decisions more than I used to.
2 I have greater difficulty in making decisions than before.
3 I can't make decisions at all anymore.

14. 0 I don't feel I look any worse than I used to.
1 I am worried that I am looking old or unattractive.
2 I feel that there are permanent changes in my appearance that make me look unattractive.
3 I believe that I look ugly.

15. 0 I work about as well as before.
1 It takes an extra effort to get started at doing something.
2 I have to push myself very hard to do anything.
3 I can't do any work at all.

16. 0 I can sleep as well as usual.
1 I don't sleep as well as I used to.
2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3 I wake up several hours earlier than usual and find it hard to get back to sleep.

17. 0 I don't get more tired than usual.
1 I get tired more easily than I used to.
2 I get tired from doing almost anything.
3 I am too tired to do anything.

18. 0 My appetite is no worse than usual.
1 My appetite is not as good as it used to be.
2 My appetite is much worse now.
3 I have no appetite at all anymore.

19.
0 I haven't lost much weight, if any, lately.
1 I have lost more than 5 pounds.
2 I have lost more than 10 pounds.
3 I have lost more than 15 pounds.

I am purposefully trying to lose weight by eating less:

Yes_____ No_____

20.
0 I am no more worried about my health than usual.
1 I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
2 I am very worried about physical health, and it's hard to think of much else.
3 I am so worried about my physical problems that I cannot think about anything else.

21.
0 I have not noticed any recent changes in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

Total _____

Reliability ____•____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

SPIELBERGER — STATE

FORM Q

(MAR 88)

PAGE OF

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement, but give the answer which seems to describe how you generally feel.

	Not At All	Some-what	Moder-ately So	Very Much So
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I feel tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

Total: State _____

Percentile _____

Reliability Code ____•____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

SPIELBERGER — TRAIT

FORM Q

(MAR 88)

PAGE OF

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement, but give the answer which seems to describe how you generally feel.

	Almost Never	Some-times	Often	Almost Always
21. I feel pleasant	1	2	3	4
22. I feel nervous and restless	1	2	3	4
23. I feel satisfied with myself	1	2	3	4
24. I wish I could be as happy as others seem to be	1	2	3	4
25. I feel like a failure	1	2	3	4
26. I feel rested	1	2	3	4
27. I am "calm, cool, and collected"	1	2	3	4
28. I feel that difficulties are piling up so that I cannot overcome them	1	2	3	4
29. I worry too much over something that really doesn't matter	1	2	3	4
30. I am happy	1	2	3	4
31. I have disturbing thoughts	1	2	3	4
32. I lack self-confidence	1	2	3	4
33. I feel secure	1	2	3	4
34. I make decisions easily	1	2	3	4
35. I feel inadequate	1	2	3	4
36. I am content	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me	1	2	3	4
38. I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
39. I am a steady person	1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

Total: Trait _____

Percentile _____

Reliability Code ____•____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

NEUROBEHAVIORAL RATING SCALE

FORM Q

(MAR 88)

PAGE OF

	Not Present	Very Mild	Mild	Mod-erate	Mod Severe	Severe	Extremely Severe
1. **INATTENTION/REDUCED ALERTNESS**—*fails to sustain attention*, easily distracted; fails to notice aspects of environment, difficult directing attention, decreased alertness.	☐	☐	☐	☐	☐	☐	☐
2. **SOMATIC CONCERN**—volunteers complaints or elaborates about somatic symptoms (e.g., headache, dizziness, blurred vision), and about physical health in general.	☐	☐	☐	☐	☐	☐	☐
3. **DISORIENTATION**—confusion or lack of proper association for person, place, or time.	☐	☐	☐	☐	☐	☐	☐
4. **ANXIETY**—worry, fear, overconcern for present or future.	☐	☐	☐	☐	☐	☐	☐
5. **EXPRESSIVE DEFICIT**—word-finding disturbance, anomia, pauses in speech, effortful and agrammatic speech, circumlocution.	☐	☐	☐	☐	☐	☐	☐
6. **EMOTIONAL WITHDRAWAL**—lack of spontaneous interaction, isolation, deficiency in relating to others.	☐	☐	☐	☐	☐	☐	☐
7. **CONCEPTUAL DISORGANIZATION**—thought processes confused, disconnected, disorganized, disrupted; tangential social communication perseverative.	☐	☐	☐	☐	☐	☐	☐
8. **DISINHIBITION**—socially inappropriate comments and/or *actions, including aggressive/sexual*	☐	☐	☐	☐	☐	☐	☐
9. **GUILT FEELINGS**—self-blame, shame, remorse for past behavior.	☐	☐	☐	☐	☐	☐	☐
10. **MEMORY DEFICIT**—difficulty learning new information, rapidly forgets recent events, although immediate recall (forward digit span) may be intact.	☐	☐	☐	☐	☐	☐	☐
11. **AGITATION**—motor manifestations of overactivation (e.g., kicking, arm flailing, picking, roaming, restlessness, talkativeness).	☐	☐	☐	☐	☐	☐	☐
12. **INACCURATE INSIGHT AND SELF-APPRAISAL**—poor insight, exaggerated self-opinion, overrates level of ability and underrates personality change in comparison with evaluation of clinicians and family.	☐	☐	☐	☐	☐	☐	☐
13. **DEPRESSIVE MOOD**—sorrow, sadness, despondency, pessimism.	☐	☐	☐	☐	☐	☐	☐

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

NEUROBEHAVIORAL RATING SCALE

FORM Q

(MAR 88)

PAGE OF

	Not Present	Very Mild	Mild	Mod-erate	Mod Severe	Severe	Extremely Severe
14. **HOSTILITY/UNCOOPERATIVENESS**—animosity, irritability, belligerence, disdain for others, defiance of authority.	☐	☐	☐	☐	☐	☐	☐
15. **DECREASED INITIATIVE/MOTIVATION**—lacks normal initiative in work or leisure, fails to persist in tasks, is reluctant to accept new challenges.	☐	☐	☐	☐	☐	☐	☐
16. **SUSPICIOUSNESS**—mistrust, belief that others harbor malicious or discriminatory intent.	☐	☐	☐	☐	☐	☐	☐
17. **FATIGUABILITY**—rapidly fatigues on challenging cognitive tasks or complex activities, lethargic.	☐	☐	☐	☐	☐	☐	☐
18. **HALLUCINATORY BEHAVIOR**—perceptions without normal external stimulus correspondence.	☐	☐	☐	☐	☐	☐	☐
19. **MOTOR RETARDATION**—slowed movements or speech (excluding primary weakness)	☐	☐	☐	☐	☐	☐	☐
20. **UNUSUAL THOUGHT CONTENT**—unusual, odd, strange, bizarre thought content.	☐	☐	☐	☐	☐	☐	☐
21. **BLUNTED AFFECT**—reduced emotional tone, reduction in normal intensity of feelings, flatness.	☐	☐	☐	☐	☐	☐	☐
22. **EXCITEMENT**—heightened emotional tone, increased reactivity.	☐	☐	☐	☐	☐	☐	☐
23. **POOR PLANNING**—unrealistic goals, poorly formulated plans for the future, disregards prerequisites (e.g., training), fails to take disability into account.	☐	☐	☐	☐	☐	☐	☐
24. **LABILITY OF MOOD**—sudden change in mood which is disproportionate to the situation.	☐	☐	☐	☐	☐	☐	☐
25. **TENSION**—postural and facial expression of heightened tension, without the necessity of excessive activity involving the limbs or trunk.	☐	☐	☐	☐	☐	☐	☐
26. **COMPREHENSION DEFICIT**—difficulty in understanding oral instructions on single or multistage commands.	☐	☐	☐	☐	☐	☐	☐
27. **SPEECH ARTICULATION DEFECT**—misarticulation, slurring or substitution of sounds which affect intelligibility (rating is independent of linguistic content).	☐	☐	☐	☐	☐	☐	☐

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

SPREEN-BENTON: WRITING TO DICTATION

FORM Q

(MAR 88)

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

SPREEN-BENTON:
WRITING FROM COPY

FORM Q

(MAR 88)

PAGE OF

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

MAE: SPELLING

FORM Q

(APR 88)

PAGE OF

Circle Response Mode

List A	List B	List C
1. Oral	1. Oral	1. Oral
2. Written	2. Written	2. Written
3. Block	3. Block	3. Block

Record Responses

List A		List B		List C	
1. Set	_____	1. Car	_____	1. Eat	_____
2. Care	_____	2. Mile	_____	2. Rose	_____
3. Rice	_____	3. Cake	_____	3. Meat	_____
4. Storm	_____	4. Skate	_____	4. Cream	_____
5. Market	_____	5. Almost	_____	5. Relate	_____
6. Closet	_____	6. Sailor	_____	6. Strike	_____
7. Mistake	_____	7. Locate	_____	7. Climate	_____
8. Coaster	_____	8. Tiresome	_____	8. Clearest	_____
9. Trickle	_____	9. Reclaim	_____	9. Article	_____
10. Recite	_____	10. Realtor	_____	10. Isolate	_____
11. Costlier	_____	11. Trailer	_____	11. Miracle	_____

Test	Raw Score	Correction	Adjusted Score	Percentile
1. ORAL	_____	_____	_____	_____
2. WRITTEN	_____	_____	_____	_____
3. BLOCK	_____	_____	_____	_____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

MAE: READING COMPREHENSION

FORM Q

(APR 88)

Item		Choice	Score
1. Electric	(2)		
2. Buckle	(3)		
3. Tells the Year	(1)		
4. Edible	(3)		
5. Pouring	(2)		
6. Pedestrian	(1)		
7. Over the Bridge	(1)		
8. Furniture	(4)		
9. Beacon	(1)		
10. Steeple	(4)		
11. Flashlight	(3)		
12. Spiritual	(4)		
13. Recreation	(2)		
14. Lullaby	(3)		
15. Walking to Work	(4)		
16. Conversation	(1)		
17. Upholstered	(3)		
18. Cat on a Chair	(3)		

Score _____

+ Correction _____

Adjusted Score _____

Percentile Rank _____

ARMY PENETRATING HEAD INJURY PROJECT

Medical Record Number _____

Date _____

Examiner's Initials _____

BDAE: FREE CONVERSATION
COOKIE THEFT

FORM Q

(MAR 88)

Tape record response. Show the test picture and tell patient, *"Tell everything you see going on in this picture"*. Point to neglected features of the picture and ask for elaboration if patient's response is skimpier than his apparent potential. Allow two minutes.

ARMY PENETRATING HEAD INJURY PROJECT

Patient Study Number _____

PATIENT INHOSPITAL INTERVIEW

FORM P (JUN 88)

TO BE COMPLETED BY NURSE CLINICIAN

Read to Patient: *Your answers to the questions which follow will help us design more effective treatment programs. Your answers will be held in strict confidence. You will not be identified in any summaries or statistical reports.*

1P. Date of Interview

__ ____ __
Day Mo Yr

1P$. Time of Interview

_____:_____

2P. Observer Code

_____

3P. GCS (3-15)_____
(Refer to patient chart)

4P. Type of Interview
1 In person
2 Telephone
3 Mail

5P. Respondent
1 Patient
2 Other

510P. If Other, Stop: Use Informant Form

6P. Form Completion Code
0 Completed
Not Completed Because
1 Patient cognitively impaired (following commands but not yet testable)
2 Patient vegetative
3 Patient uninterviewable (aphasic)
4 Refused follow-up
5 Refused form (including refusing partway through)
6 Examiner error
7 Lost to follow-up
8 Discontinued (fatigue, ill, patient condition)
9 Other (specify in 610P)

610P. If Other, specify_____

7P. Before your injury, where were you living?
1 Home
2 Other (specify in 710P)

710P. If Other, specify_____

8P. Who lived with you? (Circle all that apply)
1 No one (patient lived alone)
2 Mother
3 Father
4 Wife/mate
5 Son(s)
6 Daughter(s)
7 Brother(s)
8 Sister(s)
9 Other (specify in 810P)

810P. If Other, specify_____

9P. What best describes what you were doing before your injury: were you working, going to school,or something else?(Circle all that apply)
1 Working full time (35 hours or more per week)
2 Working part time
3 With a job, but not at work (specify in 910P)
4 Looking for work
5 Unable to work
6 Going to school full time (College, 12 credit hours or more)
7 Going to school part time
8 Homemaker
9 Retired
10 Other (specify below)
U Unknown

910P. If With a Job, But Not at Work (Because)

_____

If Other, specify

_____

Please tell me about your last several jobs. Begin with your current job and work backward. What did you do?
(Occupation)

	Occupation	Occupational Code	Hours Worked Per Week	Number Months Job Held		Approximately When Begun		
1010P.	_____	1011P._____	1012P._____	1013P._____	1014P.	__ Day	____ Mo	__ Yr
1020P.	_____	1021P._____	1022P._____	1023P._____	1024P.	__ Day	____ Mo	__ Yr
1030P.	_____	1031P._____	1032P._____	1033P._____	1034P.	__ Day	____ Mo	__ Yr

FAMILY LIFE AND SOCIAL ACTIVITIES

11P. Are you married, separated, divorced, or single?
1 Married
2 Separated
3 Divorced
4 Single
5 Widowed

12P. How many children do you have?
(Number)
_____

13P. How many times have you been married?
(Number)
_____

14P. If currently married, how long have you been married to your wife/husband?
(Number Years)
_____

15P. What was your approximate total family income in 1987 (before taxes)?
1 0-5,000
2 5,001-10,000
3 10,001-15,000
4 15,001-20,000
5 20,001-30,000
6 30,001-50,000
7 More than 50,000
U Don't know

16P. During the month before your injury, who provided the main source of income?
(Choose Only One)
1 Patient
2 Spouse/mate
3 Patient and mate equally
4 Parents
5 Children
6 Other (specify in 1610P)

1610P. If Other, specify_____

During the month before your injury, did you receive:

		No	Yes	Unknown
1710P.	Unemployment insurance benefits	0	1	U
1720P.	Sick leave with pay	0	1	U
1730P.	Sick leave without pay	0	1	U
1740P.	Public assistance	0	1	U
1750P.	Social Security disability benefits	0	1	U
1760P.	Financial help from relatives	0	1	U
1770P.	Financial help from friends	0	1	U
1780P.	Earnings from own job(s)	0	1	U
1790P.	Other sources of income (specify in 1791P)	0	1	U

1791P. If Other Sources of Income, specify

_____

People often depend on family and friends for help, or just to spend time together. Before your injury, how often did you do the following things with friends or family members?

Code:
0 *Never*
1 *Less than once a month*
2 *At least once a month*
3 *Every couple of weeks*
4 *At least once a week*
5 *More than once a week*
6 *Every day*

1810P.	Visited with friends	0 1 2 3 4 5 6
1820P.	Visited with relatives	0 1 2 3 4 5 6
1830P.	Got financial help from someone	0 1 2 3 4 5 6
1840P.	Got advice or emotional support from someone	0 1 2 3 4 5 6
1850P.	Went out with family to have fun	0 1 2 3 4 5 6
1860P.	Went out with friend to have fun	0 1 2 3 4 5 6
1870P.	Went to meetings of clubs, organizations or religious services	0 1 2 3 4 5 6

19P. Do you have any family in the area?
0 No
1 Yes

If yes, what family members live in the area (within about 50 miles or so)?

		No	Yes	Unknown
1910P.	Wife, children	0	1	U
1920P.	Parents	0	1	U
1930P.	Brothers, sisters	0	1	U
1940P.	*Grandparents*	0	1	U
1950P.	Uncles, aunts	0	1	U
1960P.	Other (specify in 1970P)	0	1	U

1970P. If Other, specify_____

EDUCATION

20P. What was the highest grade of school you completed?
1 Kindergarten-6th grade
2 7th-9th grades
3 10th-11th grades
4 High school graduate
5 Some college
6 College graduate
7 Graduate school
8 Trade or vocational training

21P. Did you have learning problems in school?
0 No
1 Reading
2 Math
3 Other (Specify in 2110P)
U Unknown

2110P. If Other, specify_____

22P. Were you *ever* in special classes because of learning problems?
0 No
1 Yes
U Unknown

23P. Were you ever left back in school?
(i.e., ever failed a grade?)
0 No
1 Yes
U Unknown

2310P. If yes, were you left back in school (failed a grade) because of learning problems?
0 No
1 Reading
2 Math
3 Other (Specify in 2320P)
U Unknown

2320P. If Other, specify_____

PSYCHIATRIC

24P. Prior to your injury, did you receive any psychiatric or psychological counselling or treatment?
0 No
1 Yes
U Unknown

2410P. If yes, describe the nature of the problem.

_____

25P. Was a diagnosis assigned?
0 No
1 Yes

2510P. If yes, what was the diagnosis?

_____

26P. Did you receive any medications?
0 No
1 Yes
U Unknown

2610P. If yes, what were the medications?

_____

27P. Were you hospitalized?
0 No
1 Yes

2710P. If yes, how many times were you hospitalized? (for psychological/psychiatric treatment)

_____

2720P. If yes, how many days total were you hospitalized? (for psychological/psychiatric)

_____

NEUROLOGICAL

28P. Prior to your injury, did you ever have a head injury that resulted in loss of consciousness for more than five (5) minutes, skull fracture, or admission to the hospital?
0 No
1 Yes

29P. Did you ever have any previous neurological disorder or disease (including seizure)?
0 No
1 Yes

2910P. If yes, please specify_____

ALCOHOL AND DRUG INTAKE

30P. Did you consider drinking to be a problem for yourself before the injury?
0 No
1 Yes

31P. During the month before your injury, what alcoholic beverage(s) did you usually drink? (List Beverage Name[s]; If none, skip to 34P)

_____

32P. During the month before your injury, how often did you drink the above beverage(s)?
1 Several times a day
2 Daily
3 Several times a week
4 Several times a month
5 Once or twice

33P. How many drinks of this beverage did you usually drink at any one time? (Specify number)
(1 mixed drink=1 shot of liquor;
1 beer=12 oz.; 1 wine=6 oz.)

_____

3310P. Usual Size of Drinks
1 Small (8 oz.)
2 Regular (10 oz.)
3 Large (16 oz. or more)

34P. When did you last have a drink of any kind of alcoholic beverage? (If never had a drink, code Jan 99 and skip to 3610P.)

___ ___
Mo Yr

35P. During the month before your injury, how often did you have trouble remembering things that happened to you while you were intoxicated? (Choose One)
1 Nearly every time you drank
2 Some of the time you drank
3 One or two times
4 Never
U Unknown

During the month before your injury, how often did you use:

Code: 0 *Never* 1 *Once* 2 *Two to three times* 3 *Weekly* 4 *Daily* U *Unknown*

3610P.	Marijuana (hashish, pot, grass, Mary Jane)	0 1 2 3 4 U
3620P.	Cocaine (coke, "C", snow, flake)	0 1 2 3 4 U
3630P.	Heroin (smack, junk)	0 1 2 3 4 U
3640P.	PCP (angel dust)	0 1 2 3 4 U
3650P.	Other (specify in 3660P)	0 1 2 3 4 U

3660P. If Other, specify_____

LEGAL ISSUES

37P. Have you ever been arrested?
0 No
1 Yes

38P. Were you convicted?
0 No
1 Yes

If yes, please explain each arrest.

3710P. _____

3720P. _____

3730P. _____

3740P. _____

REHABILITATION

TREATMENT COURSE	First	Second	Third
Physical Therapy (Since Injury)			
3910P. Received 0 No 1 Yes			
3920P. When began? Day ___ Mo ___ Yr ___			
3930P. Usual Frequency 1 Weekly 2 Less than three times/week 3 Three times/week 4 Daily 5 Two times/day 6 Unknown 7 Other (specify in 3940P)			
3940P. If Other, specify			
3950P. Length Each Session (minutes)			
3960P. Length of Therapy (weeks)			
Occupational Therapy (Since Injury)			
4010P. Received 0 No 1 Yes			
4020P. When began? Day ___ Mo ___ Yr ___			
4030P. Usual Frequency 1 Weekly 2 Less than three times/week 3 Three times/week 4 Daily 5 Two times/day 6 Unknown 7 Other (specify in 4040P)			
4040P. If Other, specify			
4050P. Length Each Session (minutes)			
4060P. Length of Therapy (weeks)			
Speech Therapy (Since Injury)			
4110P. Received 0 No 1 Yes			
4120P. When began? Day ___ Mo ___ Yr ___			
4130P. Usual Frequency 1 Weekly 2 Less than three times/week 3 Three times/week 4 Daily 5 Two times/day 6 Unknown 7 Other (specify in 4140P)			
4140P. If Other, specify			
4150P. Length Each Session (minutes)			
4160P. Length of Therapy (weeks)			
Vocational Therapy (Since Injury)			
4210P. Received 0 No 1 Yes			
4220P. When began? Day ___ Mo ___ Yr ___			
4230P. Usual Frequency 1 Weekly 2 Less than three times/week 3 Three times/week 4 Daily 5 Two times/day 6 Unknown 7 Other (specify in 4240P)			
4240P. If Other, specify			
4250P. Length Each Session (minutes)			
4260P. Length of Therapy (weeks)			

TREATMENT COURSE	First	Second	Third
Psychological Counselling (Since Injury)			
4310P. Received 0 No 1 Yes			
4320P. When began? __ __ __ __ __ __ Day Mo Yr			
4330P. Usual Frequency 1 Weekly 5 Two times/day 2 Less than three times/week 6 Unknown 3 Three times/week 7 Other (specify in 4340P)			
4340P. If Other, specify			
4350P. Length Each Session (minutes)			
4360P. Length of Therapy (weeks)			
Other (Since Injury)(specify in 44P)			
44P. If Other, specify (hydrotherapy, hypotherapy, etc.)			
4410P. Received 0 No 1 Yes			
4420P. When began? __ __ __ __ __ __ Day Mo Yr			
4430P. Usual Frequency 1 Weekly 4 Daily 2 Less than three times/week 5 Two times/day 3 Three times/week 6 Unknown 7 Other (specify in P4440)			
4440P. If Other, specify			
4450P. Length Each Session (minutes)			
4460P. Length of Therapy (weeks)			

45P. How accurate do you think your answers to the questions in this interview have been?
- 0 Not at all accurate
- 1 Somewhat accurate
- 2 Mostly accurate
- 3 Very accurate

Interviewer's Comments and Observations

4610P. _____

4620P. _____

4630P. _____

4640P. _____

4650P. _____

Read to Patient: *Your answers to the questions which follow will help us design more effective treatment programs. Your answers will be held in strict confidence. You will not be identified in any summaries or statistical reports.*

1P. Date of Interview

__ ___ __
Day Mo Yr

1P$. Time of Interview

_____:_____

51P. Which interview is this?
1 Six months from injury
2 Twelve months from injury
3 Twenty-four months from injury

52P. Observer Code_____

53P. Type of Interview
1 In person
2 Telephone
3 Mail

54P. Respondent
1 Patient
2 Other

5410P. If Other, Stop: Use Informant Form

55P. Form Completion Code
0 Completed
Not Completed Because
1 Patient cognitively impaired (following commands but not yet testable)
2 Patient vegetative
3 Patient uninterviewable (aphasic)
4 Refused follow-up
5 Refused form (including refusing partway through)
6 Examiner error
7 Lost to follow-up
8 Discontinued (fatigue, ill, patient condition)
9 Other (specify in 5510P)

5510P. If Other, specify_____

56P. Where are you living now?
1 Home
2 Hospital
3 Rehabilitation center
4 Nursing home
5 Adult home/transitional living center
6 Other (specify in 5610P)

5610P. If Other, specify_____

57P. Who are you living with now?
1 No one, living alone
2 Family
3 Friends
4 In nursing home, rehabilitation center, or other institution
5 Other (specify in 5710P)

5710P. If Other, specify_____

58P. How many times have you been hospitalized since your injury? (If not hospitalized since discharge from APHIP hospital, skip to 61P)

_____

When were you hospitalized?

5910P. Hospital Stay One

__ ___ __
Day Mo Yr

5920P. Hospital Stay Two

__ ___ __
Day Mo Yr

5930P. Hospital Stay Three

__ ___ __
Day Mo Yr

5940P. Hospital Stay Four

__ ___ __
Day Mo Yr

Give length of hospital stay in days.

6010P. Hospital Stay One_____ 6030P. Hospital Stay Three_____

6020P. Hospital Stay Two_____ 6040P. Hospital Stay Four_____

What was the reason/admitting diagnosis?

6110P. Hospital Stay One_____

6120P. Hospital Stay Two_____

6130P. Hospital Stay Three_____

6140P. Hospital Stay Four_____

62P. Other than hospitalizations, how many places have you lived since your injury?

_____(Number)

	Location (City)		Kind of Residence (Home, Nursing Home, etc.)		When Lived There From			To	
6210P.	_____	6211P.	_____	6212P.	__ Mo	__ Yr	6213P.	__ Mo	__ Yr
6220P.	_____	6221P.	_____	6222P.	__ Mo	__ Yr	6223P.	__ Mo	__ Yr
6230P.	_____	6231P.	_____	6232P.	__ Mo	__ Yr	6233P.	__ Mo	__ Yr
6240P.	_____	6241P.	_____	6242P.	__ Mo	__ Yr	6243P.	__ Mo	__ Yr
6250P.	_____	6251P.	_____	6252P.	__ Mo	__ Yr	6253P.	__ Mo	__ Yr

WORK EXPERIENCE

63P. Did you have a full time job just prior to your injury?
- 0 No
- 1 Yes

64P. Did you return to your old job?
- 0 No
- 1 Yes (Skip to 66P)

65P. Do you feel that you could have returned to your previous job?
- 0 No
- 1 Yes

66P. What best describes your work since your discharge?
- 1 Unable to work
- 2 Unemployed the entire time, though looked for work
- 3 Was often unemployed, but worked now and then
- 4 Worked about half the time
- 5 Worked most of the time
- 6 Changed jobs at least once, but worked steadily
- 7 Worked steadily at one job

67P. Are you now working at all?
- 0 No (Skip to 69P)
- 1 Yes

Now consider the work you do and respond to (circle) only those statements that you are sure describe you and are related to your state of health.

		No	Yes
68P.	Are you doing part of your job at home?	0	1
6810P.	Are you accomplishing less than usual at work?	0	1
6820P.	Do you often act irritable toward your work associates? (For example, snap at them, give sharp answers, criticize easily.)	0	1
6830P.	Are you working shorter hours?	0	1
6840P.	Are you doing only light work?	0	1
6850P.	Do you work only for short periods of time or take frequent rests?	0	1
6860P.	Are you working at your usual job, but with some changes? (For example, using different tools or special aids, trading some tasks with other workers?)	0	1
6870P.	Are you doing your job as carefully and accurately as usual?	0	1
6880P.	Are you having difficulty understanding instructions or deciding what to do?	0	1
6890P.	Do you sometimes feel the job is beyond your capabilities?	0	1

If you have worked since your injury, please tell me about your jobs. Begin with your current job and go back in time to the injury/last follow-up interview.

	Occupation	Occupational Code	Average Hours Per Week	Number Months Job Held	Approximate Date Begun
6910P.	_____	6911P._____	6912P._____	6913P._____	6914P. ___ Day ____ Mo __ Yr
6920P.	_____	6921P._____	6922P._____	6923P._____	6924P. ___ Day ____ Mo __ Yr
6930P.	_____	6931P._____	6932P._____	6933P._____	6934P. ___ Day ____ Mo __ Yr

70P. **Were you doing any work for pay last week?**
- 0 No
- 1 Yes

[If patient works at all.] Not everyone with head injuries is able to return to work. Why do you think you have been successful?

7110P. _____

7120P. _____

7130P. _____

72P. **Are you now working in a sheltered workshop?**
- 0 No
- 1 Yes
- U Don't know

73P. **If you are not working full time, which of the following may prevent or interfere with employment?** (Read List and Circle all that apply.)
- 1 No jobs available
- 2 No transportation
- 3 Bad temper
- 4 No motivation/doesn't care
- 5 No pep or energy
- 6 Can't walk/climb stairs
- 7 Depression
- 8 Poor vision
- 9 In school
- 10 Can't speak properly
- 11 Can't understand speech
- 12 Memory Problems
- 13 Seizures
- 14 Medically ill, sick, etc.
- 15 Thinking problems
- 16 Trouble using hands, arms, legs
- 17 Other (specify in 7310P)

7310P. **If Other,** specify

_____

FAMILY LIFE AND SOCIAL ACTIVITIES

74P. Are you married, separated, divorced, or single?

1 Married
2 Separated
3 Divorced
4 Single
5 Widowed

75P. Has your marital status changed since your injury?

0 No
1 Yes (Skip to 7510P)

7510P. If Yes, explain and give approximate date

_____

76P. During the last month, who provided the main source of income? (Choose Only One)

1 Patient
2 Spouse/mate
3 Patient and mate equally
4 Parents
5 Children
6 Other (specify in 7610P)

7610P. If Other, specify_____

77P. What was your approximate total family income in 1987 (before taxes)?

1 0-5,000
2 5,001-10,000
3 10,001-15,000
4 15,001-20,000
5 20,001-30,000
6 30,001-50,000
7 More than 50,000
U Don't know

78P. Has this income changed since your injury, or has it stayed about the same?

1 Stayed the same
2 Less
3 More
4 Don't know

7810P. If Less, because_____

7820P. If More, because_____

During the last month, did you receive:

		No	Yes	Unknown
7910P.	Unemployment insurance benefits	0	1	U
7920P.	Sick leave with pay	0	1	U
7930P.	Sick leave without pay	0	1	U
7940P.	Public assistance	0	1	U
7950P.	Social Security disability benefits	0	1	U
7960P.	Financial help from relatives	0	1	U
7970P.	Financial help from friends	0	1	U
7980P.	Earnings from own job(s)	0	1	U
7990P.	*Other sources of income* (specify in 7991P)	0	1	U

7991P. If Other Sources of Income, specify

_____

HEALTH

People often depend on family and friends for help, or just to spend time together. Since your injury, how often have you done the following things with friends or family members?

Code:
0 *Never*
1 *Less than once a month*
2 *At least once a month*
3 *Every couple of weeks*
4 *At least once a week*
5 *More than once a week*
6 *Every day*

8010P.	**Visited with friends**	0	1	2	3	4	5	6
8020P.	**Visited with relatives**	0	1	2	3	4	5	6
8030P.	**Got physical help from someone**	0	1	2	3	4	5	6
8040P.	**Got financial help from someone**	0	1	2	3	4	5	6
8050P.	**Got advice or emotional support from someone**	0	1	2	3	4	5	6
8060P.	**Went out with family to have fun**	0	1	2	3	4	5	6
8070P.	**Went out with friend to have fun**	0	1	2	3	4	5	6
8080P.	**Went to meetings of clubs, organizations or religious services**	0	1	2	3	4	5	6

81P. **Over the past month, which of the following best describes your family's participation in your care?** (Circle all that apply.)
- 1 My spouse/mate helps me with my physical care
- 2 My children help me with my physical care
- 3 My parents help me with my physical care
- 4 Other relatives help me with my physical care
- 5 They are not involved with my care at all

(specify in 8110P)

8110P. If 5, specify why not_____

82P. **Over the past month, who has provided most of the physical care?**
- 0 Not applicable, care not needed
- 1 Family
- 2 Friends
- 3 Institutional care
- 4 Other (specify in 8210P)

8210P. If Other, specify_____

83P. **Families differ in the amount of time they spend with each other. How does the time your family spent with you during the last month compare to before your accident?** (Choose only one.)
- 1 They spend less time with me now
- 2 They spend more time with me now
- 3 They spend about the same time with me
- U Not applicable (no family in area, etc.; or unknown)

84P. **Other, than for medical visits, about how often do you go outside?**
- 1 Daily
- 2 Several times a week
- 3 At least once a week
- 4 Less than once a week
- 5 Not at all

85P. **About how many hours a day do you watch TV?** (That is, in a typical 24 hour period.)

_____(hours)

86P. **About how many hours in a usual 24-hour period do you sleep?**

_____(hours)

RELATIONSHIPS AND HEALTH

Please respond to (circle) only those statements that you are sure describe you currently and that are related to your state of health.

		No	Yes	Unknown
87P.	**Are you going out less to visit people?**	0	1	U
88P.	**Do you ever go out to visit people?**	0	1	U
89P.	**Do you show less interest in other people's problems?** (For example, don't listen when they tell you about their problems, don't offer to help?)	0	1	U
90P.	**Do you often act irritable toward those around you?** (For example, snap at people, give sharp answers, criticize easily?)	0	1	U
91P.	**Do you show less affection?**	0	1	U
92P.	**Are you doing fewer social activities with groups of people?**	0	1	U
93P.	**Are you avoiding social visits from others?**	0	1	U
94P.	**Is your sexual activity decreased?**	0	1	U
95P.	**Is your sexual activity increased?**	0	1	U
96P.	**Do you often express concern over what might be happening to your health?**	0	1	U
97P.	**Do you talk less with those around you?**	0	1	U
98P.	**Do you make many demands?** (For example, insist that people do things for you, tell them how to do things?)	0	1	U
99P.	**Do you stay alone much of the time?**	0	1	U
100P.	**Do you act disagreeable to family members?** (For example, act spiteful or stubborn?)	0	1	U
101P.	**Do you have frequent outbursts of anger at family members?** (For example, strike at them, scream, throw things at them?)	0	1	U
102P.	**Do you isolate yourself as much as you can from the rest of the family?**	0	1	U
103P.	**Are you paying less attention to the children?**	0	1	U
104P.	**Do you refuse contact with family members?** (For example, turn away from them?)	0	1	U
105P.	**Are you doing less than you usually do to take care of your children or family?**	0	1	U
106P.	**Are you joking less with family members than you usually do?**	0	1	U

ALCOHOL AND DRUG INTAKE

107P. Do you consider drinking to be a problem for you now?
- 0 No
- 1 Yes

108P. During the last month, what alcoholic beverage(s) did you usually drink? (If None, skip to 112P)

_____
(Beverage Name[s])

109P. During the last month, how often did you drink this beverage (these beverages)?
- 1 Several times a day
- 2 Daily
- 3 Several times a week
- 4 Several times a month
- 5 Once or twice
- U Unknown

110P. During the last month, how many drinks of the above beverage(s) did you usually drink at any one time? (Specify number)
(1 mixed drink=1 shot of liquor;
1 beer=12 oz.; 1 wine=6 oz.)

_____

111P. Usual size of drinks
- 1 Small (8 oz.)
- 2 Regular (10 oz.)
- 3 Large (16 oz. or more)

112P. When did you last have a drink of any kind of alcoholic beverage? (If never had a drink, code Jan 99 and skip to 11510P.)

___ ___
Mo Yr

113P. Have you noticed a change in your tolerance to alcohol since your head injury?
- 0 No
- 1 Yes, affects more now
- 2 Yes, affects less now
- U Unknown

114P. During the last month, how often did you have trouble remembering things that happened to you while you were intoxicated? (Choose One)
- 1 Nearly every time you drank
- 2 Some of the time you drank
- 3 One or two times
- 4 Never
- U Unknown

During the last month, how often have you used:

Code: 0 *Never* 1 *Once* 2 *Two to three times* 3 *Weekly* 4 *Daily* U *Unknown*

11510P.	Marijuana (hashish, pot, grass, Mary Jane)	0 1 2 3 4 U
11520P.	Cocaine (coke, "C", snow, flake)	0 1 2 3 4 U
11530P.	Heroin (smack, junk)	0 1 2 3 4 U
11540P.	PCP (angel dust)	0 1 2 3 4 U
11550P.	Other (specify in P)	0 1 2 3 4 U

11560P. If Other, specify_____

LEGAL ISSUES

116P. Have you been arrested since your injury?
- 0 No
- 1 Yes (go to 1161P)

If yes, please explain each arrest.

1161P. _____

1162P. _____

1163P. _____

1164P. _____

117P. Were you convicted?
- 0 No
- 1 Yes (go to 1171P)

If yes, please explain each conviction.

1171P. _____

1172P. _____

1173P. _____

1174P. _____

SCHOOL AND HEALTH

118P. Were you in school before your injury?
- 0 No
- 1 Yes (Go to 119P)

119P. If in school before your injury, but not now, why are you not going to school?
- 1 Working
- 2 Injury prevents
- 3 Other (Specify in 1191P)

1191P. If Other, specify_____

120P. Since your injury, have you taken any courses or been enrolled in school or college?
- 0 No (Skip to 135P)
- 1 Yes

121P. What year are you in school?
- 1 Sixth to 12th grade
- 2 First year college
- 3 Second year college
- 4 Third year college
- 5 Fourth year college
- 6 Graduate school
- 7 Vocational training
- 8 Taking courses, but not for degree or vocational training
- U Unknown

122P. Do you go to school full time or part time?
- 1 Full time
- 2 Part time
- 3 Not going at all presently

Students often have problems at school after injuries such as yours. Since being injured, how often did you:

Code: 1 *Almost always (daily)*; 2 *Often (several times a week)*; 3 *Sometimes (several times a month)*; 4 *Seldom (several times a year)*; 5 *Never*; U *Unknown*

123P. Complete assignments on time?	1	2	3	4	5	U
124P. Have difficulty understanding lessons?	1	2	3	4	5	U
125P. Get an unsatisfactory grade on an assignment or test?	1	2	3	4	5	U
126P. Feel your schoolwork was beyond your capabilities?	1	2	3	4	5	U
127P. Have difficulty organizing your time efficiently?	1	2	3	4	5	U
128P. Have trouble getting along with teachers or other students?	1	2	3	4	5	U
129P. Do your best?	1	2	3	4	5	U
130P. Come late to class?	1	2	3	4	5	U
131P. Skip classes?	1	2	3	4	5	U
132P. Come to class unprepared?	1	2	3	4	5	U
133P. Turn in sloppy or incomplete assignments?	1	2	3	4	5	U

134P. Since your injury would you say school is harder for you, easier, or about the same:
- 1 Harder for you
- 2 Easier for you
- 3 About the same as before
- U Unknown

REHABILITATION. Note to patient: Please do the best you can; estimates are fine.

TREATMENT COURSE	First	Second	Third
Physical Therapy (Since Last Interview)			
1371P. Received 0 No 1 Yes			
1372P. When began? __ ___ __ Day Mo Yr			
1373P. Usual Frequency 1 Weekly 4 Daily 2 Less than three times/week 5 Two times/day 3 Three times/week 6 Unknown 7 Other (specify in 1374P)			
1374P. If Other, specify			
1375P. Length Each Session (minutes)			
1376P. Length of Therapy (weeks)			
Occupational Therapy (Since Last Interview)			
1381P. Received 0 No 1 Yes			
1382P. When began? __ ___ __ Day Mo Yr			
1383P. Usual Frequency 1 Weekly 4 Daily 2 Less than three times/week 5 Two times/day 3 Three times/week 6 Unknown 7 Other (specify in 1384P)			
1384P. If Other, specify			
1385P. Length Each Session (minutes)			
1386P. Length of Therapy (weeks)			
Speech Therapy (Since Last Interview)			
1391P. Received 0 No 1 Yes			
1392P. When began? __ ___ __ Day Mo Yr			
1393P. Usual Frequency 1 Weekly 4 Daily 2 Less than three times/week 5 Two times/day 3 Three times/week 6 Unknown 7 Other (specify in 1394P)			
1394P. If Other, specify			
1395P. Length Each Session (minutes)			
1396P. Length of Therapy (weeks)			
Vocational Therapy (Since Last Interview)			
1401P. Received 0 No 1 Yes			
1402P. When began? __ ___ __ Day Mo Yr			
1403P. Usual Frequency 1 Weekly 4 Daily 2 Less than three times/week 5 Two times/day 3 Three times/week 6 Unknown 7 Other (specify in 1404P)			
1404P. If Other, specify			
1405P. Length Each Session (minutes)			
1406P. Length of Therapy (weeks)			

TREATMENT COURSE	First	Second	Third
Psychological Counselling (Since Last Interview)			
1411P. Received 0 No 1 Yes			
1412P. When began? __ __ Day __ __ __ Mo __ __ Yr			
1413P. Usual Frequency 1 Weekly 4 Daily 2 Less than three times/week 5 Two times/day 3 Three times/week 6 Unknown 7 Other (specify in 1414P)			
1414P. If Other, specify			
1415P. Length Each Session (minutes)			
1416P. Length of Therapy (weeks)			
Other (Since Last Interview) (specify in 44P)			
142P. If Other, specify (hydrotherapy, hypotherapy, etc.)			
1421P. Received 0 No 1 Yes			
1422P. When began? __ __ Day __ __ __ Mo __ __ Yr			
1423P. Usual Frequency 1 Weekly 4 Daily 2 Less than three times/week 5 Two times/day 3 Three times/week 6 Unknown 7 Other (specify in 1424P)			
1424P. If Other, specify			
1425P. Length Each Session (minutes)			
1426P. Length of Therapy (weeks)			

143P. How accurate do you think your answers to the questions in this interview have been?
- 0 Not at all accurate
- 1 Somewhat accurate
- 2 Mostly accurate
- 3 Very accurate

Interviewer's Comments and Observations

1441P. _____

1442P. _____

1443P. _____

1444P. _____

1445P. _____

Patient Study Number _____

INFORMANT INHOSPITAL INTERVIEW

FORM Z

(MAR 88)

To Be Completed by Nurse Clinician

Read to Informant: *Your answers to the questions which follow will help us design more effective treatment programs. Your answers will be held in strict confidence. Neither you nor the patient will be identified in any summaries or statistical reports.*

1Z. Date of Interview

__ ____ __
Day Mo Yr

1Z$. Time of Interview

_____:_____

2Z. Observer's Code_____

3Z. GCS (3-15) (Refer to patient's chart)

_____

4Z. Type of Interview
1 In person
2 Telephone
3 Mail

5Z. Respondent
1 Spouse/mate
2 Parent
3 Friend
4 Other relative (Specify in 510Z)
5 Other (Specify in 520Z)

510Z. If Other Relative, specify_____

520Z. If Other, specify_____

6Z. Form Completion Code
0 Completed
Not Completed Because
1 No informant
2 Informant refused form (including refusing part-way through)
3 Discontinued (fatigue, ill)
4 Examiner error
5 Other (Specify in 610Z)

610Z. If Other, specify_____

7Z. How long have you known the patient? (Number years)

_____

8Z. Before injury, where was the patient living?
1 Home
2 Other (specify in 810Z)

810Z. If Other, specify_____

9Z. Who lived with the patient? (Circle all that apply)
1 No one (patient lived alone)
2 Mother
3 Father
4 Wife/mate
5 Friend
6 Son(s)
7 Daughter(s)
8 Brother(s)
9 Sister(s)
10 Other (specify in 910Z)

910Z. If Other, specify_____

10Z. What best describes what the patient was doing before injury: working, going to school, or something else? (Circle all that apply)
1 Working full time (35 hours or more per week)
2 Working part time
3 With a job, but not at work (specify in 1010Z)
4 Looking for work
5 Unable to work
6 Going to school full time (College, 12 credit hours or more)
7 Going to school part time
8 Homemaker
9 Retired
10 Other (specify in 1020Z)
U Unknown

1010Z. If With a Job, But Not at Work (Because)

_____

If Other, specify_____

Please tell me about the patient's last several jobs. Begin with the current job and work backwards. What did the patient do (occupation)?

	Occupation	Occupational Code	Hours Worked Per Week	Number Months Job Held		Approximately When Begun		
1110Z.	_____	1111Z._____	1112Z._____	1113Z._____	1114Z.	__ Day	____ Mo	__ Yr
1120Z.	_____	1121Z._____	1122Z._____	1123Z._____	1124Z.	__ Day	____ Mo	__ Yr
1130Z.	_____	1131Z._____	1132Z._____	1133Z._____	1134Z.	__ Day	____ Mo	__ Yr

FAMILY LIFE AND SOCIAL ACTIVITIES

12Z. **Is the patient married, separated, divorced, or single?**
1 Married
2 Separated
3 Divorced
4 Single
5 Widowed

13Z. **How many children does the patient have?** (Number)
_____

14Z. **How many times has the patient been married?** (Number)
_____

15Z. **If currently married, how long has the patient been married?** (Number Years)
_____

16Z. **What was the patient's approximate total family income in 1987 (before taxes)?**
1 0-5,000
2 5,001-10,000
3 10,001-15,000
4 15,001-20,000
5 20,001-30,000
6 30,001-50,000
7 More than 50,000
U Don't know

17Z. **During the month before injury, who provided the patient's main source of income?** (Choose Only One)
1 Patient
2 Spouse/mate
3 Patient and mate equally
4 Parents
5 Children
6 Other (specify in 1710P)

1710Z. **If Other, specify**_____

	During the month before injury, did the patient receive:	No	Yes	Unknown
1810Z.	Unemployment insurance benefits	0	1	U
1820Z.	Sick leave with pay	0	1	U
1830Z.	Sick leave without pay	0	1	U
1840Z.	Public assistance	0	1	U
1850Z.	Social Security disability benefits	0	1	U
1860Z.	Financial help from relatives	0	1	U
1870Z.	Financial help from friends	0	1	U
1880Z.	Earnings from own job(s)	0	1	U
1890Z.	Other sources of income (specify in 1891P)	0	1	U

1891Z. **If Other Sources of Income, specify**
_____

People often depend on family and friends for help, or just to spend time together. Before injury, how often did the patient do the following things with friends or family members?

Code:
0 *Never*
1 *Less than once a month*
2 *At least once a month*
3 *Every couple of weeks*
4 *At least once a week*
5 *More than once a week*
6 *Every day*

1910Z.	Visited with friends	0	1	2	3	4	5	6
1920Z.	Visited with relatives	0	1	2	3	4	5	6
1930Z.	Got financial help from someone	0	1	2	3	4	5	6
1940Z.	Got advice or emotional support from someone	0	1	2	3	4	5	6
1950Z.	Went out with family to have fun	0	1	2	3	4	5	6
1960Z.	Went out with friend to have fun	0	1	2	3	4	5	6
1970Z.	Went to meetings of clubs, organizations or religious services	0	1	2	3	4	5	6

20Z. Does the patient have any family in the area?
0 No
1 Yes

If yes, what family members live in the area (within about 50 miles or so)?

		No	Yes	Unknown
2010Z.	Wife, children	0	1	U
2020Z.	Parents	0	1	U
2030Z.	Brothers, sisters	0	1	U
2040Z.	Grandparents	0	1	U
2050Z.	Uncles, aunts	0	1	U
2060Z.	Other (Specify in 2070Z)	0	1	U

2070Z. If Other, specify_____

EDUCATION

21Z. What was the highest grade of school the patient completed?
1 Kindergarten-6th grade
2 7th-9th grades
3 10th-11th grades
4 High school graduate
5 Some college
6 College graduate
7 Graduate school
8 Trade or vocational training

22Z. Did the patient have learning problems in school?
0 No
1 Reading
2 Math
3 Other (Specify in 2210Z)
U Unknown

2210Z. If Other, specify_____

23Z. Was the patient ever in special classes because of learning problems?
0 No
1 Yes
U Unknown

24Z. Was the patient ever left back in school? (i.e., ever failed a grade?)
0 No
1 Yes
U Unknown

2410Z. If yes, was the patient left back in school (failed a grade) because of learning problems?
0 No
1 Reading
2 Math
3 Other (Specify in 2420Z)
U Unknown

2420Z. If Other, specify_____

PSYCHIATRIC

25Z. Prior to injury, did the patient receive any psychiatric or psychological counselling or treatment?
0 No
1 Yes
U Unknown

2510Z. If yes, describe the nature of the problem.

_____

26Z. Was a diagnosis assigned?
0 No
1 Yes

2610Z. If yes, what was the diagnosis?

_____

27Z. Did the patient receive any medications?
0 No
1 Yes
U Unknown

2710Z. If yes, what were the medications?

_____

28Z. Was the patient hospitalized?
0 No
1 Yes

2810Z. If yes, how many times was the patient hospitalized? (for psychological/psychiatric treatment)

_____

2820Z. If yes, how many days total hospitalized? (for psychological/psychiatric)

_____

NEUROLOGICAL

29Z. Prior to injury, did the patient ever have a head injury that resulted in loss of consciousness for more than five (5) minutes, skull fracture, or admission to the hospital?
0 No
1 Yes

30Z. Did the patient ever have any previous neurological disorder or disease (including seizure)?
0 No
1 Yes

3010Z. If yes, please specify_____

ALCOHOL AND DRUG INTAKE

31Z. Did you consider drinking to be a problem for the patient before the injury?
- 0 No
- 1 Yes

32Z. During the month before injury, what alcoholic beverage(s) did the patient usually drink? (List Beverage Name[s]; If none, skip to 35Z)

_____

33Z. During the month before injury, how often did the patient drink the above beverage(s)?
- 1 Several times a day
- 2 Daily
- 3 Several times a week
- 4 Several times a month
- 5 Once or twice

34Z. How many drinks of this beverage did the patient usually drink at any one time? (Specify number)
(1 mixed drink=1 shot of liquor;
1 beer=12 oz.; 1 wine=6 oz.)

_____

3410Z. Usual Size of Drinks
- 1 Small (8 oz.)
- 2 Regular (10 oz.)
- 3 Large (16 oz. or more)

35Z. When did the patient last have a drink of any kind of alcoholic beverage? (If never had a drink, code JAN 99 and skip to 3710Z.)

___ ___
Mo Yr

36Z. During the month before injury, how often did the patient have trouble remembering things that happened while intoxicated? (Choose One)
- 1 Nearly every time you drank
- 2 Some of the time you drank
- 3 One or two times
- 4 Never
- U Unknown

During the month before injury, how often did the patient use:

Code: 0 *Never* 1 *Once* 2 *Two to three times* 3 *Weekly* 4 *Daily* U *Unknown*

3710Z.	Marijuana (hashish, pot, grass, Mary Jane)	0 1 2 3 4 U
3720Z.	Cocaine (coke, "C", snow, flake)	0 1 2 3 4 U
3730Z.	Heroin (smack, junk)	0 1 2 3 4 U
3740Z.	PCP (angel dust)	0 1 2 3 4 U
3750Z.	Other (specify in 3760P)	0 1 2 3 4 U

3760Z. If Other, specify_____

LEGAL ISSUES

38Z. Has the patient ever been arrested?
- 0 No
- 1 Yes

39Z. Was the patient convicted?
- 0 No
- 1 Yes

If yes, please explain each arrest.

3810Z. _____

3820Z. _____

3830Z. _____

3840Z. _____

40Z. How accurate do you think your answers to the questions in this interview have been?

0 Not at all accurate
1 Somewhat accurate
2 Mostly accurate
3 Very accurate

Interviewer's Comments and Observations

4110Z. _____

4120Z. _____

4130Z. _____

4140Z. _____

4150Z. _____

ARMY PENETRATING HEAD INJURY PROJECT

Patient Study Number _____

INFORMANT FOLLOW-UP INTERVIEW

FORM Z

TO BE COMPLETED BY NURSE CLINICIAN

(MAR 88)

Read to Informant: *Your answers to the questions which follow will help us design more effective treatment programs. Your answers will be held in strict confidence. Neither you nor the patient will be identified in any summaries or statistical reports.*

1Z. Date of Interview

__ ___ __
Day Mo Yr

1Z$. Time of Interview

_____:_____

51Z. Which interview is this?
1 Six months from injury
2 Twelve months from injury
3 Twenty-four months from injury

52Z. Observer's Code_____

53Z. Type of Interview
1 In person
2 Telephone
3 Mail

54Z. Respondent
1 Spouse/mate
2 Parent
3 Friend
4 Other relative (Specify in 5410Z)
5 Other (Specify in 5420Z)

5410Z. If Other Relative, specify_____

5420Z. If Other, specify_____

55Z. Form Completion Code
0 *Completed*
Not Completed Because
1 No informant
2 Informant refused form (including refusing part-way through)
3 Discontinued (fatigue, ill)
4 Examiner error
5 Other (Specify in 5510Z)

5510Z. If Other, specify_____

56Z. How long have you known the patient? (Number Years)

_____

57Z. Where is the patient living now?
1 Home
2 Hospital
3 Rehabilitation center
4 Nursing home
5 Adult home/transitional living center
6 Other (specify in 5710Z)

5710Z. If Other, specify_____

58Z. Who is the patient living with now?
1 No one, living alone
2 Family
3 Friends
4 In nursing home, rehabilitation center, or other institution
5 Other (specify in 5810Z)

5810Z. If Other, specify_____

59Z. How many times has patient been hospitalized since injury? (If not hospitalized since discharge from APHIP hospital, skip to 63Z)

_____

Give Dates of:

6010Z. Hospital Stay One __ ___ __ (Day Mo Yr)

6020Z. Hospital Stay Two __ ___ __ (Day Mo Yr)

6030Z. Hospital Stay Three __ ___ __ (Day Mo Yr)

6040Z. Hospital Stay Four __ ___ __ (Day Mo Yr)

Give length of hospital stay in days.

6110Z. Hospital Stay One_____ 6130Z. Hospital Stay Three_____

6120Z. Hospital Stay Two_____ 6140Z. Hospital Stay Four_____

What was the reason/admitting diagnosis?

6210Z. Hospital Stay One_____

6220Z. Hospital Stay Two_____

6230Z. Hospital Stay Three_____

6240Z. Hospital Stay Four_____

63Z. Other than hospitalizations, how many places has the patient lived since injury?_____(Number)

	Location (City)		Kind of Residence (Home, Nursing Home, etc.)		When Lived There From (Mo / Yr)			To (Mo / Yr)	
6310Z.	_____	6311Z.	_____	6312Z.	__	__	6313Z.	__	__
6320Z.	_____	6321Z.	_____	6322Z.	__	__	6323Z.	__	__
6330Z.	_____	6331Z.	_____	6332Z.	__	__	6333Z.	__	__
6340Z.	_____	6341Z.	_____	6342Z.	__	__	6343Z.	__	__
6350Z.	_____	6351Z.	_____	6352Z.	__	__	6353Z.	__	__

WORK EXPERIENCE

64Z. Did the patient have a full time job just prior to his/her injury?
- 0 No
- 1 Yes

65Z. Did the patient return to his/her old job?
- 0 No
- 1 Yes (Skip to 67P)

66Z. In your opinion, was the patient capable of returning to his/her previous job?
- 0 No
- 1 Yes

67Z. What best describes the patient's work since discharge?
- 1 Unable to work
- 2 Unemployed the entire time, though looked for work
- 3 Was often unemployed, but worked now and then
- 4 Worked about half the time
- 5 Worked most of the time
- 6 Changed jobs at least once, but worked steadily
- 7 Worked steadily at one job

68Z. Does the patient now work at all?
- 0 No (Skip to 70P)
- 1 Yes

Now consider the work the patient does and respond to (circle) only those statements that you are sure describes him/her and are related to his/her state of health.

		No	Yes
69Z.	Is the patient doing part of his/her job at home?	0	1
6910Z.	Is the patient accomplishing less than usual at work?	0	1
6920Z.	Does the patient often act irritable toward his/her work associates? (For example, snap at them, give sharp answers, criticize easily.)	0	1
6930Z.	Is the patient working shorter hours?	0	1
6940Z.	Is the patient doing only light work?	0	1
6950Z.	Does the patient work only for short periods of time or take frequent rests?	0	1
6960Z.	Is the patient working at his/her usual job, but with some changes? (For example, using different tools or special aids, trading some tasks with other workers?)	0	1
6970Z.	Is the patient doing his/her job as carefully and accurately as usual?	0	1
6980Z.	Is the patient having difficulty understanding instructions or deciding what to do?	0	1
6990Z.	Does the patient sometimes feel the job is beyond his/her capabilities?	0	1

If patient has worked since his/her injury, please tell me about his/her jobs. Begin with current job and go back in time to injury/last follow-up interview.

	Occupation	Occupational Code	Average Hours Per Week	Number Months Job Held	Approximate Date Job Began
7010Z.	_____	7011Z._____	7012Z._____	7013Z._____	7014Z. __ Day ___ Mo __ Yr
7020Z.	_____	7021Z._____	7022Z._____	7023Z._____	7024Z. __ Day ___ Mo __ Yr
7030Z.	_____	7031Z._____	7032Z._____	7033Z._____	7034Z. __ Day ___ Mo __ Yr

71Z. **Was the patient doing any work for pay last week?**
- 0 No
- 1 Yes

72Z. **Is the patient now working in a sheltered workshop?**
- 0 No
- 1 Yes
- U Don't know

73Z. **If the patient is not working full time now, which of the following may prevent or interfere with employment?** (Read List and Circle all items that apply.)

1 No jobs available	7 Depression	14 Medically ill, sick, etc.
2 No transportation	8 Poor vision	15 Thinking problems
3 Bad temper	9 In school	16 Trouble using hands, arms, legs
4 No motivation/ doesn't care	10 Can't speak properly	17 Other (Specify in 7310Z)
	11 Can't understand speech	
5 No pep or energy	12 Memory Problems	
6 Can't walk/climb stairs	13 Seizures	

7310Z. **If Other, list**_____

FAMILY LIFE AND SOCIAL ACTIVITIES

74Z. **What is the patient's marital status?**
1 Married
2 Separated
3 Divorced
4 Single
5 Widowed

75Z. **Has patient's marital status changed since injury?**
0 No (Skip 76Z)
1 Yes

7510Z. **If Yes,** *explain and give approximate date*

_____

76Z. **During the last month, who provided the main source of income?** (Choose Only One)
1 Self
2 Spouse/mate
3 Patient and mate equally
4 Parents
5 Children
6 Other (Specify in 7610Z)

7610Z. **If Other,** specify_____

77Z. **What was patient's approximate total family income in 1987** (before taxes)?
1 0-5,000
2 5,001-10,000
3 10,001-15,000
4 15,001-20,000
5 20,001-30,000
6 30,001-50,000
7 More than 50,000
U Don't know

78Z. **Has the patient's income changed since injury, or has it stayed about the same?**
1 Stayed the same
2 Less
3 More
4 Don't know

7810Z. **If Less,** because_____

7820Z. **If More,** because_____

	During the month before injury, did patient receive:	No	Yes	Unknown
7910Z.	Unemployment insurance benefits	0	1	U
7920Z.	Sick leave with pay	0	1	U
7930Z.	Sick leave without pay	0	1	U
7940Z.	Public assistance	0	1	U
7950Z.	Social Security disability benefits	0	1	U
7960Z.	Financial help from relatives	0	1	U
7970Z.	Financial help from friends	0	1	U
7980Z.	Earnings from own job(s)	0	1	U
7990Z.	Other sources of income (Specify in 7991Z)	0	1	U

7991Z. **If Other Sources of Income,** specify

_____

HEALTH

People often depend on family and friends for help, or just to spend time together. Since the patient's injury, how often has he/she done the following things with friends or family members?

Code:
0 *Never*
1 *Less than once a month*
2 *At least once a month*
3 *Every couple of weeks*
4 *At least once a week*
5 *More than once a week*
6 *Every day*

8010Z.	Visited with friends	0	1	2	3	4	5	6
8020Z.	Visited with relatives	0	1	2	3	4	5	6
8030Z.	Got physical help from someone	0	1	2	3	4	5	6
8040Z.	Got financial help from someone	0	1	2	3	4	5	6
8050Z.	Got advice or emotional support from someone	0	1	2	3	4	5	6
8060Z.	Went out with family to have fun	0	1	2	3	4	5	6
8070Z.	Went out with friend to have fun	0	1	2	3	4	5	6
8080Z.	Went to meetings of clubs, organizations or religious services	0	1	2	3	4	5	6

81Z. **Over the past month, which of the following best describes the family's participation in the care of the patient?** (Circle all that apply.)
- 1 Spouse/mate helps with the physical care
- 2 Children help with the physical care
- 3 Parents help with the physical care
- 4 Other relatives help with the physical care
- 5 They are not involved with the care at all

(specify in 8110Z)

8110Z. If 5, specify why not_____

82Z. **Over the past month, who has provided most of the physical care?**
- 0 Not applicable, care not needed
- 1 Family
- 2 Friends
- 3 Institutional care
- 4 Other (specify in 8210Z)

8210Z. If Other, specify_____

83Z. **Families differ in the amount of time they spend with each other. How does the time the family spent with the patient during the last month compare to before the accident?** (Choose only one.)
- 1 They spend less time with the patient now
- 2 They spend more time with the patient now
- 3 They spend about the same time with the patient
- U Not applicable (no family in area, etc.; or unknown)

84Z. **Other, than for medical visits, about how often does the patient go outside?**
- 1 Daily
- 2 Several times a week
- 3 At least once a week
- 4 Less than once a week
- 5 Not at all
- U Unknown

85Z. **About how many hours a day does the patient watch TV?** (i.e., in a typical 24 hour period.)

_____(hours)
- U Unknown

86Z. **About how many hours in a usual 24-hour period does the patient sleep?**

_____(hours)
- U Unknown

RELATIONSHIPS AND HEALTH

Please respond to (circle) only those statements that you are sure describe the patient currently and that are related to his/her state of health.

		No	Yes	Unknown
87Z.	**Is patient going out less to visit people?**	0	1	U
88Z.	**Does patient ever go out to visit people?**	0	1	U
89Z.	**Does patient show less interest in other people's problems?** (For example, doesn't listen when they tell him/her about their problems, doesn't offer to help.)	0	1	U
90Z.	**Does patient often act irritable toward those around him/her?** (For example, snaps at people, gives sharp answers, criticizes easily.)	0	1	U
91Z.	**Does patient show less affection?**	0	1	U
92Z.	**Is patient doing fewer social activities with groups of people?**	0	1	U
93Z.	**Is patient avoiding social visits from others?**	0	1	U
94Z.	**Is patient's sexual activity decreased?**	0	1	U
95Z.	**Is patient's sexual activity increased?**	0	1	U
96Z.	**Does patient often express concern over what might be happening to his/her health?**	0	1	U
97Z.	**Does patient talk less with those around him/her?**	0	1	U
98Z.	**Does patient make many demands?** (For example, insist that people do things for him/her, tell them how to do things.)	0	1	U
99Z.	**Does patient stay alone much of the time?**	0	1	U
100Z.	**Is patient disagreeable with family members?** (For example, spiteful or stubborn.)	0	1	U
101Z.	**Does patient have frequent outbursts of anger at family members?** (For example, strike at them, scream, throw things at them.)	0	1	U
102Z.	**Does patient isolate himself/herself as much as possible from the rest of the family?**	0	1	U
103Z.	**Is patient paying less attention to the children?**	0	1	U
104Z.	**Does patient refuse contact with family members?**(For example, turn away from them.)	0	1	U
105Z.	**Is patient doing less than usual to take care of his/her children or family?**	0	1	U
106Z.	**Is patient joking less than usual with family members?**	0	1	U

ALCOHOL AND DRUG INTAKE

107Z. **Do you consider drinking to be a problem for the patient now?**
- 0 No
- 1 Yes

108Z. **During the last month, what alcoholic beverage(s) did the patient usually drink?** (If None, skip to 112Z)

_____
(Beverage Name[s])

109Z. **During the last month, how often did the patient drink this beverage (these beverages)?**
- 1 Several times a day
- 2 Daily
- 3 Several times a week
- 4 Several times a month
- 5 Once or twice
- U Unknown

110Z. **During the last month, how many drinks of the above beverage(s) did the patient usually drink at any one time?** (Specify number)
(1 mixed drink=1 shot of liquor;
1 beer=12 oz.; 1 wine=6 oz.)

_____

111Z. **Usual size of drinks**
- 1 Small (8 oz.)
- 2 Regular (10 oz.)
- 3 Large (16 oz. or more)

112Z. **When did the patient last have a drink of any kind of alcoholic beverage?** (If never had a drink, code JAN 99, and skip to 11510Z.)

___ ___
Mo Yr

113Z. **Have you noticed a change in the patient's tolerance to alcohol since his/her injury?**
- 0 No
- 1 Yes, affects more now
- 2 Yes, affects less now
- U Unknown

114Z. **During the last month, how often did the patient have trouble remembering things that happened to him/her while he/she was intoxicated?** (Choose One)
- 1 Nearly every time he/she drank
- 2 Some of the time he/she drank
- 3 One or two times
- 4 Never
- U Unknown

During the last month, how often has the patient used:

Code: 0 *Never* 1 *Once* 2 *Two to three times* 3 *Weekly* 4 *Daily* U *Unknown*

11510Z.	**Marijuana** (hashish, pot, grass, Mary Jane)	0 1 2 3 4 U
11520Z.	**Cocaine** (coke, "C", snow, flake)	0 1 2 3 4 U
11530Z.	**Heroin** (smack, junk)	0 1 2 3 4 U
11540Z.	**PCP** (angel dust)	0 1 2 3 4 U
11550Z.	**Other** (specify in 11560P)	0 1 2 3 4 U

11560Z. **If Other**, specify_____

LEGAL ISSUES

116Z. **Has the patient been arrested since injury?**
- 0 No
- 1 Yes (go to 1161Z)

If yes, please explain each arrest.

1161Z. _____

1162Z. _____

1163Z. _____

1164Z. _____

117Z. **Was the patient convicted?**
- 0 No
- 1 Yes (go to 1171Z)

If yes, please explain each conviction.

1171Z. _____

1172Z. _____

1173Z. _____

1174Z. _____

SCHOOL AND HEALTH

118Z. **Was the patient in school before his/her injury?**
- 0 No
- 1 Yes

119Z. **If in school before the injury, but not now, why is the patient not going to school?**
- 1 Working
- 2 Injury prevents
- 3 Other (Specify in 1191Z)

1191Z. **If Other, specify**_____

120Z. **Since the patient's injury, has he/she taken any courses or been enrolled in school or college?**
- 0 No (Skip to 135Z)
- 1 Yes

121Z. **What year is the patient in school?**
- 1 Sixth to 12th grade
- 2 First year college
- 3 Second year college
- 4 Third year college
- 5 Fourth year college
- 6 Graduate school
- 7 Vocational training
- 8 Taking courses, but not for degree or vocational training
- U Unknown

122Z. **Does the patient go to school full time or part time?**
- 1 Full time
- 2 Part time
- 3 Not going at all presently

Students often have problems at school after injuries such as the patients. Since being injured, how often did the patient:

Code:
- 1 *Almost always (daily)*
- 2 *Often (several times a week)*
- 3 *Sometimes (several times a month)*
- 4 *Seldom (several times a year)*
- 5 *Never*
- U *Unknown*

123Z.	**Complete assignments on time?**	1	2	3	4	5	U
124Z.	**Have difficulty understanding lessons?**	1	2	3	4	5	U
125Z.	**Get an unsatisfactory grade on an assignment or test?**	1	2	3	4	5	U
126Z.	**Feel his/her schoolwork was beyond his/her capabilities?**	1	2	3	4	5	U
127Z.	**Have difficulty organizing his/her time efficiently?**	1	2	3	4	5	U
128Z.	**Have trouble getting along with teachers or other students?**	1	2	3	4	5	U
129Z.	**Do his/her best?**	1	2	3	4	5	U
130Z.	**Come late to class?**	1	2	3	4	5	U
131Z.	**Skip classes?**	1	2	3	4	5	U
132Z.	**Come to class unprepared?**	1	2	3	4	5	U
133Z.	**Turn in sloppy or incomplete assignments?**	1	2	3	4	5	U

134Z. **Since the patient's injury would you say school is harder for him/her, easier, or about the same?**
- 1 Harder for him/her
- 2 Easier for him/her
- 3 About the same as before
- U Unknown

OVERALL CHANGES AND ADJUSTMENTS

What, if any, are the main improvements you have noticed in the patient since his/her injury?

135Z. _____

1351Z. _____

1352Z. _____

1353Z. _____

136Z. **Overall, how much strain or distress have you personally felt because of changes in the patient since the injury?** (Circle one)

0 No strain
1 Very mild strain
2 Mild strain
3 Moderate strain
4 Moderately severe strain
5 Severe strain
6 Extremely severe strain

Which changes, if any, since the patient's injury have been most disturbing to you?

137Z. _____

1371Z. _____

1372Z. _____

1373Z. _____

How have you personally coped with these changes? (That is, coping strategies: counselling, involvement in outside interests, etc.)

138Z. _____

1381Z. _____

1382Z. _____

1383Z. _____

REHABILITATION. Note to informant: Please do the best you can; estimates are fine.

TREATMENT COURSE		First	Second	Third
Physical Therapy (Since Last Interview)				
1391Z. Received	0 No 1 Yes			
1392Z. When began?	Day Mo Yr			
1393Z. Usual Frequency	1 Weekly 2 Less than three times/week 3 Three times/week 4 Daily 5 Two times/day 6 Unknown 7 Other (specify in 1394Z)			
1394Z. If Other, specify				
1395Z. Length Each Session (minutes)				
1396Z. Length of Therapy (weeks)				
Occupational Therapy (Since Last Interview)				
1401Z. Received	0 No 1 Yes			
1402Z. When began?	Day Mo Yr			
1403Z. Usual Frequency	1 Weekly 2 Less than three times/week 3 Three times/week 4 Daily 5 Two times/day 6 Unknown 7 Other (specify in 1404Z)			
1404Z. If Other, specify				
1405Z. Length Each Session (minutes)				
1406Z. Length of Therapy (weeks)				
Speech Therapy (Since Last Interview)				
1411Z. Received	0 No 1 Yes			
1412Z. When began?	Day Mo Yr			
1413Z. Usual Frequency	1 Weekly 2 Less than three times/week 3 Three times/week 4 Daily 5 Two times/day 6 Unknown 7 Other (specify in 1414Z)			
1414Z. If Other, specify				
1415Z. Length Each Session (minutes)				
1416Z. Length of Therapy (weeks)				
Vocational Therapy (Since Last Interview)				
1421Z. Received	0 No 1 Yes			
1422Z. When began?	Day Mo Yr			
1423Z. Usual Frequency	1 Weekly 2 Less than three times/week 3 Three times/week 4 Daily 5 Two times/day 6 Unknown 7 Other (specify in 1424Z)			
1424Z. If Other, specify				
1425Z. Length Each Session (minutes)				
1426Z. Length of Therapy (weeks)				

TREATMENT COURSE	First	Second	Third
Psychological Counselling (Since Last Interview)			
1431Z. Received 0 No 1 Yes			
1432Z. When began? __ ____ __ Day Mo Yr			
1433Z. Usual Frequency 1 Weekly 2 Less than three times/week 3 Three times/week 4 Daily 5 Two times/day 6 Unknown 7 Other (specify in 1434Z)			
1434Z. If Other, specify			
1435Z. Length Each Session (minutes)			
1436Z. Length of Therapy (weeks)			
Other (Since Last Interview)(specify in 144Z)			
144Z. If Other, specify (hydrotherapy, hypotherapy, etc.)			
1441Z. Received 0 No 1 Yes			
1442Z. When began? __ ____ __ Day Mo Yr			
1443Z. Usual Frequency 1 Weekly 2 Less than three times/week 3 Three times/week 4 Daily 5 Two times/day 6 Unknown 7 Other (specify in 1444Z)			
1444Z. If Other, specify			
1445Z. Length Each Session (minutes)			
1446Z. Length of Therapy (weeks)			

145Z. How accurate do you think your answers to the questions in this interview have been?
- 0 Not at all accurate
- 1 Somewhat accurate
- 2 Mostly accurate
- 3 Very accurate

Interviewer's Comments and Observations

1461Z. _____

1462Z. _____

1463Z. _____

1464Z. _____

1465Z. _____

ARMY PENETRATING HEAD INJURY PROJECT (APHIP)
PROTOCOL SOD-605

SURGERY AND SUPEROXIDE DISMUTASE IN THE MANAGEMENT OF VERY SEVERE PENETRATING HEAD INJURY

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Development Command

_____ _____

Date Principal Investigator

TABLE OF CONTENTS

1.0 INTRODUCTION

Head injury is the major cause of death and disability in young adults today. The average annual incidence of head injury is about 200/100,000. The incidence for penetrating head injury in the USA is about 12/100,000, the highest of any developed country in the world.

Similarly, penetrating head injury accounts for a large proportion of serious casualties in the military setting; about 40% of battlefield fatalities in the Vietnam war were due to head and neck wounds. Eighty percent of those surviving to reach the hospital received surgical treatment, and 90% of those survived long term. The overwhelming majority of those long-term survivors could be classified as having moderate or good long-term outcomes, about 30% were returned to some duty.

Surgical Issues

Acute surgical debridement of missile tracts is the traditionally accepted management for patients with gunshot wounds and other penetrating brain injuries.[1] This time honored strategy of care, however, has never been subject to rigorous investigation (e.g., in a randomized trial), and a recent survey of neurosurgical management practices reveals that only about 27% of neurosurgeons believe that intracranial surgical debridement is helpful in severely injured patients in deep coma (Glasgow Coma Score [GCS] 3-5). There are reasons to believe that such patients may actually be harmed by an acute operation that requires manipulation and retraction of their brains. This often results in elevated intracranial pressure and may increase the risk of death or further injury. Medical management alone may thus improve on their outcome. This group of patients has had a particularly poor prognosis in civilian practice (they almost all die or remain vegetative regardless of treatment). On the other hand, patients with GCS 6-15 are able to tolerate early surgical debridement adequately. For purposes of treatment modalities, it is thus important to consider the two groups separately.

The current practice of providing prompt and thorough surgical debridement after penetrating head injury has evolved mostly from the experience in military conflicts over the past half century. The rationale has been that injured brain tissue serves as a nidus for delayed reaction and infection and must be removed as soon as possible. Yet a closer look at previous experience shows that the question is still controversial.

As early as the mid-1950's, French neurosurgeons in Vietnam were able to successfully delay debridement for days by doing a superficial wound closure and providing general support and antibiotics. The Israeli military experience in the recent Lebanese war has also demonstrated that many patients with severe, deep penetrating wounds could be successfully managed with early resuscitation, antibiotics, superficial wound closure, intracranial pressure (ICP) monitoring, and general medical support. Such patients generally had a good outcome and may have had less ultimate tissue loss.[2] Computerized tomography played a crucial role in management decisions.[3] In addition, recent long-term re-evaluation of Vietnam veterans in the Vietnam Head Injury Study (VHIS) has shown that retained bone fragments, do not, per se, result in increased complications, and their mere presence does not justify repeated operations for removal.[4] Preliminary analysis of the same population has also shown that complication rates (including post-operative sepsis) did not begin to rise until surgical delays of longer than 48-72 hours post-injury were encountered. The implications of this controversy can be quite far reaching, not only for the individual patient, but, in a military setting, for the logistician who must plan for deployment of war-time medical and neurosurgical resources.

Secondary Injury Issues

Over the past decade, delayed secondary injury at the cellular level has come to be recognized as a major contributor to the ultimate tissue loss after CNS trauma, stroke and other injury.[5] A cascade of biochemical events has been shown to be set in motion in injured tissue and involves a multitude of systems, including possible changes in neuropeptides, excitatory amino acids, arachidonic acid metabolites, and the formation of oxygen free radicals. These products can result in progressive secondary injury to otherwise viable tissue through a number of mechanisms, e.g., by producing further ischemia (via vasospasm, clot formation or secondary vascular occlusion), by injuring neurones and glia directly or activating macrophages that result in such injury, by producing brain swelling (edema or hyperemia), or by establishing conditions favorable to secondary infection. High circulating blood glucose has also been shown to have a detrimental effect in some brain injury models.[6] In the case of penetrating brain wounds, this can occur along the entrance tract; or with higher velocity missiles it can also be diffuse. Classically, this problem has been managed through the surgical removal of the offending tissue along the missile path, as outlined above, whether it was ultimately viable or not. One long-term objective of

the present study is to test alternative medical adjunctive treatment for this secondary injury that will not only minimize or delay the need for such surgery in the local area of missile penetration, but can also be used to manage the more diffuse secondary injury which is not amenable to surgery.

Oxygen Free Radicals and SOD

Oxygen Free Radicals are very active species biologically, and have been shown to be produced early in tissue injury, both in the CNS and elsewhere.[7,8,9,10] Such radicals are formed through a variety of pathways, including the xanthine oxidase and arachidonic chains, and result in tissue injury by combining directly with cellular elements or by participating in lipid peroxidation.[11] The superoxide anion radical, hydrogen peroxide, and free hydroxyl radicals may all be involved. The hydroxyl radical, which may be particularly destructive is formed largely in an iron catalyzed reaction between $-O_2$ and H_2O_2.[11,12] The principal products of the arachidonic cascade, prostaglandins and leukotrienes, can themselves result in tissue injury.[13] Pharmacologic intervention to reduce the formation of such radicals, and/or to scavenge those already formed, would thus be expected to reduce ultimate tissue injury. Animal models have confirmed this expected benefit in several systems.[8,11,13,14,15]

Since oxygen radicals are formed through a number of biochemical pathways, a variety of drugs or drug combinations may be useful to control them.[11] Superoxide Dismutase (SOD) may be particularly attractive in this regard since it scavenges all superoxide radicals regardless of their source by dismutating the oxygen free radical to form H_2O_2 and O_2. A beneficial effect of SOD has been shown in myocardial ischemia,[9] kidney ischemia,[16,17,18] cerebral ischemia,[19] and cerebral trauma.[8,13,20]

Problems associated with the use of SOD clinically have included the short half-life (six minutes) and the antigenicity of the free enzyme. The former had exacerbated the problem of expense and availability of the drug as well. One solution has been the covalent attachment of monomethoxy-polyethylene glycol (PEG) to SOD, with a resultant polymer-enzyme conjugate (PEG-SOD) that has a markedly extended circulating half-life (two to four days), and markedly decreased antigenicity.[21] The activity of the enzyme is not significantly diminished by the conjugation.

Toxicology

Animal toxicology evaluations of PEG-SOD have shown no adverse effects on appearance, behavior, food consumption, body weight, urinalysis, hematology, blood chemistry and organ weights. At very large doses (100-200 times the recommended human dose, five times a week for four weeks), there was splenic stimulation and vacuolation of splenic macrophages in rats.[22]

Clinical Studies

Administration of PEG-SOD to healthy human volunteers at doses of 500, 1000, and 2000 U/kg IM and IV resulted in no adverse reaction or changes in laboratory parameters. A dose of 1000 U/kg intravenously resulted in a peak level of 26 units which was maintained for about 12 hours, and a half-life of about four days.[23] PEG-SOD has been filed with the FDA at the Center for Drugs and Biologics for investigational use in humans, IND # BOD 28,915 held by Enzon, Inc.

Hypotheses

1. Since delayed secondary injury has been shown to be a major contributor to ultimate tissue damage after brain trauma, and excessive formation of oxygen free radicals plays a major role in such delayed secondary injury, we felt that PEG-SOD, by scavenging free radicals will minimize ultimate brain damage and result in decreased mortality and improved outcome.

2. Early surgical debridement of missile tracts complicates the management of very severely injured (Glasgow Coma Score [GCS] 3-5) patients with penetrating injuries in whom no accessible surgical mass lesion is found. This is particularly so with regard to management of intracranial pressure. These patients are thus best managed medically in the first five days postinjury.

2.0 OBJECTIVES

1. To evaluate the safety, tolerance, and efficacy of PEG-SOD with low glucose versus low glucose intensive care alone in the management of severe (Glasgow Coma Score 3-5) acute penetrating head injury.

2. To develop and further refine practical therapeutic outcome criteria or end-points for drug trials in penetrating head injury patients.

3. To study the metabolic, biochemical and vascular responses to penetrating head injury in humans.

4. To determine predictors of mortality and both short and long-term outcome after penetrating head injury.

5. To compare the value of prompt vs delayed intracranial surgical debridement in the management of very severe acute penetrating head injury.

3.0 STUDY DESIGN

This is a third party blind, placebo controlled, multicenter (four) study which will evaluate the safety, tolerance, and efficacy of PEG-SOD in patients diagnosed as having severe penetrating head injury (GCS 3-5) after nonsurgical resuscitation.

The study will be conducted at four centers, each center enrolling 22 patients. Once the diagnosis of PHI is established and a GCS between 3-5 is determined, the patient will be randomized into either Group A or Group B. A total of 88 patients from all four centers will be studied, 44 patients in each group.

Treatment for each group is as follows:

Group A An IV infusion of PEG-SOD 2000 U/kg will be given in 100 cc of normal saline over a one-hour period via an infusion pump on day 1 and day 4.

Group B An IV infusion of 100 cc of normal saline will be given over a one-hour period via an infusion pump on day 1 and day 4.

TABLE 1

Group	Number Patients	Drug	Surgery
A	44	PEG-SOD, 2000 U/kg PEG-SOD, 2000 U/kg	Acute Delayed
B	44	Normal Saline Normal Saline	Acute Delayed

Patients will be further randomized into prompt (acute) and delayed surgery (120 hours) groups (see table above).

However, patients with mass lesions requiring immediate surgery will be randomized into a separate, blinded drug group. These patients will receive study medication (PEG-SOD 2000 U/kg or normal saline), and undergo acute surgery.

All patients will receive intensive care and low glucose management. Efficacy of treatment will be evaluated by the following parameters: neurological status (GCS, ICP), CT scans, incidence of complications, and mortality. Safety and tolerance will include an evaluation of changes in blood chemistry, hematology, physical examinations (including cardiac and respiratory function), urinalysis, coagulation profiles, and evaluation of adverse reactions.

4.0 SELECTION OF PATIENTS

Eighty-eight (88) patients with a diagnosis of very severe penetrating head injury will be enrolled into this multicenter study. Each patient will have a GCS of 3-5 after non-surgical resuscitation. The following centers will participate in the study:

The University of Texas, Galveston, Texas

Medical College of Virginia, Richmond, Virginia

Louisiana State University Medical Center,
New Orleans, Louisiana

Baylor College of Medicine, Houston, Texas

5.0 INCLUSION/EXCLUSION CRITERIA

5.1 Inclusion Criteria

5.1.1 Patients must be at least 15 years of age or older.

5.1.2 Patients must be enrolled into the study within 24 hours of penetrating head injury (foreign body or missile has penetrated the skull and dura). In addition, patients must have post resuscitation GCS between 3 and 5 at the time of randomization.

5.1.3 Female patients must be of non-childbearing potential (surgically sterile or postmenopausal) to be entered into the drug trial.

5.1.4 Patients must not have a known life-threatening disease prior to the PHI. However, patients with a stable medical illness in the opinion of the investigator may be allowed to enter the study.

5.1.5 The patient must be competent to give written informed consent. If the patient is not competent, a legal guardian or next-of-kin must give a written informed consent.

5.1.6 Patients with PHI and who have had other injuries will be enrolled if the investigator deems it will be beneficial to the patient.

5.2 **Exclusion Criteria**

5.2.1 Patients who are unwilling to cooperate with the investigator.

5.2.2 Patients who are currently receiving any other investigational drugs.

5.2.3 Patients known to have severe ischemic heart disease or congestive heart failure or other severe systemic illness.

5.2.4 Patients who are brain dead after resuscitation, as defined in the APHIP Manual.

5.2.5 Patients in which written informed consent could not be obtained.

5.3 **Exclusion Criteria for Surgical Randomization: Scheme I**

5.3.1 The patient has an extra-axial or accessible intracranial mass lesion or lesions on CT, defined as a mixed or hyperdense mass with a volume greater than 30 cc anywhere in the brain or 20 cc in the temporal fossa.

5.3.2 The patient has a coagulopathy not controllable within 24 hours postinjury.

6.0 CONDUCT OF THE STUDY

Standard measures to normalize vital signs will be undertaken and treatment of immediately life-threatening injuries such as hemorrhage from major vessels, tension pneumothorax, etc., will take precedence over all other activities. In addition, the use of glucose-containing IV fluids and steroids will not be used. If a patient receives glucose or steroids prior to arrival at the APHIP hospital, those treatments will be discontinued and the dosages given recorded. Such patients will still be entered in the study.

6.1 Pretreatment Evaluations

6.1.1 The following evaluations should be done at the time of enrollment:

Complete Medical History
Complete Physical Examination
Neurological Evaluation

When possible, information pertaining to the time of injury, weapon distance, seizures, anoxia, progression of neurological deficits, drugs/alcohol, vital signs and GCS should be obtained.

6.1.2 All patients who are comatose or who have respiratory compromise will be intubated. The GCS, pupillary reaction, doll's eye movements, corneal responses, and respiratory efforts should be recorded prior to intubation and paralysis.

6.1.3 The following laboratory tests should be performed:

Hematology: Hemoglobin, hematocrit, RBC, WBC (total and differential), and platelets.

Blood Chemistry: Glucose, BUN, creatinine, uric acid, total protein, albumin, inorganic phosphorous, alkaline

phosphatase, total bilirubin, SGOT, SGPT, LDH, sodium, potassium, chloride, and osmolality.

Coagulation Profile: PT, PTT, fibrinogen, and fibrinogen split products.

Arterial blood gases will be done as clinically indicated.

Blood will be drawn for an alcohol level.

Urine will be collected for toxic screen and a baseline routine urinalysis.

6.1.4 Skull x-rays will be obtained in all cases. Other x-rays will be obtained as indicated.

6.1.5 A CT scan will be obtained on all patients as soon as possible and within three (3) hours of admission. Medical therapy will be given during this period as stated in CONCURRENT THERAPY (section 6.2).

6.1.6 After the results of the CT scan are obtained, detailed information concerning the head injury will be obtained at this time.

6.2 Concurrent Therapy

6.2.1 All patients will receive phenytoin sodium 500 mg IV over a ten-minute period for seizure prophylaxis within the first 24 hours. Nafcillin 1 gm IV and chloramphenicol 1 gm IV will be administered as soon as possible on a prophylactic basis.

6.2.2 All other medication that is given will be recorded on the CONCURRENT THERAPY RECORD.

6.3 Randomization

All patients will be assigned to the treatment groups under third party blind conditions. A randomization schedule will be provided by Enzon, Inc., and will define which subjects will receive which treatment. Since a matching placebo for PEG-SOD is not available, all study medication will be prepared by the pharmacist or nurse,

who will not participate in patient evaluations. A randomization card with sealed "windows" will be provided to the investigator and will contain the drug code for each patient. A "window" is only to be opened at the discretion of the investigator in the best interest of the patient. Only the "window" for the patient in question should be opened. If the investigator finds it necessary to break the code, the sponsor should be notified by phone immediately and should follow up with a letter documenting this event.

Patients will be randomized a second time into delayed or acute surgery groups.

TABLE 1A

Group	Average Number Patients	Medication
A	44	PEG-SOD, 2000 U/kg
B	44	Normal Saline

The investigator will be provided with a separate randomization scheme for patients that require immediate surgery (see section 5.3). These patients will be randomized into either Group A1 (PEG-SOD 2000 U/kg) or Group B1 (Normal Saline).

6.4 Study Drug Administration

6.4.1 Randomization Scheme 1: Patients who qualify for surgical randomization.

Group A — PEG-SOD will be administered intravenously at a dose of 2000 U/kg in 100 cc of normal saline. The infusion will be given over a one-hour period via an infusion pump on day 1 and on day 4.

Group B — An infusion of 100 cc of normal saline will be given over a one-hour period via an infusion pump on day 1 and on day 4.

6.4.2 Randomization Scheme 2: Patients who require immediate acute surgery.

Group A1 — PEG-SOD will be administered intravenously at a dose of 2000 U/kg in 100 cc of normal saline. The infusion will be given over a one-hour period via an infusion pump on day 1 and on day 4.

Group B1 An infusion of 100 cc of normal saline will be given over a one-hour period via an infusion pump on day 1 and on day 4.

In the opinion of the investigator, if the patient experiences a tremendous loss of blood or plasma from the vascular space and once the bleeding has been controlled, the patient may receive an additional infusion of the study medication at the same initial dose level.

If a significant adverse experience is observed, the infusion will be terminated immediately and the appropriate treatment will be instituted.

Hypersensitivity and allergic type reactions (including anaphylaxis) may occur following PEG-SOD administration. As a routine precaution, epinephrine, antihistamine (Benadryl), and steroid injections should be immediately available if required.

If the investigator must know what treatment the patient has received, the code for the particular patient can be broken, however, the sponsor should be notified immediately by telephone. The investigator should send a letter to the sponsor immediately documenting this event. Only the "window" for the patient in question should be opened.

6.5 Surgical Debridement

After the results of the CT scan are known, the patients will undergo a second randomization into two subgroups. One group will have acute surgical debridement and the second group will have superficial closure of the wound without extensive debridement and with delayed surgery.

6.6 Treatment Evaluations

6.6.1 A neurological screen will be performed daily while the patient is in the ICU. The neurological screens will be performed once per week after the patient is discharged from the ICU. This is to include the following tests:

GCS (best score for recording period).

Modified Kurtzke Scale (Disability Status Score, DSS).

Intracranial Pressure/Therapeutic Intensity Level, for as long as the ICP can be measured.

6.6.2 An Acute Neuropsychological Evaluation will be done on patients maintaining a GCS motor response of 6 (obeys commands) for 24 hours. This evaluation will then be repeated daily for three days, and then every other day for three sessions.

A Full Neuropsychological Test Battery will be administered at approximately ten days after the beginning of the acute evaluations or at discharge, whichever is sooner.

6.6.3 Vital signs (blood pressure, pulse, respiration, and temperature) will be recorded twice daily while the patient is in the ICU and once per day thereafter through day 30.

6.6.4 A nonenhanced CT scan will be obtained on days 1, 3, 7, and 30, or on day of discharge, whichever is sooner.

6.6.5 The following laboratory tests will be performed daily in the ICU and on days 7, 15, and 30, or discharge:

Hematology: Hemoglobin, hematocrit, RBC, WBC (total and differential), and platelets.

Blood Chemistry: Glucose, BUN, creatinine, uric acid, total protein, albumin, inorganic phosphorous, alkaline phosphatase, total bilirubin, SGOT, SGPT, LDH, sodium, potassium, and chloride.

Coagulation Profile: PT, PTT, fibrinogen, and fibrinogen split products.

Arterial blood gases, as well as cerebral blood flow measurements, will be done as clinically indicated.

6.6.6 Blood samples for the determination of SOD levels will be done every eight hours for the two days following each injection. One sample per day will be required on day 3, and days 7 to 14.

Five to eight mls of blood for the determination of plasma SOD activity will be collected in green top vacutainer tubes for each sample. Samples will be kept on ice until centrifuged and the separated plasma will be frozen immediately (see section 10.0).

6.6.7 Samples of cerebral spinal fluid (CSF) for determination of SOD levels will be collected at the time of surgery (via a ventricular catheter), and, if possible, every 12 hours for the two days following each injection and once per day on days 3, 7, and 8.

7.0 FINAL EVALUATIONS

7.1 The following evaluations will be done on day 30, or on the day of discharge if prior to day 30:

7.1.1 Glasgow Outcome Score.

7.1.2 A complete physical and neurological examination.

7.1.3 A nonenhanced CT scan.

7.1.4 The following laboratory tests will be performed:

Hematology: Hemoglobin, hematocrit, RBC, WBC (total and differential), and platelets.

Blood Chemistry: Glucose, BUN, creatinine, uric acid, total protein, albumin, inorganic phosphorous, alkaline phosphatase, total bilirubin, SGOT, SGPT, LDH, sodium, potassium, chloride, and osmolality.

7.2 Follow-up evaluations will be done if possible at 3, 6, 12, and 24 months post-injury.

8.0 DISCONTINUATION OF TREATMENT

The patient will be terminated from the study for one of the following reasons:

8.1 The patient decides that it is in his best interest.

8.2 The clinical investigator deems it necessary or in the patient's best interest.

8.3 The patient will be discontinued for any serious adverse drug experiences.

9.0 STUDY MEDICATION

PEG-SOD will be provided by the drug sponsor (Enzon, Inc.) in 5 ml vials containing 3.5 ml of an injectable solution with the specific activity provided on the label. The drug will be mixed with 100 ml of normal saline (which will be provided by the investigator) and administered by an IV infusion pump over a period of one hour. Placebo will be normal saline which will be provided by the investigator. The placebo will be given in an appropriate volume based on body weight as determined by the dosage (U/kg) and given as an intravenous infusion. The drug will be prepared for intravenous infusion under third party blind conditions. All study medication will be prepared by the pharmacist or nurse who will not participate in patient evaluations.

9.1 Packaging and Accountability

A record of all drugs dispensed will be kept by the individual responsible for administering the study medication. This record will include the patient's initials, the date the drug was administered, the lot number of the drug, and the vial number according to the randomization schedule provided by Enzon, Inc. A randomization code contained in a "window" card will be provided to the individual dispensing the study medication. At the end of the study, all drugs will be accounted for and unused supplies will be returned to the sponsor.

9.2 Storage

All study medication must be stored under refrigeration at 2-8° C (36-40°F). DO NOT FREEZE THE STUDY MEDICATION.

10.0 LABELING AND SHIPMENT OF SAMPLES

Five to eight ml of blood will be collected in green top vacutainer tubes for each sample. Samples will be kept on ice until centrifuged and the plasma will be frozen immediately at -20°C or less.

To facilitate collection of multiple samples, a heparin lock may be used. Care must be taken to clear the tubing of heparin before obtaining the sample, as excess heparinized saline would dilute the plasma. This can be done by withdrawing 2 ml of blood prior to sample collection. Approximately 5 ml of cerebral spinal fluid should be collected when possible, via ventricular catheter. Samples are to be kept on ice until frozen at -20°C or less. Any sample of CSF that is contaminated with blood should be centrifuged prior to freezing.

The samples must be properly labeled with self-adhesive labels identifying the study number, date, patient number, and collection time. The labels will be provided by the sponsor (Enzon, Inc.).

Samples will be shipped via Federal Express on dry ice in appropriate containers to Enzon, Inc., 300-C Corporate Court, South Plainfield, NJ 07080. The study monitor will be notified on the date of shipment and given the airway bill or invoice numbers.

There should be sufficient dry ice to maintain the samples in a frozen state for at least 48 hours. The sponsor (Enzon) will provide a Sample Inventory form which should accompany each sample shipment. Any deviation from the blood collection schedule, such as a missed sample or breakage of a sample, will be recorded in the comment section on the Sample Inventory form.

11.0 EVALUATION OF SAFETY

11.1 Hepatic toxicity will be assessed from changes in SGOT, SGPT, alkaline phosphatase and bilirubin.

11.2 Changes in hematologic and coagulation profiles will be evaluated.

11.3 Cardiac and respiratory function will be assessed with daily monitoring of vital signs and blood gas analysis (if indicated).

11.4 Adverse drug experiences will be evaluated.

12.0 ADVERSE EXPERIENCES

Any adverse experience occurring during treatment with PEG-SOD must be reported. The investigator must state whether the adverse experience was related to the study drug, concurrent drug therapy, underlying disease, a combination of these factors or unknown. Patients with an adverse experience will be carefully followed to determine the outcome.

Any significant adverse reaction is to be reported immediately to the Human Use Review and Regulatory Affairs Office, USAMR&DC, telephone 301-663-2165.

If a serious or alarming adverse experience occurs which may be related to PEG-SOD, the drug will be discontinued immediately and the study monitor will be notified within 24 hours. If a patient dies, the monitor will also be notified within 24 hours; if possible, an autopsy will be performed, including histological examination and written report (including Form FDA 1639), which will provide details of the patient's death. Form FDA 1639 will also be completed by the sponsor in collaboration with the principal investigator for each patient with a serious or unexpected adverse experience.

The completed forms will be mailed to the monitor for submission to the Food and Drug Administration. This form will include date of onset, severity, duration, the relationship to the study drug, whether the drug was discontinued or its dosage changed because of the experience, treatment given, and the outcome.

13.0 EVALUATION OF EFFICACY

13.1 Incidence of mortality.

13.2 Change in Glasgow Coma Scores.

13.3 Time required to attain a Glasgow Coma Score of 14.

13.4 Glasgow Coma Score at day 10.

13.5 Glasgow Outcome Score at day 30 or on day of discharge if prior to day 30.

13.6 Maximum Intracranial Pressure and Therapeutic Intensity Level will be evaluated.

13.7 Changes on Sequential CT Scans will be evaluated.

13.8 The incidence of complications (coagulopathy, infection, delayed hemorrhage) will be evaluated.

13.9 Performance on Acute Neuropsychology Battery test.

13.10 Psychosocial functioning at six months post-injury.

14.0 ANALYSIS OF DATA

This is a Phase II clinical trial involving the participation of four collaborating hospitals. The population to be studied consists of all penetrating head injured patients 15 years of age or older admitted to participating centers. A patient log will be kept on all PHI admissions to the study centers. If a patient is not randomized into the study, the nurse coordinator will record the reason.

The design is a 2 x 2 factorial design, allowing the simultaneous test of two hypotheses in the treatment of penetrating head injury: (1) that delay of surgery improves outcome in severely injured PHI patients, and (2) that PEG-SOD improves outcome of severely injured PHI patients. The major advantage of the factorial design in this study is that it permits a test for interaction between the drug and delayed surgery treatments. PEG-SOD may work more effectively in patients whose surgery is delayed, since the drug may substitute for some of the beneficial effects of surgery. The overall efficiency of a factorial design should compare favorably with a single factor trial of the same size unless interaction is found, such as PEG-SOD working more efficaciously when surgery is delayed. Such a finding would be of sufficient clinical importance as to override any decreased statistical efficiency which might result.

A total of 88 patients will be randomized into the study. Using a one-sided alpha of 10%, the study will have an 80% power to detect sizeable differences in rates favorable outcome. That is, assuming a rate of unfavorable outcome of 98%, as has been found in previous studies, the study could detect a population change of 15% or larger; that is, a decline to a rate of 83% unfavorable outcome. Since this is a

Phase II study aimed at identifying promising therapies, a significance level of 10% seems justified.

The drug trial will be third party blind, placebo controlled with patients randomly assigned PEG-SOD or a placebo, which will be normal saline. The randomization scheme will use random permuted blocks, with blocking done for each center. Patients giving informed consent within 24 hours of their injury will receive simultaneous random assignment to the drug and delayed surgery trials unless they are excluded from the study for the reasons listed above.

For purposes of this study, the following statistical analyses will be done:

Comparability of the drug and saline/placebo groups prior to treatment will be assessed by comparing the relevant demographic and prognostic variables (i.e., GCS just prior to treatment, age, other injuries, history of significant prior disease, etc.). A parallel analysis will determine the comparability of the acute and delayed surgery groups just prior to treatment. An evaluation of the drug's efficacy will be conducted on the measures specified in 13.0 above, with mortality and GOS at discharge being the primary endpoints for the study. The Mantel-Haenszel statistic will be used to determine whether GOS and mortality rates differed among patients receiving PEG-SOD and those receiving the saline.[24] An identical analysis will be conducted to determine the effect of time of surgery, stratifying on whether the patients received PEG-SOD or the saline. To test for interaction between the drug and surgery treatments, the difference in the log of the mortality rate ratios will be calculated for PEG-SOD and saline within each surgery group and a parallel analysis will be conducted of the surgery treatment within each drug group. For continuous variables, analysis of variance will be conducted to determine the strength of the main effects and the presence or absence of interaction.

Analyses will be done to determine whether treatment effects vary by research hospital. Central staff will seek to decrease treatment by hospital interaction by careful and continuous review of the forms completed by the research groups, by monitoring patient accession rates, and by training new personnel. The effect of treatment by hospital interaction upon mortality and GOS will then be assessed with the Mantel-Haenszel statistic. Analysis of variance will be used to test such interaction upon continuous variables. Such interactions should be and will be taken into account in analysis if the F ratio for interaction is significant at even the 0.10 level.[25]

The safety of the drug will be assessed by comparing the PEG-SOD and saline groups on the incidence of reported abnormal reactions, using the chi-square statistical test. Interim analyses will be conducted approximately every six months to determine whether the incidence of toxicity varies between the two drug groups. Strong differences in efficacy will be monitored at the same time intervals.

REFERENCES

1. Meirowsky AM. Penetrating Craniocerebral Trauma. CC Thomas: Springfield, 1984.
2. Feinsod M. Personal communication. 1986.
3. Rappaport ZH, Sahar A, Findler G, Tadmor R. Computerized tomography in combat related craniocerebral penetrating missile injuries. Israel Journal of Medical Sciences 20:668-671, 1984.
4. Myers PW, Salazar AM, Dillon JD, Meirowsky AM, Schlesselman S. The significance of retained intracranial bone fragments. Congress of Neurological Surgeons, September 1983; Neurosurgery 1983.
5. Cooper P. Delayed brain injury: Secondary insults. In: Becker DP, Povlishock JT, eds. Central Nervous System Trauma Status Report. NIH, pp 217-228, 1985.
6. Plum F. What causes infarction in ischemic brain?: The Robert Wartenberg lecture. Neurology 33:222-233, 1983.
7. Kontos HA. Oxygen radicals in cerebral vascular injury. Circulation Research 57:508-516, 1985.
8. Chan PH, Longar S, Fishman RA. Protective effects of liposome-entrapped superoxide dismutase on posttraumatic brain edema. Annals of Neurology 21:540-547, 1987.
9. McCord JM. Oxygen-derived free radicals in postischemic tissue injury. In: Epstein FH, ed. Mechanisms of Disease. New England Journal of Medicine 312(3):159-163, 1985.
10. Demopoulos HB, Flamm E, Seligman M, Pietronigro DD. Oxygen free radicals in central nervous system ischemia and trauma. In: Pathology of Oxygen. Academic Press, pp 127-155, 1982.

11. Borg DC, Schaich KM. Cytotoxicity from coupled redox cycling of autooxidizing xenobiotics and metals. Israel Journal of Chemistry 24:38-53, 1984.
12. Willmore LJ, Rubin JJ. Formation of malonaldehyde and focal brain edema induced by subpial injection of FeCl2 into rat isocortex. Brain Research 246:113-119, 1982.
13. Wei EP, Kontos HA, Dietrich WD, et al. Inhibition by free radical scavengers and by cyclooxygenase inhibitors of pial arteriolar abnormalities from concussive brain injury in cats. Circulation Research 48:95-103, 1981.
14. Manning AS, Coltart DJ, Hearse DJ. Ischemia and reperfusion-induced arrhythmias in the rat: Effects of xanthine oxidase inhibition with allopurinol. Circulation Research 55(4), 1984.
15. Taylor MD, Palmer GC, Callahan III AS. Protective action by methylprednisolone, allopurinol and indomethacin against stroke-induced damage to adenylate cyclase in gerbil cerebral cortex. Stroke 15(2):329-335, 1984.
16. Hansson R, Jonsson O, Lundstam S, Pettersson S, Schersten T, Waldenstrom J. Effects of free radial scavengers on renal circulation after ischemia in the rabbit. Clinical Science 65:605, 1983.
17. Paller MS, Hoidal JR, Ferris TF. Oxygen free radicals in ischemic acute renal failure in the rat. Journal of Clinical Investigation 74:1156, 1984.
18. Baker GL, Corry RJ, Autor AP. Oxygen free radical induced damage in kidneys subjected to warm ischemia and reperfusion. Annals of Surgery 202:628, 1985.
19. Becker J.
20. Kontos. Unpublished work.
21. Pyatak PS, Abuchowski A, Davis FF. Preparation of a polyethylene glycol: Superoxide dismutase adduct, and an examination of its blood circulating life and anti-inflammatory activity. Research Comm Chemical Pathological Pharmacology 29:113, 1980.

22. Enzon, Inc. Investigator's Brochure, PEG-SOD, September 1986.

23. Gural R, et al. Unpublished work.

24. Snedcor GW, Cochran WG. Statistical Methods. Iowa State University Press, pp 221-223, 1972.

25. Fleiss JL. Analysis of data from multiclinic trial. Controlled Clinical Trials, 7:267-275, 1986.

APHIP DATA COLLECTION TABLE

MARCH 1988

PARAMETER:	APHIP Forms	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 10	Day 15	Day 20	Day30† or Discharge
GCS	E,U,N	TID	TID	TID	TID	TID	TID	2x/Wk††				Yes
GOS/Mortality	N,F	PRN										Yes
Vital Signs	H	Daily x 30 days; or discharge, whichever is sooner										
ICP & TIL	O	Hourly while monitor in place										
Drug Side Effects	K	PRN										
Neurologic History&Exam	F	Yes						Yes				Yes
Neurologic Screen (DSS)	N	Yes	Yes	Yes	Yes	Yes	Yes	2xWk		Yes		Yes
Neuropsych Acute Battery	Y		Yes*									
Full Standard Neuropsych	Q								Yes**			
Psychosocial Battery	P,Z											Yes
LABORATORY:	E,U,L											
Coagulation Profile		Yes	Yes	Yes	Yes	Yes	Yes	Yes	PRN	PRN	PRN	PRN
Blood Gases/pH		PRN										
ETOH/Drug Screen		Yes										
Serum Osmolarity		Yes	PRN	PRN								
SMAC Profile		Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes		Yes
CBC		Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes		Yes
CSF***		Yes	BID	BID	BID	BID		Yes				
Cultures		Surgery	PRN									
Anticonvulsant Levels				Yes						Yes		Yes
SOD Levels		q 8-12 hr post treatment(see Protocol)										
CT Scan	C	Yes (48±24h)	Yes					Yes (d7±1)				(5mm) Yes
MRI (Optional)	R							Yes (d7±1)				Yes
Skull X-Ray	W	Yes										
Physical Examination	U	Yes						Yes				Yes

*Starting when following command for 24h: do neuropsychological screen daily x3, then q.o.d. x3.

**On final day of acute battery or discharge, whichever is sooner.

***When possible via ventricular catheter (see Protocol).

†Or at discharge, whichever is sooner.

††Until stable at 15 for 48 h.

APHIP DATA COLLECTION TABLE
MARCH 1988

OTHER FORMS

(COMPLETE ONCE; EXCEPT S & A FORMS, AS NEEDED)

	APHIP Forms	By Day 14	By Discharge
Base Data	B	X	
Patient Identification	I	X	
Surgical Treatment	S	X	
Patient Diagnoses	D		X
Multiple Injury	M		X
Chronology of Events	V		X
Wound Ballistics	W		X
Complications Summary	X		X
Study Termination Record	A		X

FOLLOW-UP DATA

	APHIP Forms	3 Mos	6 Mos	12 Mos	24 Mos
PARAMETER:					
GOS/Mortality	F	Yes	Yes	Yes	Yes
Neurologic History & Examination	F	Yes	Yes	Yes	Yes
Neurologic Screen (DSS)	F	Yes	Yes	Yes	Yes
Neuropsychological Acute Battery	Y	Yes	Yes	Yes	Yes
Full Standard Neuropsychological	Q	Yes	Yes	Yes	Yes
Psychosocial Battery	P,Z		Yes	Yes	Yes
LABORATORY:	E,U,L				
Coagulation Profile		PRN	PRN		
Anticonvulsant Levels			Yes	Ye	
CT Scan	C				
MRI (Optional)	R		Yes		

APPENDIX A

ETHICAL AND REGULATORY CONSIDERATIONS

The following must be observed to comply with the Food and Drug Administration regulations for the conduct and monitoring of clinical investigations. They also represent good clinical research practices:

INFORMED CONSENT

The principles of informed consent are described in the Code of Federal Regulations, Title 21, Part 50. They must be followed to comply with Food and Drug Administration regulations for the conduct and monitoring of clinical investigations. In obtaining informed consent the following information shall be provided in a language understandable to the subject.

1. *BASIC ELEMENTS OF INFORMED CONSENT*

The following are the basic elements of informed consent which must be provided to each subject.

a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

b. A description of any reasonably foreseeable risks or discomforts to the subject.

c. A description of any benefits to the subject or to others which may reasonably be expected from the research.

d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

e. A statement describing the extent, if any to which confidentiality of the records identifying the subject will be maintained and that notes the possibility that the FDA and the sponsor may inspect the records.

f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

g. An explanation of whom to contact for pertinent questions about the research and the research subject's rights, and whom to contact in the event of a research-related injury to the subject.

h. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. *ADDITIONAL ELEMENTS OF INFORMED CONSENT*

When appropriate, one or more of the following elements of information shall also be provided to each subject:

a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

b. Anticipated circumstances (including termination by the Sponsor) under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

c. Any additional costs to the subject that may result from participation in the research.

d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

f. The approximate number of subjects involved in the study.

A subject (and/or the subject's legally authorized representative) must give his/her written informed consent to participate in the study. This consent must be witnessed and dated and retained by the investigator as part of the study records. A copy of the consent form must be given to the subject.

If Experimental Subject's Bill of Rights is applicable in your state, that form must also be prepared and signed by each subject and retained as a part of the required study records. A copy of the Bill of Rights must be given to the subject.

A copy of the proposed consent form must be submitted to the Institutional Review Board together with the protocol for approval. A copy of the IRB approved consent form must be submitted to the study monitor at Enzon, Inc. prior to shipment of drug supplies to the investigator. Each subject's signed informed consent must be kept on file by the investigator for FDA inspection at any time.

FOREIGN TRIALS

The Declaration of Helsinki/Tokyo/Venice Recommendations guiding doctors in Clinical Research must be signed by the principal investigator and returned to the Enzon Medical Research Department. A copy must also be kept on file by the investigator.

INSTITUTIONAL REVIEW

This study must be approved by an appropriate Institutional Review Board as defined by FDA Regulations (21 CFR 56) including composition of the IRB and all other requirements contained therein.

The protocol and informed consent form for this study, must be approved in writing by the appropriate Institutional Review Board. The Letter of Approval from the Board must include the statement that "The Institutional Review Board granting this approval is in compliance with the regulations of the FDA contained in Part 56 Title 21 of the Code of Federal Regulations." If the IRB uses an approval form which does not contain this or a similiar statement, the investigator should request a separate letter or memo from the Chairperson of the IRB which does include this statement.

A copy of the Letter of Approval from the Board, which also contains specific identification of the documents approved, must be received by the study monitor at Enzon, Inc. prior to shipment of drug supplies to the investigator.

SIGNIFICANT CHANGES IN THE PROTOCOL, AS WELL AS A CHANGE OF PRINCIPAL INVESTIGATOR, must also be approved by the IRB and documentation of this approval must be submitted to Enzon, Inc. Records of IRB review and approval of all documents pertaining to this study must be kept on file by the investigator and are subject to FDA inspection at any time during the study.

PERIODIC STATUS REPORTS MUST BE SUBMITTED TO THE IRB AT LEAST YEARLY, AS WELL AS NOTIFICATION OF COMPLETION OF THE STUDY AND A FINAL REPORT WITHIN 3 MONTHS OF STUDY COMPLETION OR TERMINATION. A copy of these reports should be sent to the study monitor. The investigator must maintain an accurate and complete record of all submissions made to the IRB, including a list of all reports and documents submitted.

DRUG ACCOUNTABILITY

Each shipment of drug supplies for a study will contain a drug accountability record form to assist the investigator in maintaining current and accurate inventory records covering receipt, dispensing and return of study drug supplies.

The form will be included routinely for all studies and will identify for each shipment the subject number (as applicable) and the quantity of drugs contained in the shipment.

When shipment is received, the investigator must sign the letter or form verifying the quantities received and return the original to Enzon, Inc.

DRUG SUPPLIES MUST BE KEPT IN A SECURE, LIMITED ACCESS STORAGE AREA UNDER THE RECOMMENDED STORAGE CONDITIONS.

During the course of the study, the following information must be noted on the accountability record form: The subject number, the date(s) and quantity of drug dispensed to the subject, and the date(s) and quantity of unused drug.

THESE INVENTORY RECORDS MUST BE READILY AVAILABLE FOR INSPECTION BY THE STUDY MONITOR AND/OR THE FDA AT ANY TIME.

When drug supplies are to be returned, the investigator signs the drug accountability record form verifying that all unused supplies have been returned for each subject, and that no study supplies remain in the investigator's possession.

ADVERSE EXPERIENCES

Any serious or unexpected adverse experience whether deemed drug-related or not must be reported to Enzon, Inc. immediately by telephone or telegram. Such a report MUST BE FOLLOWED UP WITHIN 5 WORKING DAYS BY A WRITTEN REPORT TO THE MONITOR (using form FDA 1639) followed by a full description of the event and any sequelae. All DEATHS, whether considered drug related or not, must also be reported immediately to Enzon, Inc.

Any serious or unexpected adverse experiences (including all deaths) must also be reported to the IRB within 10 days and documentation of this report should be sent to Enzon, Inc.

CASE REPORT FORMS

Case report forms for each subject will be provided by Enzon, Inc. They must be signed by the principal investigator or co-investigator listed on form FDA 1572/73 for each subject enrolled in the study. Errors should be lined out but not obliterated and the correction inserted, initialed and dated. Subjects are not to be identified by name, however, the investigator must keep a separate log of patient names and addresses. This log is not subject to FDA inspection.

CASE REPORT FORMS AND ALL COPIES OF TEST RESULTS MUST BE AVAILABLE AT ALL TIMES FOR FDA INSPECTION AND REVIEW BY STUDY MONITOR

Data Collection

Case report forms which are generated by REDS (Remote Entry Data System) are to be handled as follows:

- One copy is kept by the investigator.
- One copy is released along with the data disk to Enzon, Inc.
- Keypunch errors are to be corrected according to the procedure described for the handwritten CRFS.
- Only authorized Enzon, Inc. personnel will be allowed to access the database.

WHEN ALL DATA ERRORS HAVE BEEN RESOLVED, A FINAL COPY OF THE REDS CASE REPORT FORMS WILL BE GENERATED BY ENZON INC., AND SENT TO THE INVESTIGATOR FOR HIS OR HER APPROVAL AND SIGNATURE. THIS WILL BE THE INVESTIGATOR'S OFFICIAL COPY OF THE CRFS AND WILL SUPERSEDE ALL OTHER COPIES. THE INVESTIGATOR WILL MAKE A COPY OF THE SIGNED CRFS FOR THIS FILE AND SEND THE ORIGINAL TO THE MEDICAL RESEARCH DEPARTMENT AT ENZON, INC.

GENERAL INFORMATION

All study records including case report forms, signed FDA 1572/73, originals of test results and informed consent forms, IRB approval letters (and all correspondence), and all other documents pertaining to the conduct of the study must be kept on file by the investigator. ALL STUDY RECORDS ARE SUBJECT TO FDA INSPECTION AT ANY TIME. STUDY RECORDS MUST BE MAINTAINED FOR A MINIMUM OF 2 YEARS FOLLOWING WRITTEN NOTIFICATION BY ENZON, INC. OF EITHER NDA APPROVAL OR DISCONTINUATION OF THE IND.

Changes to the protocol can be made only by written amendment agreed upon by Enzon, Inc. and the investigator. The IRB must be informed of all changes and must approve all changes that may increase risk to the subjects.

If there is an addition of a co-investigator, a letter stating this change and a copy of his C.V. must be sent to Enzon, Inc. A copy must also be retained in the investigator's file.

Monitoring visits will be scheduled regularly. It is essential that the investigator set aside time for these visits to allow for an adequate review of the study's progress.

The investigator is free to publish the results of the study, however, a draft manuscript must be submitted to Enzon, Inc. for review before submission for publications or presentation.

Enzon, Inc., reserves the right to terminate the study after notification has been given to the investigator.

ARMY PENETRATING HEAD INJURY PROJECT (APHIP)
PROTOCOL SOD-606

PEG SUPEROXIDE DISMUTASE

IN THE MANAGEMENT OF MODERATE PENETRATING HEAD INJURY

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U.S. Army Medical Research and
Development Command

Date

Principal Investigator

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1.0 INTRODUCTION

Head injury is the major cause of death and disability in young adults today. The average annual incidence of head injury is about 200/100,000. The incidence for penetrating head injury in the USA is about 12/100,000, the highest of any developed country in the world.

Similarly, penetrating head injury accounts for a large proportion of serious casualties in the military setting; about 40% of battlefield fatalities in the Vietnam war were due to head and neck wounds. Eighty percent of those surviving to reach the hospital received surgical treatment, and 90% of those survived long term. The overwhelming majority of those long-term survivors could be classified as having moderate or good long-term outcomes, about 30% were returned to some duty.

Surgical Issues

Acute surgical debridement of missile tracts is the traditionally accepted management for patients with gunshot wounds and other penetrating brain injuries.[1] This time honored strategy of care, however, has never been subject to rigorous investigation (e.g., in a randomized trial), and a recent survey of neurosurgical management practices reveals that only about 27% of neurosurgeons believe that intracranial surgical debridement is helpful in severely injured patients in deep coma (Glasgow Coma Score [GCS] 3-5). There are reasons to believe that such patients may actually be harmed by an acute operation that requires manipulation and retraction of their brains. This often results in elevated intracranial pressure and may increase the risk of death or further injury. Medical management alone may thus improve on their outcome. This group of patients has had a particularly poor prognosis in civilian practice (they almost all die or remain vegetative regardless of treatment). On the other hand, patients with GCS 6-15 are able to tolerate early surgical debridement adequately. For purposes of treatment modalities, it is thus important to consider the two groups separately.

The current practice of providing prompt and thorough surgical debridement after penetrating head injury has evolved mostly from the experience in military conflicts over the past half century. The rationale has been that injured brain tissue serves as a nidus for delayed reaction and infection and must be removed as soon as possible. Yet a closer look at previous experience shows that the question is still controversial.

As early as the mid-1950's, French neurosurgeons in Vietnam were able to successfully delay debridement for days by doing a superficial wound closure and providing general support and antibiotics. The Israeli military experience in the recent Lebanese war has also demonstrated that many patients with severe, deep penetrating wounds could be successfully managed with early resuscitation, antibiotics, superficial wound closure, intracranial pressure (ICP) monitoring, and general medical support. Such patients generally had a good outcome and may have had less ultimate tissue loss.[2] Computerized tomography played a crucial role in management decisions.[3] In addition, recent long-term re-evaluation of Vietnam veterans in the Vietnam Head Injury Study (VHIS) has shown that retained bone fragments, do not, per se, result in increased complications, and their mere presence does not justify repeated operations for removal.[4] Preliminary analysis of the same population has also shown that complication rates (including post-operative sepsis) did not begin to rise until surgical delays of longer than 48-72 hours post-injury were encountered. The implications of this controversy can be quite far reaching, not only for the individual patient, but, in a military setting, for the logistician who must plan for deployment of war-time medical and neurosurgical resources.

Secondary Injury Issues

Over the past decade, delayed secondary injury at the cellular level has come to be recognized as a major contributor to the ultimate tissue loss after CNS trauma, stroke and other injury.[5] A cascade of biochemical events has been shown to be set in motion in injured tissue and involves a multitude of systems, including possible changes in neuropeptides, excitatory amino acids, arachidonic acid metabolites, and the formation of oxygen free radicals. These products can result in progressive secondary injury to otherwise viable tissue through a number of mechanisms, e.g., by producing further ischemia (via vasospasm, clot formation or secondary vascular occlusion), by injuring neurones and glia directly or activating macrophages that result in such injury, by producing brain swelling (edema or hyperemia), or by establishing conditions favorable to secondary infection. High circulating blood glucose has also been shown to have a detrimental effect in some brain injury models.[6] In the case of penetrating brain wounds, this can occur along the entrance tract; or with higher velocity missiles it can also be diffuse. Classically, this problem has been managed through the surgical removal of the offending tissue along the missile path, as outlined above, whether it was ultimately viable or not.

Oxygen Free Radicals and SOD

Oxygen Free Radicals are very active species biologically, and have been shown to be produced early in tissue injury, both in the CNS and elsewhere.[7,8,9,10] Such radicals are formed through a variety of pathways, including the xanthine oxidase and arachidonic chains, and result in tissue injury by combining directly with cellular elements or by participating in lipid peroxidation.[11] The superoxide anion radical, hydrogen peroxide, and free hydroxyl radicals may all be involved. The hydroxyl radical, which may be particularly destructive is formed largely in an iron catalyzed reaction between $-O_2$ and H_2O_2.[11,12] The principal products of the arachidonic cascade, prostaglandins and leukotrienes, can themselves result in tissue injury.[13] Pharmacologic intervention to reduce the formation of such radicals, and/or to scavenge those already formed, would thus be expected to reduce ultimate tissue injury. Animal models have confirmed this expected benefit in several systems.[8,11,13,14,15]

Since oxygen radicals are formed through a number of biochemical pathways, a variety of drugs or drug combinations may be useful to control them.[11] Superoxide Dismutase (SOD) may be particularly attractive in this regard since it scavenges all superoxide radicals regardless of their source by dismutating the oxygen free radical to form H_2O_2 and O_2. A beneficial effect of SOD have been shown in myocardial ischemia,[9] kidney ischemia,[16,17,18] cerebral ischemia,[19] and cerebral trauma.[8,13,20]

Problems associated with the use of SOD clinically have included the short half-life (six minutes) and the antigenicity of the free enzyme. The former had exacerbated the problem of expense and availability of the drug as well. One solution has been the covalent attachment of monomethoxy-polyethylene glycol (PEG) to SOD, with a resultant polymer-enzyme conjugate (PEG-SOD) that has a markedly extended circulating half-life (two to four days), and markedly decreased antigenicity.[21] The activity of the enzyme is not significantly diminished by the conjugation.

Toxicology

Animal toxicology evaluations of PEG-SOD have shown no adverse effects on appearance, behavior, food consumption, body weight, urinalysis, hematology, blood chemistry and organ weights. At very large doses (100-200 times the recommended human dose, five times a week for four weeks), there was splenic stimulation and vacuolation of splenic macrophages in rats.[22]

Clinical Studies

Administration of PEG-SOD to healthy human volunteers at doses of 500, 1000, and 2000 U/kg IM and IV resulted in no adverse reaction or changes in laboratory parameters. A dose of 1000 U/kg intravenously resulted in a peak level of 26 units which was maintained for about 12 hours, and a half-life of about four days.[23] PEG-SOD has been filed with the FDA at the Center for Drugs and Biologics for investigational use in humans, IND # BOD 28,915 held by Enzon, Inc.

Since delayed secondary injury has been shown to be a major contributor to ultimate tissue damage after brain trauma, and excessive formation of oxygen free radicals plays a major role in such delayed secondary injury, we felt that PEG-SOD, by scavenging free radicals will minimize ultimate brain damage and result in decreased mortality and improved outcome.

2.0 OBJECTIVES

1. To evaluate the safety, tolerance, and efficacy of PEG-SOD with low glucose versus low glucose intensive care alone in the management of moderately severe to severe (Glasgow Coma Score 6-15) acute penetrating head injury.

2. To develop and further refine practical therapeutic outcome criteria or endpoints for drug trials in penetrating head injury patients.

3. To study the metabolic, biochemical and vascular responses to penetrating head injury in humans.

4. To determine predictors of mortality and both short and long-term outcome after penetrating head injury.

3.0 STUDY DESIGN

This is a third party blind, placebo controlled, multicenter study which will evaluate the safety, tolerance, and efficacy of PEG-SOD in patients diagnosed as having a moderately severe to severe penetrating head injury (GCS 6-15).

The study will be conducted at four centers, each center enrolling an average of 26 patients. Once the diagnosis of PHI is established and a GCS between 6-15 is

104 patients from all four centers will be studied, 52 patients in each group. Treatment for each group is as follows:

Group A An IV infusion of PEG-SOD 2000 U/kg will be given in 100 cc of normal saline over a one-hour period via an infusion pump on day 1 and day 4.

Group B An IV infusion of 100 cc of normal saline will be given over a one-hour period via an infusion pump on day 1 and day 4.

All patients will receive study drug, prompt (within 24 hours) surgical debridement and closure of the penetrating head injury. Whenever possible, the study medication will be given prior to surgical intervention.

All patients will receive intensive care and low glucose management. Efficacy of treatment will be evaluated by the following parameters: neurological status (GCS, ICP), CT scans, incidence of complications, and mortality. Safety and tolerance will include an evaluation of changes in blood chemistry, hematology, physical examinations (including cardiac and respiratory function), urinalysis, coagulation profiles, and evaluation of adverse reactions.

4.0 SELECTION OF PATIENTS

A minimum of 104 patients with a diagnosis of penetrating head injury will be enrolled into this multicenter study. Each patient will have a GCS of 6-15 after nonsurgical resuscitation, and will be randomly assigned to either Group A (PEG-SOD) or Group B (normal saline). A total of 26 patients will be enrolled in each of the following centers:

The University of Texas, Galveston, Texas

Medical College of Virginia, Richmond, Virginia

Louisiana State University Medical Center,
New Orleans, Louisiana

Baylor College of Medicine, Houston, Texas

5.0 INCLUSION/EXCLUSION CRITERIA

5.1 Inclusion Criteria

5.1.1 Patients must be at least 15 years of age or older.

5.1.2 Patients must be enrolled into the study within 24 hours of penetrating head injury (foreign body or missile has penetrated the skull and dura) and have a Glasgow Coma Score (GCS) of 6-15 following resuscitation.

5.1.3 Female patients must be of non-childbearing potential (surgically sterile or postmenopausal).

5.1.4 Patients must not have a known life-threatening disease prior to the PHI. However, patients with a stable medical illness in the opinion of the investigator may be allowed to enter the study.

5.1.5 The patient must be competent to give written informed consent. If the patient is not competent, a legal guardian or next-of-kin must give a written informed consent.

5.1.6 Patients with PHI and who have had other injuries will be enrolled if the investigator deems it will be beneficial to the patient.

5.2 Exclusion Criteria

5.2.1 Patients who are unwilling to cooperate with the investigator.

5.2.2 Patients who are currently receiving any other investigational drugs.

5.2.3 Patients known to have severe ischemic heart disease or congestive heart failure or other severe systemic illness.

5.2.4 Patients in which written informed consent could not be obtained.

6.0 CONDUCT OF THE STUDY

Standard measures to normalize vital signs will be undertaken and treatment of immediately life-threatening injuries such as hemorrhage from major vessels, tension pneumothorax, etc., will take precedence over all other activities. In addition, the use of glucose-containing IV fluids and steroids will not be used. If a patient receives glucose or steroids prior to arrival at the APHIP hospital, those treatments will be discontinued and the dosages given recorded. Such patients will still be entered in the study.

6.1 Pretreatment Evaluations

6.1.1 The following evaluations should be done at the time of enrollment:

Complete Medical History
Complete Physical Examination
Neurological Evaluation

When possible, information pertaining to the time of injury, weapon distance, seizures, anoxia, progression of neurological deficits, drugs/alcohol, vital signs and GCS should be obtained.

6.1.2 All patients who are comatose or who have respiratory compromise will be intubated. The GCS, pupillary reaction, doll's eye movements, corneal responses, and respiratory efforts should be recorded prior to intubation and paralysis.

6.1.3 The following laboratory tests should be performed:

Hematology: Hemoglobin, hematocrit, RBC, WBC (total and differential), and platelets.

Blood Chemistry: Glucose, BUN, creatinine, uric acid, total protein, albumin, inorganic phosphorous, alkaline phosphatase, total bilirubin, SGOT, SGPT, LDH, sodium, potassium, chloride, and osmolality.

Coagulation Profile: PT, PTT, fibrinogen, and fibrinogen split products.

Arterial blood gases will be done as clinically indicated.

Blood will be drawn for an alcohol level.

Urine will be collected for toxic screen and a baseline routine urinalysis.

6.1.4 Skull x-rays will be obtained in all cases. Other x-rays will be obtained as indicated.

6.1.5 A CT scan will be obtained on all patients as soon as possible and within three (3) hours of admission. Medical therapy will be given during this period as stated in CONCURRENT THERAPY (section 6.2).

6.1.6 After the results of the CT scan are obtained, detailed information concerning the head injury will be obtained at this time.

6.2 Concurrent Therapy

6.2.1 All patients will receive phenytoin sodium 500 mg IV over a ten-minute period for seizure prophylaxis within the first 24 hours. Nafcillin 1 gm IV and chloramphenicol 1 gm IV will be administered as soon as possible on a prophylactic basis.

6.2.2 All other medication that is given will be recorded on the CONCURRENT THERAPY RECORD.

6.3 Randomization

All patients will be assigned to the treatment groups under third party blind conditions. A randomization schedule will be provided by Enzon, Inc., and will define which subjects will receive which treatment. Since a matching placebo for PEG-SOD is not available, all study medication will be prepared by the pharmacist or nurse, who will not participate in patient evaluations. A randomization card with sealed "windows" will be provided to the investigator and will contain the drug code for each patient. A "window" is only to be opened at the discretion of the investigator in the

best interest of the patient. Only the "window" for the patient in question should be opened. If the investigator finds it necessary to break the code, the sponsor should be notified by phone immediately and should follow up with a letter documenting this event.

TABLE 1A

Group	Average Number Patients	Medication
A	52	PEG-SOD 2000 U/kg
B	52	Normal Saline

6.4 Study Drug Administration

Group A . PEG-SOD will be administered intravenously at a dose of 2000 U/kg in 100 cc of normal saline. The infusion will be given over a one-hour period via an infusion pump on day 1 and on day 4.

Group B An infusion of 100 cc of normal saline will be given over a one-hour period via an infusion pump on day 1 and on day 4.

In the opinion of the investigator, if the patient experiences a tremendous loss of blood or plasma from the vascular space and once the bleeding has been controlled, the patient may receive an additional infusion of the study medication at the same initial dose level.

If a significant adverse experience is observed, the infusion will be terminated immediately and the appropriate treatment will be instituted.

Hypersensitivity and allergic type reactions (including anaphylaxis) may occur following PEG-SOD administration. As a routine precaution, epinephrine, antihistamine (Benadryl), and steroid injections should be immediately available if required.

If the investigator must know what treatment the patient has received, the code for the particular patient can be broken, however, the sponsor should be notified immediately by telephone. The investigator should send a letter to the sponsor immediately documenting this event. Only the "window" for the patient in question should be opened.

6.5 Surgical Debridement

6.5.1 All patients will receive prompt (within 24 hours of injury) surgical debridement and closure of the penetrating head injury. Whenever possible, the study medication should be administered prior to surgical debridement.

6.6 Treatment Evaluations

6.6.1 A neurological screen will be performed daily while the patient is in the ICU. The neurological screens will be performed once per week after the patient is discharged from the ICU. This is to include the following tests:

GCS (best score for recording period).

Modified Kurtzke Scale (Disability Status Score, DSS).

Intracranial Pressure/Therapeutic Intensity Level, for as long as the ICP can be measured.

6.6.2 An Acute Neuropsychological Evaluation will be done on patients maintaining a GCS motor response of 6 (obeys commands) for 24 hours. This evaluation will then be repeated daily for three days, and then every other day for three sessions.

A Full Neuropsychological Test Battery will be administered at approximately ten days after the beginning of the acute evaluations or at the time of discharge, whichever is sooner.

6.6.3 Vital signs (blood pressure, pulse, respiration, and temperature) will be recorded twice daily while the patient is in the ICU and once per day thereafter through day 30.

6.6.4 A nonenhanced CT scan will be obtained on days 1, 3, 7, and 30, or on day of discharge, whichever is sooner.

6.6.5 The following laboratory tests should be performed daily in the ICU and on days 7, 15, and 30, or discharge.

Hematology: Hemoglobin, hematocrit, RBC, WBC (total and differential), and platelets.

Blood Chemistry: Glucose, BUN, creatinine, uric acid, total protein, albumin, inorganic phosphorous, alkaline phosphatase, total bilirubin, SGOT, SGPT, LDH, sodium, potassium, and chloride.

Coagulation Profile: PT, PTT, fibrinogen, and fibrinogen split products.

Arterial blood gases, as well as cerebral blood flow measurements, will be done as clinically indicated.

6.6.6 Blood samples for the determination of SOD levels will be done every eight hours for the two days following each injection. One sample per day will be required on day 3, and days 7 to 14.

Five to eight mls of blood for the determination of plasma SOD activity will be collected in green top vacutainer tubes for each sample. Samples will be kept on ice until centrifuged and the separated plasma will be frozen immediately (see section 10.0).

6.6.7 Samples of cerebral spinal fluid (CSF) for determination of SOD levels will be collected at the time of surgery (via a ventricular catheter), and, if possible, every 12 hours for the two days following each injection and once per day on days 3, 7, and 8.

7.0 FINAL EVALUATIONS

7.1 The following evaluations will be done on day 30, or on the day of discharge if prior to day 30:

7.1.1 Glasgow Outcome Score.

7.1.2 A complete physical and neurological examination.

7.1.3 A nonenhanced CT scan.

7.1.4 The following laboratory tests will be performed:

Hematology: Hemoglobin, hematocrit, RBC, WBC (total and differential), and platelets.

Blood Chemistry: Glucose, BUN, creatinine, uric acid, total protein, albumin, inorganic phosphorous, alkaline phosphatase, total bilirubin, SGOT, SGPT, LDH, sodium, potassium, chloride, and osmolality.

7.2 Follow-up evaluations will be done if possible at 3, 6, 12, and 24 months post-injury.

8.0 DISCONTINUATION OF TREATMENT

The patient will be terminated from the study for one of the following reasons:

8.1 The patient decides that it is in his best interest.

8.2 The clinical investigator deems it necessary or in the patient's best interest.

8.3 The patient will be discontinued for any serious adverse drug experiences.

9.0 STUDY MEDICATION

PEG-SOD will be provided by the drug sponsor (Enzon, Inc.) in 5 ml vials containing 3.5 ml of an injectable solution with the specific activity provided on the label. The drug will be mixed with 100 ml of normal saline (which will be provided by the investigator) and administered by an IV infusion pump over a period of one hour. Placebo will be normal saline which will be provided by the investigator. The placebo will be given in an appropriate volume based on body weight as determined by the dosage (U/kg) and given as an intravenous infusion. The drug will be prepared for intravenous infusion under third party blind conditions. All study medication will be prepared by the pharmacist or nurse who will not participate in patient evaluations.

9.1 Packaging and Accountability

A record of all drugs dispensed will be kept by the individual responsible for administering the study medication. This record will include the patient's initials, the date the drug was administered, the lot number of the drug, and the vial number according to the randomization schedule provided by Enzon, Inc. A randomization code contained in a "window" card will be provided to the individual dispensing the study medication. At the end of the study, all drugs will be accounted for and unused supplies will be returned to the sponsor.

9.2 Storage

All study medication must be stored under refrigeration at 2-8° C (36-40°F). DO NOT FREEZE THE STUDY MEDICATION.

10.0 LABELING AND SHIPMENT OF SAMPLES

Five to eight ml of blood will be collected in green top vacutainer tubes for each sample. Samples will be kept on ice until centrifuged and the plasma will be frozen immediately at -20°C or less.

To facilitate collection of multiple samples, a heparin lock may be used. Care must be taken to clear the tubing of heparin before obtaining the sample, as excess heparinized saline would dilute the plasma. This can be done by withdrawing 2 ml of blood prior to sample collection. Approximately 5 ml of cerebral spinal fluid should be collected when possible, via ventricular catheter. Samples are to be kept on ice until frozen at -20°C or less. Any sample of CSF that is contaminated with blood should be centrifuged prior to freezing.

The samples must be properly labeled with self-adhesive labels identifying the study number, date, patient number, and collection time. The labels will be provided by the sponsor (Enzon, Inc.).

Samples will be shipped via Federal Express on dry ice in appropriate containers to Enzon, Inc., 300-C Corporate Court, South Plainfield, NJ 07080. The study monitor will be notified on the date of shipment and given the airway bill or invoice numbers.

There should be sufficient dry ice to maintain the samples in a frozen state for at least 48 hours. The sponsor (Enzon) will provide a Sample Inventory form which should accompany each sample shipment. Any deviation from the blood collection schedule, such as a missed sample or breakage of a sample, will be recorded in the comment section on the Sample Inventory form.

11.0 EVALUATION OF SAFETY

11.1 Hepatic toxicity will be assessed from changes in SGOT, SGPT, alkaline phosphatase and bilirubin.

11.2 Changes in hematologic and coagulation profiles will be evaluated.

11.3 Cardiac and respiratory function will be assessed with daily monitoring of vital signs and blood gas analysis (if indicated).

11.4 Adverse drug experiences will be evaluated.

12.0 ADVERSE EXPERIENCES

Any adverse experience occurring during treatment with PEG-SOD must be reported. The investigator must state whether the adverse experience was related to the study drug, concurrent drug therapy, underlying disease, a combination of these factors or unknown. Patients with an adverse experience will be carefully followed to determine the outcome.

Any significant adverse reaction is to be reported immediately to the Human Use Review and Regulatory Affairs Office, USAMR&DC, telephone 301-663-2165.

If a serious or alarming adverse experience occurs which may be related to PEG-SOD, the drug will be discontinued immediately and the study monitor will be notified within 24 hours. If a patient dies, the monitor will also be notified within 24 hours; if possible, an autopsy will be performed, including histological examination and written report (including Form FDA 1639), which will provide details of the patient's death. Form FDA 1639 will also be completed by the sponsor in collaboration with the principal investigator for each patient with a serious or unexpected adverse experience.

The completed forms will be mailed to the monitor for submission to the Food and Drug Administration. This form will include date of onset, severity, duration, the relationship to the study drug, whether the drug was discontinued or its dosage changed because of the experience, treatment given, and the outcome.

13.0 EVALUATION OF EFFICACY

13.1 Incidence of mortality.

13.2 Change in Glasgow Coma Scores.

13.3 Time required to attain a Glasgow Coma Score of 14.

13.4 Glasgow Coma Score at day 10.

13.5 Glasgow Outcome Score at day 30 or on day of discharge if prior to day 30.

13.6 Maximum Intracranial Pressure and Therapeutic Intensity Level will be evaluated.

13.7 Changes on Sequential CT Scans will be evaluated.

13.8 The incidence of complications (coagulopathy, infection, delayed hemorrhage) will be evaluated.

13.9 Performance on Acute Neuropsychology Battery test.

13.10 Psychosocial functioning at six months post-injury.

14.0 ANALYSIS OF DATA

This is a Phase II clinical trial involving the participation of four collaborating hospitals. The population to be studied consists of all penetrating head injured patients 15 years of age or older admitted to participating centers. A patient log will be kept on all PHI admissions to the study centers. If a patient is not randomized into the study, the nurse coordinator will record the reason.

A total of 104 patients will be randomized into the study. Using a one-sided alpha of 10%, the study will have an 80% power to detect sizeable differences in rates favorable outcome. That is, assuming a rate of unfavorable outcome of 50%, the study could detect a population change of 20% or larger; that is, a decline to a rate of 30% unfavorable outcome. Since this is a Phase II study aimed at identifying promising therapies, a significance level of 10% seems justified.

The drug trial will be third party blind, placebo controlled with patients randomly assigned PEG-SOD or a placebo, which will be normal saline. The randomization scheme will use random permuted blocks, with blocking done for each center. Patients giving informed consent within 24 hours of their injury will receive random assignment to the drug trial unless they are excluded from the study for the reasons listed above.

For purposes of this study, the following statistical analyses will be done:

Comparability of the drug and saline/placebo groups prior to treatment will be assessed by comparing the relevant demographic and prognostic variables (i.e., GCS just prior to treatment, age, other injuries, history of significant prior disease, etc.). An evaluation of the drug's efficacy will be conducted on the measures specified in 13.0 above. One barrier to studies of effective treatment in this patient population has been the lack of practical and measurable end points (i.e., how to determine a treatment success). One methodological objective for this study will be the systematic appraisal of practical end points for research on head injured patients. Depending upon the level of measurement of the variables (nominal or interval), chi-square and analysis of variance will be used to compare patients receiving PEG-SOD and those receiving the saline.[24]

Analyses will be done to determine whether treatment effects vary by research hospital. Central staff will seek to decrease treatment by hospital interaction by careful and continuous review of the forms completed by the research groups, by monitoring patient accession rates, and by training new personnel. The effect of treatment by hospital interaction upon the end points will then be assessed with the Mantel-Haenszel statistic. Analyses of variance will be used to test such interaction upon continuous variables. Such interactions should be and will be taken into account in analysis if the F ratio for interaction is significant at even the 0.10 level.[25]

The safety of the drug will be assessed by comparing the PEG-SOD and saline groups on the incidence of reported abnormal reactions, using the chi-square statistical test. Interim analyses will be conducted approximately every six months to determine whether the incidence of toxicity varies between the two drug groups. Strong differences in efficacy will be monitored at the same time intervals.

REFERENCES

1. Meirowsky AM. Penetrating Craniocerebral Trauma. CC Thomas: Springfield, 1984.
2. Feinsod M. Personal communication. 1986.
3. Rappaport ZH, Sahar A, Findler G, Tadmor R. Computerized tomography in combat related craniocerebral penetrating missile injuries. Israel Journal of Medical Sciences 20:668-671, 1984.
4. Myers PW, Salazar AM, Dillon JD, Meirowsky AM, Schlesselman S. The significance of retained intracranial bone fragments. Congress of Neurological Surgeons, September 1983; Neurosurgery 1983.
5. Cooper P. Delayed brain injury: Secondary insults. In: Becker DP, Povlishock JT, eds. Central Nervous System Trauma Status Report. NIH, pp 217-228, 1985.
6. Plum F. What causes infarction in ischemic brain?: The Robert Wartenberg lecture. Neurology 33:222-233, 1983.
7. Kontos HA. Oxygen radicals in cerebral vascular injury. Circulation Research 57:508-516, 1985.
8. Chan PH, Longar S, Fishman RA. Protective effects of liposome-entrapped superoxide dismutase on posttraumatic brain edema. Annals of Neurology 21:540-547, 1987.
9. McCord JM. Oxygen-derived free radicals in postischemic tissue injury. In: Epstein FH, ed. Mechanisms of Disease. New England Journal of Medicine 312(3):159-163, 1985.
10. Demopoulos HB, Flamm E, Seligman M, Pietronigro DD. Oxygen free radicals in central nervous system ischemia and trauma. In: Pathology of Oxygen. Academic Press, pp 127-155, 1982.

11. Borg DC, Schaich KM. Cytotoxicity from coupled redox cycling of autooxidizing xenobiotics and metals. Israel Journal of Chemistry 24:38-53, 1984.
12. Willmore LJ, Rubin JJ. Formation of malonaldehyde and focal brain edema induced by subpial injection of FeCl2 into rat isocortex. Brain Research 246:113-119, 1982.
13. Wei EP, Kontos HA, Dietrich WD, et al. Inhibition by free radical scavengers and by cyclooxygenase inhibitors of pial arteriolar abnormalities from concussive brain injury in cats. Circulation Research 48:95-103, 1981.
14. Manning AS, Coltart DJ, Hearse DJ. Ischemia and reperfusion-induced arrhythmias in the rat: Effects of xanthine oxidase inhibition with allopurinol. Circulation Research 55(4), 1984.
15. Taylor MD, Palmer GC, Callahan III AS. Protective action by methylprednisolone, allopurinol and indomethacin against stroke-induced damage to adenylate cyclase in gerbil cerebral cortex. Stroke 15(2):329-335, 1984.
16. Hansson R, Jonsson O, Lundstam S, Pettersson S, Schersten T, Waldenstrom J. Effects of free radial scavengers on renal circulation after ischemia in the rabbit. Clinical Science 65:605, 1983.
17. Paller MS, Hoidal JR, Ferris TF. Oxygen free radicals in ischemic acute renal failure in the rat. Journal of Clinical Investigation 74:1156, 1984.
18. Baker GL, Corry RJ, Autor AP. Oxygen free radical induced damage in kidneys subjected to warm ischemia and reperfusion. Annals of Surgery 202:628, 1985.
19. Becker J.
20. Kontos. Unpublished work.
21. Pyatak PS, Abuchowski A, Davis FF. Preparation of a polyethylene glycol: Superoxide dismutase adduct, and an examination of its blood circulating life and anti-inflammatory activity. Research Comm Chemical Pathological Pharmacology 29:113, 1980.

22. Enzon, Inc. Investigator's Brochure, PEG-SOD, September 1986.

23. Gural R, et al. Unpublished work.

24. Snedcor GW, Cochran WG. Statistical Methods. Iowa State University Press, pp 221-223, 1972.

25. Fleiss JL. Analysis of data from multiclinic trial. Controlled Clinical Trials, 7:267-275, 1986.

APHIP DATA COLLECTION TABLE

MARCH 1988

PARAMETER:	APHIP Forms	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 10	Day 15	Day 20	Day30† or Discharge
GCS	E,U,N	TID	TID	TID	TID	TID	TID	2x/Wk††				Yes
GOS/Mortality	N,F	PRN										Yes
Vital Signs	H	Daily x 30 days; or discharge, whichever is sooner										
ICP & TIL	O	Hourly while monitor in place										
Drug Side Effects	K	PRN										
Neurologic History&Exam	F	Yes						Yes				Yes
Neurologic Screen (DSS)	N	Yes	Yes	Yes	Yes	Yes	Yes	2xWk		Yes		Yes
Neuropsych Acute Battery	Y		Yes*									
Full Standard Neuropsych	Q								Yes**			
Psychosocial Battery	P,Z											Yes
LABORATORY:	E,U,L											
Coagulation Profile		Yes	Yes	Yes	Yes	Yes	Yes	Yes	PRN	PRN	PRN	PRN
Blood Gases/pH		PRN										
ETOH/Drug Screen		Yes										
Serum Osmolarity		Yes	PRN	PRN								
SMAC Profile		Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes		Yes
CBC		Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes		Yes
CSF***		Yes	BID	BID	BID	BID		Yes				
Cultures		Surgery	PRN									
Anticonvulsant Levels				Yes						Yes		Yes
SOD Levels		q 8-12 hr post treatment(see Protocol)										
CT Scan	C	Yes (48±24h)	Yes					Yes (d7±1)				Yes (5mm)
MRI (Optional)	R							Yes (d7±1)				Yes
Skull X-Ray	W	Yes										
Physical Examination	N	Yes						Yes				Yes

*Starting when following command for 24h: do neuropsychological screen daily x3, then q.o.d. x3.

**On final day of acute battery or discharge, whichever is sooner.

***When possible via ventricular catheter (see Protocol).

†Or at discharge, whichever is sooner.

††Until stable at 15 for 48 h.

APHIP DATA COLLECTION TABLE
MARCH 1988

OTHER FORMS

(COMPLETE ONCE; EXCEPT S & A FORMS, AS NEEDED)

	APHIP Forms	By Day 14	By Discharge
Base Data	B	X	
Patient Identification	I	X	
Surgical Treatment	S	X	
Patient Diagnoses	D		X
Multiple Injury	M		X
Chronology of Events	V		X
Wound Ballistics	W		X
Complications Summary	X		X
Study Termination Record	A		X

FOLLOW-UP DATA

	APHIP Forms	3 Mos	6 Mos	12 Mos	24 Mos
PARAMETER:					
GOS/Mortality	F	Yes	Yes	Yes	Yes
Neurologic History & Examination	F	Yes	Yes	Yes	Yes
Neurologic Screen (DSS)	F	Yes	Yes	Yes	Yes
Neuropsychological Acute Battery	Y	Yes	Yes	Yes	Yes
Full Standard Neuropsychological	Q	Yes	Yes	Yes	Yes
Psychosocial Battery	P,Z		Yes	Yes	Yes
LABORATORY:	E,U,L				
Coagulation Profile		PRN	PRN		
Anticonvulsant Levels			Yes	Yes	
CT Scan	C				
MRI (Optional)	R		Yes		

APPENDIX A

ETHICAL AND REGULATORY CONSIDERATIONS

The following must be observed to comply with the Food and Drug Administration regulations for the conduct and monitoring of clinical investigations. They also represent good clinical research practices:

INFORMED CONSENT

The principles of informed consent are described in the Code of Federal Regulations, Title 21, Part 50. They must be followed to comply with Food and Drug Administration regulations for the conduct and monitoring of clinical investigations. In obtaining informed consent the following information shall be provided in a language understandable to the subject.

1. *BASIC ELEMENTS OF INFORMED CONSENT*

The following are the basic elements of informed consent which must be provided to each subject.

a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

b. A description of any reasonably foreseeable risks or discomforts to the subject.

c. A description of any benefits to the subject or to others which may reasonably be expected from the research.

d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

e. A statement describing the extent, if any to which confidentiality of the records identifying the subject will be maintained and that notes the possibility that the FDA and the sponsor may inspect the records.

f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

g. An explanation of whom to contact for pertinent questions about the research and the research subject's rights, and whom to contact in the event of a research-related injury to the subject.

h. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. *ADDITIONAL ELEMENTS OF INFORMED CONSENT*

When appropriate, one or more of the following elements of information shall also be provided to each subject:

a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

b. Anticipated circumstances (including termination by the Sponsor) under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

c. Any additional costs to the subject that may result from participation in the research.

d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

f. The approximate number of subjects involved in the study.

A subject (and/or the subject's legally authorized representative) must give his/her written informed consent to participate in the study. This consent must be witnessed and dated and retained by the investigator as part of the study records. A copy of the consent form must be given to the subject.

If Experimental Subject's Bill of Rights is applicable in your state, that form must also be prepared and signed by each subject and retained as a part of the required study records. A copy of the Bill of Rights must be given to the subject.

A copy of the proposed consent form must be submitted to the Institutional Review Board together with the protocol for approval. A copy of the IRB approved consent form must be submitted to the study monitor at Enzon, Inc. prior to shipment of drug supplies to the investigator. Each subject's signed informed consent must be kept on file by the investigator for FDA inspection at any time.

FOREIGN TRIALS

The Declaration of Helsinki/Tokyo/Venice Recommendations guiding doctors in Clinical Research must be signed by the principal investigator and returned to the Enzon Medical Research Department. A copy must also be kept on file by the investigator.

INSTITUTIONAL REVIEW

This study must be approved by an appropriate Institutional Review Board as defined by FDA Regulations (21 CFR 56) including composition of the IRB and all other requirements contained therein.

The protocol and informed consent form for this study, must be approved in writing by the appropriate Institutional Review Board. The Letter of Approval from the Board must include the statement that "The Institutional Review Board granting this approval is in compliance with the regulations of the FDA contained in Part 56 Title 21 of the Code of Federal Regulations." If the IRB uses an approval form which does not contain this or a similiar statement, the investigator should request a separate letter or memo from the Chairperson of the IRB which does include this statement.

A copy of the Letter of Approval from the Board, which also contains specific identification of the documents approved, must be received by the study monitor at Enzon, Inc. prior to shipment of drug supplies to the investigator.

SIGNIFICANT CHANGES IN THE PROTOCOL, AS WELL AS A CHANGE OF PRINCIPAL INVESTIGATOR, must also be approved by the IRB and documentation of this approval must be submitted to Enzon, Inc. Records of IRB review and approval of all documents pertaining to this study must be kept on file by the investigator and are subject to FDA inspection at any time during the study.

PERIODIC STATUS REPORTS MUST BE SUBMITTED TO THE IRB AT LEAST YEARLY, AS WELL AS NOTIFICATION OF COMPLETION OF THE STUDY AND A FINAL REPORT WITHIN 3 MONTHS OF STUDY COMPLETION OR TERMINATION. A copy of these reports should be sent to the study monitor. The investigator must maintain an accurate and complete record of all submissions made to the IRB, including a list of all reports and documents submitted.

DRUG ACCOUNTABILITY

Each shipment of drug supplies for a study will contain a drug accountability record form to assist the investigator in maintaining current and accurate inventory records covering receipt, dispensing and return of study drug supplies.

The form will be included routinely for all studies and will identify for each shipment the subject number (as applicable) and the quantity of drugs contained in the shipment.

When shipment is received, the investigator must sign the letter or form verifying the quantities received and return the original to Enzon, Inc.

DRUG SUPPLIES MUST BE KEPT IN A SECURE, LIMITED ACCESS STORAGE AREA UNDER THE RECOMMENDED STORAGE CONDITIONS.

During the course of the study, the following information must be noted on the accountability record form: The subject number, the date(s) and quantity of drug dispensed to the subject, and the date(s) and quantity of unused drug.

THESE INVENTORY RECORDS MUST BE READILY AVAILABLE FOR INSPECTION BY THE STUDY MONITOR AND/OR THE FDA AT ANY TIME.

When drug supplies are to be returned, the investigator signs the drug accountability record form verifying that all unused supplies have been returned for each subject, and that no study supplies remain in the investigator's possession.

ADVERSE EXPERIENCES

Any serious or unexpected adverse experience whether deemed drug-related or not must be reported to Enzon, Inc. immediately by telephone or telegram. Such a report MUST BE FOLLOWED UP WITHIN 5 WORKING DAYS BY A WRITTEN REPORT TO THE MONITOR (using form FDA 1639) followed by a full description of the event and any sequelae. All DEATHS, whether considered drug related or not, must also be reported immediately to Enzon, Inc.

Any serious or unexpected adverse experiences (including all deaths) must also be reported to the IRB within 10 days and documentation of this report should be sent to Enzon, Inc.

CASE REPORT FORMS

Case report forms for each subject will be provided by Enzon, Inc. They must be signed by the principal investigator or co-investigator listed on form FDA 1572/73 for each subject enrolled in the study. Errors should be lined out but not obliterated and the correction inserted, initialed and dated. Subjects are not to be identified by name, however, the investigator must keep a separate log of patient names and addresses. This log is not subject to FDA inspection.

CASE REPORT FORMS AND ALL COPIES OF TEST RESULTS MUST BE AVAILABLE AT ALL TIMES FOR FDA INSPECTION AND REVIEW BY STUDY MONITOR

Data Collection

Case report forms which are generated by REDS (Remote Entry Data System) are to be handled as follows:

- One copy is kept by the investigator.
- One copy is released along with the data disk to Enzon, Inc.
- Keypunch errors are to be corrected according to the procedure described for the handwritten CRFS.
- Only authorized Enzon, Inc. personnel will be allowed to access the database.

WHEN ALL DATA ERRORS HAVE BEEN RESOLVED, A FINAL COPY OF THE REDS CASE REPORT FORMS WILL BE GENERATED BY ENZON INC., AND SENT TO THE INVESTIGATOR FOR HIS OR HER APPROVAL AND SIGNATURE. THIS WILL BE THE INVESTIGATOR'S OFFICIAL COPY OF THE CRFS AND WILL SUPERSEDE ALL OTHER COPIES. THE INVESTIGATOR WILL MAKE A COPY OF THE SIGNED CRFS FOR THIS FILE AND SEND THE ORIGINAL TO THE MEDICAL RESEARCH DEPARTMENT AT ENZON, INC.

GENERAL INFORMATION

All study records including case report forms, signed FDA 1572/73, originals of test results and informed consent forms, IRB approval letters (and all correspondence), and all other documents pertaining to the conduct of the study must be kept on file by the investigator. ALL STUDY RECORDS ARE SUBJECT TO FDA INSPECTION AT ANY TIME. STUDY RECORDS MUST BE MAINTAINED FOR A MINIMUM OF 2 YEARS FOLLOWING WRITTEN NOTIFICATION BY ENZON, INC. OF EITHER NDA APPROVAL OR DISCONTINUATION OF THE IND.

Changes to the protocol can be made only by written amendment agreed upon by Enzon, Inc. and the investigator. The IRB must be informed of all changes and must approve all changes that may increase risk to the subjects.

If there is an addition of a co-investigator, a letter stating this change and a copy of his C.V. must be sent to Enzon, Inc. A copy must also be retained in the investigator's file.

Monitoring visits will be scheduled regularly. It is essential that the investigator set aside time for these visits to allow for an adequate review of the study's progress.

The investigator is free to publish the results of the study, however, a draft manuscript must be submitted to Enzon, Inc. for review before submission for publications or presentation.

Enzon, Inc., reserves the right to terminate the study after notification has been given to the investigator.

Baylor College of Medicine
INSTITUTIONAL REVIEW BOARD FOR HUMAN RESEARCH • 713 799-4760

February 3, 1988

Raj K. Narayan, M.D.
Department of Neurosurgery
Baylor College of Medicine
Houston, Texas 77030

Dear Dr. Narayan:

The Baylor Institutional Review Board for Human Research is pleased to inform you that your research proposal Peg-Superoxide Dismutase in the Moderate Penetrating Head Injury. (U.S. Army Medical Research & Development Command, Enzon, Inc.) (BT)

was approved on February 2, 1988 according to institutional guidelines and provided it receives the unaltered approval of the institutional committee in which it is involved.

1. Continued review will be required:
   - ( ) a. After each subject's exposure
   - ( ) b. Quarterly
   - ( ) c. Semi-annually
   - (x) d. Annually
   - (x) e. Change in Protocol
   - (x) f. Development of unexpected problems or unusual complications
   - ( ) g. Other

2. Method of Review
   - (x) a. Questionnaire (example enclosed)
   - ( ) b. New Protocol
   - ( ) c. Interview with principal investigator
   - ( ) d. Other

Sincerely yours,

FE Smith III

Frank E. Smith, M.D., Chairman
Baylor Institutional Review
Board for Human Research

FES:ib

Baylor College of Medicine
INSTITUTIONAL REVIEW BOARD FOR HUMAN RESEARCH • 713 799-4760

February 3, 1988

Raj K. Narayan, M.D.
Department of Neurosurgery
Baylor College of Medicine
Houston, Texas 77030

Dear Dr. Narayan:

The Baylor Institutional Review Board for Human Research is pleased to inform you that your research proposal Pegylated-Superoxide Dismutase in the Management of Very Severe Penetrating Head Injury. (U.S. Army Medical Research & Development Command, Enzon, Inc.) (BT)

was approved on February 2, 1988 according to institutional guidelines and provided it receives the unaltered approval of the institutional committee in which it is involved.

1. Continued review will be required
   - ( ) a. After each subject's exposure
   - ( ) b. Quarterly
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   - (x) e. Change in Protocol
   - (x) f. Development of unexpected problems or unusual complications
   - ( ) g. Other

2. Method of Review
   - (x) a. Questionnaire (example enclosed)
   - ( ) b. New Protocol
   - ( ) c. Interview with principal investigator
   - ( ) d. Other

Sincerely yours,

FE Smith (M.D.)

Frank E. Smith, M.D., Chairman
Baylor Institutional Review
Board for Human Research

FES:ib

ARMY PENETRATING HEAD INJURY PROJECT

CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

SUPEROXIDE DISMUTASE IN VERY SEVERE PENETRATING HEAD INJURY
BAYLOR COLLEGE OF MEDICINE - BEN TAUB GENERAL HOSPITAL

My next-of-kin, _____,
has suffered a very severe penetrating injury of the brain. I understand that at present there are no specific therapies that have been proven to improve outcome from such injuries. In fact, data from various major trauma centers has shown that virtually all patients with such serious brain injuries die, and the few that survive are usually severely disabled or vegetative. The physicians at this hospital are conducting a study in collaboration with the U.S. Department of Defense, Enzon, Incorporated, and three other major university hospitals, to try and develop better treatments for this almost uniformly fatal condition. I am being asked to enroll my _____ (relationship) in this study. A copy of this consent form will be given to me/my next-of-kin.

THE DRUG. After suffering a penetrating head injury, the brain can develop inflammation and swelling resulting in further damage. A drug known as Superoxide Dismutase (PEG-SOD), which is a normal body protein, has been shown in animal studies to effectively limit such damage. This drug has now become available to a few select trauma centers (including this hospital) for clinical trials, to assess its usefulness in humans. Although SOD is a normal body protein, it is categorized as an experimental drug by the Food and Drug Administration. My relative will be assigned to receive either PEG-SOD or a placebo based on random selection into one of two groups: Group A: subjects who will receive PEG-SOD, 2000 U/kg intravenously mixed in 100 cc saline (salt water), and Group B: subjects who will receive 100 cc saline placebo. Neither I, nor the physicians, will know whether the patient is receiving the drug or the placebo. In the unlikely event of an adverse reaction, the code can be broken to get this information. The patient will receive two doses of the drug or placebo intravenously on the first and fourth day after injury. It is important that the treatment is started as soon after the injury as possible.

SURGERY. There is no evidence that immediate surgery makes any difference to the outcome in patients with such severe penetrating brain injuries. In fact, experience has suggested that unless there is a large blood clot in the head, a patient with such a severe injury may be managed just as effectively with superficial closure of the scalp wound and nonsurgical intensive care with monitoring of the pressure inside the head. Patients in this study will undergo immediate CT scans of the head. If a large blood clot is found along the bullet tract, the patient will be operated upon for removal of the blood clot. However, if no significant clot pressing on the brain is seen, the patient will be randomly assigned to have either brain surgery within 24 hours, or simple closure of the scalp wound. Both groups will have intracranial pressure monitors placed to allow for early treatment of increased pressure and will receive postoperative intensive care. Patients who were initially treated without extensive surgery may be operated upon at a later time, if, in the judgment of the attending physician, there is a clear reason for doing so.

BLOOD GLUCOSE. There is some evidence from both animal and human studies that high levels of sugar in the blood can be harmful to the injured brain. In the present study, the patient's blood sugar will be carefully monitored and the levels will be maintained

within normal limits as far as possible in all patients. Thus, all patients participating in this study will be receiving a special therapy regardless of which treatment arm they are selected for.

INTENSIVE CARE. The Neurosurgical Intensive Care Unit (NICU) at Ben Taub General Hospital is one of the most advanced neurotrauma units in the country. In the NICU, the patient will be carefully monitored and the best possible medical care will be rendered. Blood tests, CT scans, and spinal fluid examinations will be done as part of standard care. A ventricular catheter, or an alternate device, will be inserted for monitoring intracranial pressure. Small samples of blood and spinal fluid (less than a total of three tablespoons per day) will be collected for a few days for special tests. Because of indwelling catheters, additional needle sticks will generally not be necessary to obtain these samples. Cerebral blood flow measurements may also be obtained during the acute phase of treatment.

FOLLOW-UP. As part of this study, patients who are discharged from the hospital will be seen in follow-up in the Neurosurgery Clinic approximately once every three months for up to one year. The evaluations in the hospital and at follow-up include neurologic examination, tests concerning memory, speech, the ability to put things together, pay attention, solve problems, name objects, carry out requests to move small objects, and remember pictures and words. You (he/she) will be asked to answer questions concerning the injury and its effect on your (his/her) daily living. You (he/she) will have the choice of answering or not answering any question.

POSSIBLE RISKS. PEG-SOD has not produced any side effects in animals at doses 100 times higher than those planned for this study. Doses equal to those used in this study have been given to normal human volunteers with no adverse effects. No complications are therefore anticipated. However, unexpected problems such as allergic reactions could possibly occur and will be treated appropriately. Complications relating to surgery are the same as would occur with the surgical procedure irrespective of this study. These include infection, re-bleeding, paralysis, and even death, among others. Other discomforts or risks associated with routine intensive care include localized discomfort or hematoma with needle sticks or insertion of catheters. Regardless of the treatment rendered, there is always the possibility of long-term survival in a severely disabled or vegetative state, as a result of the brain injury.

POSSIBLE BENEFITS. As stated earlier, very few patients with such severe head injuries survive. This study is an effort to improve upon this otherwise dismal prognosis. Since every patient entering this study will be receiving at least one special therapy, it is hoped that the survival rates can be improved upon and the extent of neurological recovery improved.

COMPENSATION. There will be no additional cost to the patient as a result of participating in this study. In the unlikely event of any injury occurring as a result of this study, I understand that neither the Baylor College of Medicine, the Harris County Hospital District, Enzon, Incorporated, nor the US Department of Defense will be able to offer any financial compensation. However, you are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. By signing this consent form and participating in this study, the patient is not waiving or giving up any right he/she might have to seek recovery for damages caused by negligence or intentional misconduct of those conducting this program.

CONFIDENTIALITY. Careful records of this study will be maintained and may be reviewed by the Baylor College of Medicine, the Food and Drug Administration, the Department of Defense, and Enzon, Incorporated, to ensure patient protection. All confidentiality will be maintained within the legal limits of the investigators. Patients' names will not be used in any public presentations or publications.

NON-PARTICIPATION. Participation in this study is voluntary; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you are free to withdraw from this study at any time without prejudice to your (or the patient's) future medical care. I can contact either Raj K. Narayan, M.D., Principal Investigator, or Claudia S. Robertson, M.D., Associate Investigator, for further information or concerns relating to this study and research-related injuries. They may be reached by telephone at 713-799-4696, or in writing at Department of Neurosurgery, Baylor College of Medicine, One Baylor Plaza, Houston, Texas, 77030.

I may contact Frank E. Smith, M.D., at the Baylor College of Medicine, One Baylor Plaza, Houston, Texas, 77030; telephone: 713-799-4760, for information about the rights of a research subject.

Signature of Patient's Next-of-Kin	Signature and Name of Witness
Relationship	Date and Time
Date and Time	

ARMY PENETRATING HEAD INJURY PROJECT

CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

SUPEROXIDE DISMUTASE IN MODERATE PENETRATING HEAD INJURY
BAYLOR COLLEGE OF MEDICINE - BEN TAUB GENERAL HOSPITAL

I (or my next-of-kin), _____,
have (has) suffered a serious penetrating injury of the brain. I understand that at present there are no specific therapies that have been proven to improve outcome from such injuries. The physicians at this hospital are conducting a study in collaboration with the U.S. Department of Defense, Enzon, Incorporated, and three other major university hospitals, to try and develop better treatments for this condition. I am being asked to participate in this study. A copy of this consent form will be given to me/my next-of-kin.

THE DRUG. After suffering a penetrating head injury, the brain can develop inflammation and swelling resulting in further damage. A drug known as Superoxide Dismutase (PEG-SOD), which is a normal body protein, has been shown in animal studies to effectively limit such damage. This drug has now become available to a few select trauma centers (including this hospital) for clinical trials, to assess its usefulness in humans. Although SOD is a normal body protein, it is categorized as an experimental drug by the Food and Drug Administration. I (or my injured relative) will be assigned to receive either PEG-SOD or a placebo based on random selection into one of two groups: Group A: subjects who will receive PEG-SOD, 2000 U/kg intravenously mixed in 100 cc saline (salt water), and Group B: subjects who will receive 100 cc saline placebo. Neither I, nor the physicians, will know whether the patient is receiving the drug or the placebo. In the unlikely event of an adverse reaction, the code can be broken to get this information. The patient will receive two doses of the drug or placebo intravenously on the first and fourth day after injury. It is important that the treatment is started as soon after the injury as possible.

SURGERY. All patients in this study will undergo immediate CT scans of the head, and the appropriate operation will be performed for debridement of the bullet tract and closure of the scalp wound. Patients who are unable to follow simple commands as a result of their injuries will also receive intracranial pressure monitors to allow for early treatment of increased pressure. These will be left in place for a few days in order to guide treatment of the intracranial pressure.

BLOOD GLUCOSE. There is some evidence from both animal and human studies that high levels of sugar in the blood can be harmful to the injured brain. In this study, the patient's blood sugar will be carefully monitored and the levels will be maintained within normal limits as far as possible in all patients. Thus, all patients participating in this study will be receiving a special therapy regardless of whether they receive the PEG-SOD or not.

INTENSIVE CARE. The Neurosurgical Intensive Care Unit (NICU) at Ben Taub General Hospital is one of the most advanced neurotrauma units in the country. In the NICU, the patient will be carefully monitored and the best possible medical care will be rendered. Blood tests, CT scans, and spinal fluid examinations will be done as part of standard care. Small samples of blood and spinal fluid (less than a total of three tablespoons per day) will be collected for a few days for special tests. Because of indwelling catheters, additional needle sticks will generally not be necessary to obtain these

samples. Cerebral blood flow measurements may also be obtained during the acute phase of treatment.

FOLLOW-UP. As part of this study, patients who are discharged from the hospital will be seen in follow-up in the Neurosurgery Clinic approximately once every three months for up to one year. The evaluations in the hospital and at follow-up include neurologic examination, tests concerning memory, speech, the ability to put things together, pay attention, solve problems, name objects, carry out requests to move small objects, and remember pictures and words. You (he/she) will be asked to answer questions concerning the injury and its effect on your (his/her) daily living. You (he/she) will have the choice of answering or not answering any question.

POSSIBLE RISKS. PEG-SOD has not produced any side effects in animals at doses 100 times higher than those planned for this study. Doses equal to those used in this study have been given to normal human volunteers with no adverse effects. No complications are therefore anticipated as a result of the use of this drug. However, unexpected problems such as allergic reactions could possibly occur and will be treated appropriately. Complications relating to surgery are the same as would occur with any neurosurgical procedure irrespective of this study. These include infection, re-bleeding, paralysis, and even death, among others. Other discomforts or risks associated with routine intensive care include localized discomfort or hematoma with needle sticks.

POSSIBLE BENEFITS. As stated earlier, this study is an effort to improve upon this the results from very serious injury. Every patient entering this study will be receiving at least one special therapy, and it is hoped that the survival rate and the extent of neurological recovery can be improved upon over what has been previously possible.

COMPENSATION. There will be no additional cost to the patient as a result of participating in this study. In the unlikely event of any injury occurring as a result of this study, I understand that neither Baylor College of Medicine, the Harris County Hospital District, Enzon, Incorporated, nor the US Department of Defense will be able to offer any financial compensation. However, you are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. By signing this consent form and participating in this study, the patient is not waiving or giving up any right he/she might have to seek recovery for damages caused by negligence or intentional misconduct of those conducting this program.

CONFIDENTIALITY. Careful records of this study will be maintained and may be reviewed by Baylor College of Medicine, the Food and Drug Administration, the Department of Defense, and Enzon, Incorporated, to ensure patient protection. All confidentiality will be maintained within the legal limits of the investigators. Patients' names will not be used in any public presentations or publications.

NON-PARTICIPATION. Participation in this study is voluntary; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you are free to withdraw from this study at any time without prejudice to your (or the patient's) future medical care. I can contact either Raj K. Narayan, M.D., Principal Investigator, or Claudia S. Robertson, M.D., Associate Investigator, for further information or concerns relating to this study and research-related injuries. They may be reached by telephone at 713-799-4696, or in writing at Department of Neurosurgery, Baylor College of Medicine, One Baylor Plaza, Houston, Texas, 77030.

I may contact Frank E. Smith, M.D., at the Baylor College of Medicine, One Baylor Plaza, Houston, Texas, 77030; telephone: 713-799-4760, for information about the rights of a research subject.

Signature of Patient's Next-of-Kin	Signature and Name of Witness
Relationship	Date and Time
Date and Time	

The University of Texas Medical Branch at Galveston

School of Medicine
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing

Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals

May 9, 1988

MEMORANDUM

TO: Howard M. Eisenberg, M.D./Harvey S. Levin, Ph.D.
Department of Surgery/Neurosurgery E17

FROM: E. Ray Stinson, Ph.D. Nancy Hammock
for Director of Sponsored Programs-Academic

SUBJECT: OSP #88-73 - Final Approval
"Development of Medical Adjunctive Treatment for Acute Penetrating Head Injury"

Having met the conditions set forth by the Institutional Review Board at its meeting of March 23, 1988, your research protocol is now approved. You may now proceed with your research project.

This protocol has been administratively approved by Dr. Yielding for the inclusion of nonconsenting subjects and a copy of that letter is attached for your files.

Attached are the revised subject consent forms with the date of IRB approval. Please use these copies of the revised consent forms with the IRB approval date and make additional copies as they are needed.

ERS/nh

Attachment: 4 Revised Consent Forms

The University of Texas Medical Branch at Galveston

School of Medicine
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing

Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals

May 9, 1988

M E M O R A N D U M

TO: Jack B. Alperin, M.D., Chairman
Pharmacy and Therapeutics Committee E63

FROM: E. Ray Stinson, Ph.D. Harvey Hammack
for Director of Sponsored Programs-Academic

SUBJECT: IRB Approved Protocol which Involves an Investigational Drug

The following protocol has been reviewed and approved by the Institutional Review Board on March 23, 1988. FINAL APPROVAL: May 9, 1988.

Principal Investigator: Howard M. Eisenberg, M.D./ OSP # 88-73
Harvey S. Levin, Ph.D.

Title: Professor and Chief/Professor

Department: Surgery/Division of Neurosurgery

Project Title: "Development of Medical Ajunctive Treatment for Acue Penetrating Head Injury"

IND Number and Drug: IND# 28,195 - PEG-Sod - Superoxide Dismutase (Enzon, Inc.)

The principal investigator will provide the Pharmacy Department with a copy of the research protocol and the investigational use material generated by the pharmaceutical company prior to beginning this study.

Please contact me if I can provide additional information or assistance.

ERS/nh

xc: Mr. E. Galvan, Pharmacy Department
Michael Newton, B.S. Pharm., R.Ph., Pharmacy Department
Principal Investigator

ARMY PENETRAING HEAD INJURY PROJECT

ADULT CONSENT

The University of Texas Medical Branch - Galveston

Superoxide Dismutase and Surgery in Very Severe Penetrating Head Injury

My next of kin has been asked to participate as a subject in the research project entitled "Development of Medical Adjunctive Treatment for Acute Penetrating Head Injury" under the direction of Howard M. Eisenberg, M.D. A copy of this consent form will be given to me (my next of kin).

My next of kin _____ has suffered a very severe penetrating injury of the brain. I understand that at present there are no specific therapies that have been proven to improve outcome from such injuries. The physicians at this institution are conducting a study in collaboration with the U.S. Department of Defense, Enzon Incorporated and 3 other major university hospitals.

The purpose of this study is to try to develop better treatments for this almost uniformly fatal condition. I am being asked to enroll my _____ (relationship) in this study.

The drug: After suffering a penetrating head injury, the brain can develop inflammation and swelling, resulting in further damage. A drug known as Superoxide Dismutase (PEG-SOD), which is a normal body protein, has been shown in animal studies to limit such damage. This drug has now become available to a few select trauma centers (including this hospital) for clinical trials, to assess its usefulness in humans. Although SOD is a normal body protein, it is categorized as an experimental drug by the Food and Drug Administration. My injured relative will be randomly assigned to receive either PEG-SOD or a placebo. Neither I, nor my physicians, will know whether the patient is receiving the drug or the placebo. In the unlikely event of an adverse reaction, the code can be broken to get this information. The patient will receive 2 doses of the drug or placebo (an inactive substance with no medical effects) intravenously on the first and fourth days after injury. It is important that the treatment is started as soon after the injury as possible.

Possible benefits: As stated earlier, very few patients with such severe head injuries survive. This study is an effort to improve upon this otherwise dismal prognosis. It is hoped that the survival rates can be improved upon and the extent of neurological recovery improved.

Possible risks: PEG-SOD has not produced any side effects in animals at doses 100 times higher than those planned for this study. Doses equal to those used in this study have been given to normal human volunteers with no adverse effects. No complications are therefore anticipated as a result of the use of this drug. However, unknown risks from allergic reactions could possibly occur and these will be treated appropriately. Complications relating to surgery are the same as would occur with any neurosurgical procedure irrespective of this study. These include infection, re-bleeding, paralysis and even death, amongst others. Other discomforts or risks associated with routine intensive care include localized discomfort or hematoma with needle sticks or insertion of catheters. Regardless of treatment rendered, there is always the possibility of long term survival in a severely disabled or vegetative state as a result of brain injury.

Surgery: There is no evidence that immediate surgery makes any difference to the outcome in patients with such severe penetrating brain injuries. In fact, experience has suggested that unless there is a large blood clot in the head, a patient with such a severe injury may be managed just as effectively with superficial closure of the scalp wound and nonsurgical intensive care with monitoring of pressure inside the head. Patients in this study will undergo immediate CT scans of the head. If a large blood clot is found along the bullet tract, the patient will be operated upon for removal of the blood clot. However, if no significant clot is seen, the patient will be randomly assigned to have either immediate brain surgery, or simple closure of the scalp wound. Both groups will have intracranial pressure monitors placed to allow for early treatment of increased pressure and will receive postoperative intensive care. Patients who were initially treated without extensive surgery may be operated upon at a later time if, in the judgement of the attending physician, there is a clear reason for doing so.

Blood glucose: There is some evidence from both animal and human studies that high levels of sugar in the blood can be harmful to the injured brain. In the present study, the patient's blood sugar will be carefully monitored and the levels will be maintained within normal limits as far as possible in all patients. Thus, all patients participating in this study will receive a special therapy regardless of which treatment arm they are selected for.

Intensive care: In the Neurosurgical Intensive Care Unit at The University of Texas Medical Branch, the patient will be carefully monitored and the best possible medical care will be rendered. Blood tests, CT scans and spinal fluid examinations will be done as part of standard care. A ventricular catheter or an alternate device will be inserted for monitoring intracranial pressure. Small samples of blood and spinal fluid [5 cc (1 teaspoon) of blood every 8 hours and, when possible, 1 cc of spinal fluid every 12 hours for 48 hours after each administration of the drug] will be collected for a few days for special tests. Because of indwelling catheters, additional needle sticks or procedures will generally not be necessary to obtain these samples.

Follow-up: As a part of this study, patients who are discharged from the hospital will be followed up in the Neurosurgery Clinic approximately once every 3 months for up to 1 year. The evaluations include neurological examinations, tests concerning memory, speech, the ability to put things together, pay attention, solve problems, name objects, carry out requests to move small objects, and remember pictures and words. You (he/she) will be asked to answer questions concerning the injury and its effect on your (his/her) daily living. You (he/she) will have the choice of answering or not answering any questions.

Compensation: There will be no additional cost to the patient as a result of participating in this study. In the unlikely event of any injury occurring as a result of this study, I understand that neither the University of Texas Medical Branch, Enzon Incorporated, or the U.S. Department of Defense will be able to offer any financial compensation. However, you are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. The patient or patient's insurance carrier will still be responsible for costs of hospitalization, including the routine CT scans done at discharge.

1. I understand that informed consent is required of all persons in this project.

2. The principal and alternate procedures, including the experimental procedures in this project, have been identified and explained to me in language that I can understand.

3. The risks and discomforts from the procedures have been explained to me.

4. The expected benefits from the procedures have been explained to me.

5. An offer has been made to answer any questions that I may have about these procedures. I may contact Dr. Howard M. Eisenberg, Principal Investigator at (409) 761-1500 or Ms. Barbara Turner at (409) 761-3965, Research Nurse, at the Division of Neurosurgery E-17, The University of Texas Medical Branch, Galveston, Texas 77550, for further information or concerns relating to this study or research related injuries. I may contact Dr. E. Ray Stinson, Director, Sponsored Programs-Academic at (409) 761-3482, Sponsored Programs-Academic, The University of Texas Medical Branch, Galveston, Texas 77550, if I have any questions regarding the rights of the research subject.

6. I have been told that participation in this study is voluntary, and I may stop my participation in this project at any time without prejudice or loss of any benefits to which I am otherwise entitled.

7. I have been told that The University of Texas Medical Branch at Galveston, like virtually all other universities in the United States, does not have a mechanism for compensation of the injured research subject. Therefore, I understand that I cannot look to

any such mechanism to receive financial remuneration for any such injuries resulting from my participation in this project. However, I understand I am authorized all necessary medical care for injury or disease which is the proximate result of my participation in this research.

8. Each patient has a right to privacy, and all information that is obtained in connection with this study that can be identified with this patient will remain confidential as far as possible within state and federal law. Information gained from this study that can be identified with my relative will be released to no one other than the investigators, my physician, Enzon, Inc., the U.S. Department of Defense and the United States Food and Drug Administration, which, through its regulatory powers may inspect records involving research participants. The results of this study may be published in scientific journals without identifying me by name.

I voluntarily agree that _____ may participate as a subject in the above named project.

_____ _____

Date Signature of Patient's Next of Kin

_____ _____

Signature of witness Relationship of Next of Kin to Subject

Using language that is understandable and appropriate, I have discussed this project and the eight items listed above with the subject's next of kin.

Date	Signature of Project Director or his Representative

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

OFFICE OF CHARITY HOSPITAL AT NEW ORLEANS

1532 Tulane Avenue

New Orleans, Louisiana 70140

(504) 568-2311
(Linc) 621-2311

EDWIN EDWARDS
GOVERNOR

SANDRA L. ROBINSON, M.D., M.P.H.
SECRETARY

March 29, 1988

M E M O R A N D U M

To: Michael E. Carey, M.D.
Department of Neurosurgery
LSU School of Medicine

From: Robert L. Marier, M.D. RM
Associate Medical Director

Re: Project Title: Army Penetrating Head Injury Project

Approval is given for this study providing that:

1. The study is approved by IRB and clinical departments involved.
2. There are no additional hospital days, or special tests.
3. All special medications will be furnished by you.

/bd

cc: Kathleen Kennedy, Ph.D. - Director, Pharmacy
Maureen Thomas, ART - Director, Medical Records
Director, IRB

DEPARTMENT OF HEALTH AND HUMAN RESOURCES
OFFICE OF CHARITY HOSPITAL AT NEW ORLEANS
1532 Tulane Avenue
New Orleans, Louisiana 70140
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/bd

cc: Kathleen Kennedy, Ph.D. - Director, Pharmacy
Maureen Thomas, ART - Director, Medical Records
Director, IRB

LOUISIANA STATE UNIVERSITY

MEDICAL CENTER

FROM: LSUMC Institutional Review Board

TO: Dr. Donna H. Ryan, Vice-Chancellor
for Clinical Affairs
LSU Medical Center

RE: Grant Application By: Michael E. Carey, M.D.

Entitled: Army Penetrating Head Injury Project

This is to document review of the above research proposal. In the judgement of this Board, the procedures delineated in said application conform to the pertinent DHHS and FDA rules and regulations regarding use to human subjects.

THE INVESTIGATOR agrees to report to the Committee any emergent problems, serious adverse reactions, or procedural changes that may affect the status of the investigation, and that no such change will be without Board Approval, except where necessary to eliminate apparent immediate hazards. The investigator also agrees to periodic review of this project by the Board at intervals appropriate to the degree of risk to assure that the new project is being conducted in compliance with the Board's understanding and recommendations.

Records regarding action of the Board, referable to said project, are on file in the Office of the Chairman.

Please note that other institutional approvals may be required before the study can be initiated.

DATE OF APPROVAL: March 14, 1988

Michael E Carey
Principal Investigator

DATE: 15 Mar 1988

Ron E. Gardner, M.P.H.
Chairman

DATE: 3/14/88

Revised 5/86

Tulane University Medical Center

Office of the Chancellor
1430 Tulane Avenue
New Orleans, Louisiana 70112
(504) 588-5295

TO INVESTIGATOR:

The Committee on Use of Human Subjects reviewed and approved the study listed in the enclosed letter of certification.

It is your responsibility to forward the enclosed certification of the Committee's review and approval to the granting agency.

If your study involves patients or facilities at Charity Hospital, Tulane Medical Center Hospital and Clinic and/or the Veterans Administration Hospital, it is your responsibility to inform the Medical Director of the institution(s) prior to initiating your research project. The Committee presumes, unless otherwise stated, that minors and mentally incompetent individuals are not to be enrolled in this study.

Sincerely,

Erna Bauer

Erna Bauer
Administrative Assistant
Committee on Use of Human Subjects

Enclosure

Robert C. Hastings, M.D., Ph.D.
Chairman

Juan J. L. Lertora, M.D., Ph.D.
Vice-Chairman

Oren B. Gum, Ph.D., M.D.
Alternate Vice-Chairman

Tulane University Medical Center

Office of the Chancellor
1430 Tulane Avenue
New Orleans, Louisiana 70112
(504) 588-5295

DATE March 4, 1988

COMMITTEE ON USE OF HUMAN SUBJECTS

This is to certify that the grant, contract or study entitled

ARMY PENETRATING HEAD INJURY PROJECT

Submitted by Michael Carey, M.D.
Donald Richardson, M.D.
Judith Hickey, R.N.

Title Co-Investigators

To ENZON, INC / U.S. ARMY

for consideration has been reviewed by the Committee and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequate methods of securing legally effective informed consent from these individuals and not involving undue risk in the light of the potential medical benefits to be derived therefrom.

This IRB is in compliance with the requirements in Part 56, Subchapter D, part 312 of the 21 Code of Federal Regulations, published January 27, 1981. This informed consent statement has been approved by the Committee

HUMAN SUBJECTS - REVIEWED - AT RISK - APPROVED February 25, 1988

Robert C. Hastings, MD, PhD/eb
Robert C. Hastings, M.D., Ph.D.

Chairman
Committee on Use of Human Subjects

GENERAL ASSURANCE NUMBER M1260

VOLUNTEER INFORMED CONSENT FORM SOD1 (GCS 3-5)
for the
ARMY PENETRATING HEAD INJURY PROJECT

LSU MEDICAL CENTER, CHNO, TULANE UNIV. MEDICAL CENTER

MICHAEL E. CAREY, M.D. 568-6123 (B)
NANCY L. ROGERS, M.D. 568-6120 (B)
JUDITH HICKEY, R.N. 568-6120 (B)
Any of the above may be contacted for questions related to this study

BACKGROUND AND OBJECTIVES:

You or your next of kin are being asked to participate in a multicenter research study with two objectives: 1) to determine the value of early surgery in the treatment of brain wounds and 2) to determine the value of low glucose treatment and the experimental drug Superoxide Dismutase(PEG-SOD) in the treatment of brain wounds. A copy of this consent form will be given to me/ my next of kin.

Although a brain operation is often the recommended treatment for patients with brain wounds, experience has suggested to us that patients with extremely severe wounds, such as your next of kin, may not able to tolerate extensive surgery well and may be more effectively treated with intensive supportive care and medications in the first few days after their injury as long as we can be sure that they do not have any large blood clots pressing on their brain. In this study, once we are certain that you or your of kin does not have such a blood clot, we will randomly select extremely severely injured patients to be treated with surgery within 24 hours or with intensive non-surgical care and drugs.

Recent research has also suggested that the brain's reaction to the injury, including inflammation and swelling, may be excessive and cause more damage over the first few days after the injury. Superoxide dismutase (SOD) is a normal enzyme or protein which helps to break down some of the harmful chemicals produced by injured tissue. In this study we will test the effects of providing extra amounts of this enzyme to the body to help reduce inflamation and swelling. Although SOD is a normal body protein, it is considered an experimental drug by the Food and Drug Administration. To help the SOD work it has been chemically attached to polyethylene glycol(PEG) and thus is known as PEG-SOD.

There is also some evidence that high levels of blood sugar may also be harmful to the injured brain. In this study we will specifically limit the administration of sugar

solutions.

INCLUSION AND EXCLUSION CRITERIA:

Those included in the study: patients who have sustained a gunshot wound to the brain within 24 hours of admission and are not brain dead.

Those excluded from the study: women of childbearing potential: individuals with known severe heart disease or other serious illness.

PROCEDURES TO BE FOLLOWED:

After emergency room entry, you or your next of kin will be randomly divided into two groups. You or your next of kin will receive either an intravenous infusion with PEG-SOD or a normal saline (salt water) infusion. You or your next of kin will also receive a second infusion of PEG-SOD or saline four days later. Unless it is absolutely necessary in the judgement of your doctors, neither you nor your doctor will know which group your next of kin is in. However, since we do not know the effect of extra amounts of this drug on the unborn child, women of child-bearing age will not be given PEG-SOD.

You or your next of kin will also receive a CAT scan as soon as possible. If you or your next of kin has a large blood clot pressing on the brain he (she) will receive an operation if recommended by their doctor. If you or your next of kin does not have a large blood clot he (she) will be placed in one of two groups by a randomization procedure. One group will undergo an immediate brain operation (within 24 hours after the injury), and the second group will undergo a simple superficial cleaning and closing of the wound. In the second group the brain operation will be delayed until 120 hours after the injury. You or your next of kin will then receive intensive care in the Neurosurgery Intensive Care Unit including antibiotics, monitoring, and low sugar solutions. At the end of five days, patients in the second group may undergo a brain operation if recommended by their doctors. If a large blood clot develops in you or your next of kin at any time after injury, he (she) will undergo an operation for its removal as recommended by his (her) doctor.

To our knowledge, no other experimental studies have been done to test the effectiveness of PEG-SOD or of deep brain operations in the treatment of severe brain wounds.

Your next of kin's condition will be carefully monitored and recorded throughout his or her hospitalization,

including specific blood tests, CAT scans, and other examinations which are standard in the care of such patients. The evaluation in the hospital and at followup include neurologic examination, tests concerning memory, speech, the ability to put things together, pay attention, solve problems, name objects, carry out requests to move small objects, and remember pictures and words. You (he/ she) will be asked to answer questions concerning the injury and its effect on your (his/ her) daily living. you (he/ she) will have the choice of answering or not answering any questions. They will be invited to return for followup visits at 1,3,6, and 12 months after injury.

BLOOD DRAWING STATEMENT:

In addition to the usual blood samples required for daily patient management, 23 additional blood samples will be taken to measure the level of PEG-SOD in the blood. Only 5 milliliters (a teaspoon) of blood will be required for each sample. When possible, the blood will be taken without "sticking" the patient in a vein. Blood samples will be taken prior to each treatment of PEG-SOD and every 8 hours for 2 days following each treatment. One sample per day will be collected on days 3 and 7 to 14 after the injury.

CEREBROSPINAL FLUID SAMPLE STATEMENT:

Brain or spinal fluid will periodically be withdrawn for analysis of brain or spinal fluid chemicals. When possible this fluid will be obtained from tubes already placed in the brain. 5 milliliters (teaspoon) of spinal fluid will be needed for each sample. When possible, samples will be collected at the time of surgery and every 12 hours following each treatment of PEG-SOD. If possible, one sample per day will be collected on days 3,7, and 8 after the injury. These samples will be collected from tubes already placed in the brain.

DURATION OF PARTICIPATION:

You or your next of kin will remain in the study for as long as he (she) is hospitalized and will be invited to return for followup at about 1,3,6, and 12 months after injury. Participation in the study will not change the period of hospitalization.

Treatment with PEG-SOD will be given in two intravenous infusions lasting about an hour each.

If you or your next of kin withdraws or is withdrawn from the study the he (she) will not be penalized and medical care will not be compromised.

FORSEEABLE RISKS OR DISCOMFORTS:

PEG-SOD has not produced any side effects in animals at doses 100 times higher than those planned for the study, or in normal human volunteers at the doses planned for the study. However unexpected problems such as an allergic reaction could possibly occur and will be treated appropriately. Complications relating to surgery are the same as would occur with the surgical procedure irrespective of this study. These include infection, rebleeding, paralysis, and even death, among others. Other discomforts or risks associated with routine intensive care include localized discomfort or hematoma with needle sticks or insertions of catheters.

YOU MUST UNDERSTAND THAT YOUR NEXT OF KIN HAS SUFFERED AN EXTREMELY SEVERE BRAIN WOUND, AND THAT HIS OR HER CHANCES FOR SURVIVAL WITH THE STANDARD TREATMENTS NOW AVAILABLE ARE VERY LOW. Regardless of the treatment rendered, there is always the possibility of long term survival in a severely disabled or vegetative state as a result of the brain injury.

POTENTIAL BENEFITS:

ONE INTENT OF THIS STUDY IS TO PROVIDE SOME TREATMENT BENEFIT TO ALL PATIENTS PARTICIPATING. WE EXPECT TO SEE THIS BENEFIT AS AN INCREASE IN THE PERCENTAGE OF PARTICIPANTS WHO SURVIVE THEIR INJURY. THERE CAN BE NO GUARANTEE THAT PARTICIPATION IN THIS STUDY WILL PROVIDE TREATMENT BENEFIT ESPECIALLY FOR THOSE HAVE RECEIVED AN EXTREMELY SEVERE BRAIN WOUND.

THE CHANCES FOR SURVIVAL AFTER AN EXTREMELY SEVERE BRAIN WOUND ARE STILL LOW.

CONFIDENTIALITY:

Research records of your participation in this study will be maintained by the principal investigator. These records may be reviewed by the Hospital Department of Clinical Investigation and the Institutional Review Board as well as the Food & Drug Administration, Department of Defense, or Enzon Inc. representatives as part of their responsibilities for insuring the protection of research volunteers. However confidentiality will be strictly maintained. You will not be identified by name in any publication or presentation resulting from this study.

CIRCUMSTANCES UNDER WHICH PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT:

Your participation may be terminated without your consent if health conditions or other conditions occur that might be dangerous or detrimental to you or your health or if military contingency requires it. Your participation will be terminated without your consent if the drug becomes unavailable from the drug study sponsor or if the study is cancelled by the sponsor.

SAFEGUARDS:

The condition of all study participants will be closely monitored and recorded. Most patients will be in the intensive care unit at the time that they receive the experimental drug. If there is any unusual reaction to the experimental treatment, the treatment will be stopped if recommended by your doctor.

In addition, the ongoing results of the study will be monitored by the company providing the drug and by the project monitoring committee. If there is any significant difference between treatments, and particularly if there is any evidence of an unsuspected harmful effect of the drug, the study may be stopped.

APPROXIMATE NUMBER OF SUBJECTS IN THE STUDY:

About 22 patients will be entered in this study at each of four University Medical Centers, for a total of 88 patients overall.

ALTERNATIVE PROCEDURES OR TREATMENTS:

Participation in this study is voluntary; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you are free to withdraw from this study at anytime without prejudice to your (or the patients') future medical care. If you decide not to participate in this study you will receive the standard surgical and/or intensive care treatment for penetrating head injured patients at this hospital.

UNFORSEEABLE RISKS TO SUBJECT:

Because the effect of PEG-SOD on the unborn child is unknown, women of childbearing age cannot receive this treatment.

ADDITIONAL COSTS THAT MAY RESULT FROM PARTICIPATION:

There is no additional cost to you for participation in this study. You will receive $50 per followup visit to compensate you for your participation in this study. Participation in this study will not result in any extra charges above and beyond those routinely incurred by patients with similar illnesses. In the unlikely event of any injury occuring as a result of this study, I understand that neither LSU, Charity Hospital, Orleans parish, Enzon Inc., nor the United States Department of Defense will be able to offer any financial compensation. However, you are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. By signing this consent form and participating in this study, the patient is not waiving or giving up any right he/ she might have to seek recovery for damages caused by negligence or intentional misconduct of those conducting this program.

SIGNIFICANT NEW FINDINGS:

Any significant new findings that develop during the study which could affect your willingness to continue particpation will be made available to you. The results of the research will be made available to you if you so desire.

INVESTIGATIONAL DRUG:

This study involves the use of an investigational drug called Superoxide dismutase(PEG-SOD). This means that the drug has not been approved by the Food and Drug Administration for commercial use, but has been approved for use in this study to determine its safety and effectiveness in the treatment of head injury.

WAIVER OF COMPENSATION FOR PRIVATE CITIZENS:

You agree that you will not be entitled to any compensation for your participation in the study (other than the $50 for each followup visit).

INFORMATION:

I understand that full information concerning the availability of compensation, treatment, or patient's rights can be obtained from the Office of M. Wayne Hurst, Ph. D., L.S.U. Medical Center, 1542 Tulane Avenue, New Orleans, Louisiana, (504) 568-4970.

The contact person for answers to questions about research and whom to contact in the event of a research related injury is Michael E. Carey, M.D., Principal Investigator; Department of Neurosurgery; Louisiana State University Medical Center; 1542 Tulane Avenue; New Orleans, LA 70112; (504) 568-6123.

SIGNATURES:

I agree to voluntarily participate in this project or to have my relative or guardee participate in this project:

Patient age 15-18yrs	Date
Patient age 19 or older	Date
Relative or Legal Guardian	Date
Witness	Date

I am unable to read, but this consent form has been explained to me by _____. I understand the information stated above and I willingly sign this consent form.

Patient age 15-18yrs	Date
Patient age 19 or older	Date
Relative or Legal Guardian	Date
Witness	Date

Questions:

1. I have been given an opportunity to ask all questions and all questions have been answered to my satisfaction.

2. I have been assured that all future questions arising in the course of this study will be answered.

_____ _____

Patient, Relative or Legal Guardian — Date

I have been given a copy of this consent form.

_____ _____

Patient, Relative or Legal Guardian — Date

VOLUNTEER INFORMED CONSENT FORM SOD2 (GCS 6-15)
for the
ARMY PENETRATING HEAD INJURY PROJECT

LSU MEDICAL CENTER, CHNO, TULANE UNIV. MEDICAL CENTER

MICHAEL E. CAREY, M.D. 568-6123 (B)
NANCY L. ROGERS, M.D. 568-6120 (B)
JUDITH HICKEY, R.N. 568-6120 (B)
Any of the above may be contacted for questions related to this study

BACKGROUND AND OBJECTIVES:

You or your next of kin are being asked to participate in a multicenter research study to determine the value of low glucose treatment and the experimental drug Superoxide Dismutase(PEG-SOD) in the treatment of brain wounds. A copy of this consent form will be given to me/ my next of kin.

Recent research has also suggested that the brain's reaction to the injury, including inflamation and swelling, may be excessive and cause more damage over the first few days after the injury. Superoxide dismutase (SOD) is a normal enzyme or protein which helps to break down some of the harmful chemicals produced by injured tissue. In this study we will test the effects of providing extra amounts of this enzyme to the body to help reduce inflamation and swelling. Although SOD is a normal body protein, it is considered an experimental drug by the Food and Drug Administration. To help the SOD work it has been chemically attached to polyethylene glycol(PEG) and thus is known as PEG-SOD.

There is also some evidence that high levels of blood sugar may also be harmful to the injured brain. In this study we will specifically limit the administration of sugar solutions.

INCLUSION AND EXCLUSION CRITERIA:

Those included in the study: patients who have sustained a gunshot wound to the brain within 24 hours of admission and are not brain dead.

Those excluded from the study: women of childbearing potential; individuals with known severe heart disease or other serious illness.

PROCEDURES TO BE FOLLOWED:

After emergency room entry, you or your next of kin will be randomly divided into two groups. You or your next of kin will receive either an intravenous infusion with PEG-SOD or a normal saline (salt water) infusion. You or your next of kin will also receive a second infusion of PEG-SOD or saline four days later. Unless it is absolutely necessary in the judgement of your doctors, neither you nor your doctor will know which group your next of kin is in. However, since we do not know the effect of extra amounts of this drug on the unborn child, women of child-bearing age will not be given PEG-SOD.

You or your next of kin will also receive a CAT scan as soon as possible. You or your next of kin may receive a brain operation to clean out the wound as recommended by their doctor. You or your next of kin will then receive intensive care in the Neurosurgery Intensive Care Unit including antibiotics, monitoring, and low sugar solutions. If a large blood clot develops in you or your next of kin at any time after injury, he (she) may undergo an operation for its removal as recommended by their doctor.

To our knowledge, no other experimental studies have been done to test the effectiveness of PEG-SOD in the treatment of head injury in humans.

Your next of kin's condition will be carefully monitored and recorded throughout his or her hospitalization, including specific blood tests, CAT scans, and other examinations which are standard in the care of such patients. The evaluation in the hospital and at follow up includes neurologic examination, tests concerning memory, speech, the ability to put things together, pay attention, solve problems, name objects, carry out requests to move small objects, and remember pictures and words. You (he/ she) will be asked to answer questions concerning the injury and its effect on your (his/ her) daily living. You (he/ she) will have the choice of answering or not answering any question. They will be invited to return for followup visits at 1,3,6, and 12 months after injury.

BLOOD DRAWING STATEMENT:

In addition to the usual blood samples required for daily patient management, 23 additional blood samples will be taken to measure the level of PEG-SOD in the blood. Only 5 milliliters (a teaspoon) of blood will be required for each sample. When possible, the blood will be taken without "sticking" the patient in a vein. Blood samples will be taken prior to each treatment of PEG-SOD and every 8 hours for 2 days following each treatment. One sample per day will be collected on days 3 and 7 to 14 after the injury.

CEREBROSPINAL FLUID SAMPLE STATEMENT:

Brain or spinal fluid will periodically be withdrawn for analysis of brain or spinal fluid chemicals. When possible this fluid will be obtained from tubes already placed in the brain. 5 milliliters (a teaspoon) of spinal fluid will be needed for each sample. When possible, samples will be collected at the time of surgery and every 12 hours following each treatment with PEG-SOD. If possible, one sample per day will be collected on days 3,7, and 8 after the injury. These samples will be collected from tubes already placed in the brain.

DURATION OF PARTICIPATION:

You or your next of kin will remain in the study for as long as he (she) is hospitalized and will be invited to return for followup at about 1,3,6, and 12 months after injury. Participation in the study will not change the period of hospitalization.

Treatment with PEG-SOD will be given in two intravenous infusions lasting about an hour each.

If you or your next of kin withdraws or is withdrawn from the study he (she) will not be penalized and medical care will not be compromised.

FORSEEABLE RISKS OR DISCOMFORTS:

PEG-SOD has not produced any side effects in animals at doses 100 times higher than those planned for the study, or in normal human volunteers at the doses planned for the study. We do not forsee any major adverse effects. However, PEG-SOD is an experimental drug and has not been used to treat brain injured persons before. However, unexpected problems such as an allergic reaction could possibly occur and will be treated appropriately. Complication relating to surgery are the same as would occur with the surgical procedure irrespective of this study. These include infection, rebleeding, paralysis, and even death, among others. Other discomforts or risks associated with routine intensive care include localized discomfort or hematoma with needle sticks or insertion of catheters.

POTENTIAL BENEFITS:

ONE INTENT OF THIS STUDY IS TO PROVIDE SOME TREATMENT BENEFIT TO ALL PATIENTS PARTICIPATING. WE EXPECT TO SEE THIS BENEFIT AS AN INCREASE IN THE PERCENTAGE OF PARTICIPANTS WHO SURVIVE THEIR INJURY. THERE CAN BE NO GUARANTEE THAT

PARTICIPATION IN THIS STUDY WILL PROVIDR TREATMENT BENEFIT ESPECIALLY FOR THOSE HAVE RECEIVED AN EXTREMELY SEVERE BRAIN WOUND. Regardless of the treatment rendered, there is always the possibility of long term survival in a severely disabled or vegetative state as a result of the brain injury.

CONFIDENTIALITY:

Research records of your participation in this study will be maintained by the principal investigator. These records may be reviewed by the Hospital Department of Clinical Investigation and the Institutional Review Board as well as the Food & Drug Administration, Department of Defense, or Enzon Inc. representatives as part of their responsibilities for insuring the protection of research volunteers. However confidentiality will be strictly maintained. You will not be identified by name in any publication or presentation resulting from this study.

CIRCUMSTANCES UNDER WHICH PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT:

Your participation may be terminated without your consent if health conditions or other conditions occur that might be dangerous or detrimental to you or your health or if military contingency requires it. Your participation will be terminated without your consent if the drug becomes unavailable from the drug study sponsor or if the study is cancelled by the sponsor.

SAFEGUARDS:

The condition of all study participants will be closely monitored and recorded. Most patients will be in the intensive care unit at the time that they receive the experimental drug. If there is any unusual reaction to the experimental treatment, the treatment will be stopped if recommended by your doctor.

In addition, the ongoing results of the study will be monitored by the company providing the drug and by the project monitoring committee. If there is any significant difference between treatments, and particularly if there is any evidence of an unsuspected harmful effect of the drug, the study may be stopped.

APPROXIMATE NUMBER OF SUBJECTS IN THE STUDY:

About 26 patients will be entered in this study at each of four University Medical Centers, for a total of 104 patients overall.

ALTERNATIVE PROCEDURES OR TREATMENTS:

Participation in this study is voluntary; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you are free to withdraw from this study at anytime without prejudice to your (or the patients') future medical care. If you decide not to participate in this study you will receive the standard surgical and/or intensive care treatment for penetrating head injured patients at this hospital.

UNFORSEEABLE RISKS TO SUBJECT:

Because the effect of PEG-SOD on the unborn child is unknown, women of childbearing age cannot receive this treatment.

ADDITIONAL COSTS THAT MAY RESULT FROM PARTICIPATION:

There is no additional cost to you for participation in this study. You will receive $50 per followup visit to compensate you for your participation in this study. Participation in this study will not result in any extra charges above and beyond those routinely incurred by patients with similar illnesses. In the unlikely event of any injury occuring as a result of this study, I understand that neither LSU, Charity Hospital, Orleans parish, Enzon Inc., nor the United States Department of Defense will be able to offer any financial compensation. However, you are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. By signing this consent form and participating in this study, the patient is not waiving or giving up any right he/ she might have to seek recovery for damages caused by negligence or intentional misconduct of those conducting this program.

SIGNIFICANT NEW FINDINGS:

Any significant new findings that develop during the study which could affect your willingness to continue particpation will be made available to you. The results of the research will be made available to you if you so desire.

INVESTIGATIONAL DRUG:

This study involves the use of an investigational drug called Superoxide dismutase(PEG-SOD). This means that the drug has not been approved by the Food and Drug Administration for commercial use, but has been approved for use in this study to determine its safety and effectiveness in the treatment of head injury.

WAIVER OF COMPENSATION FOR PRIVATE CITIZENS:

You agree that you will not be entitled to any compensation for your participation in the study (other than the $50 for each followup visit).

INFORMATION:

I understand that full information concerning the availability of compensation, treatment, or patient's rights can be obtained from the Office of M. Wayne Hurst, L.S.U. Medical Center, 1542 Tulane Avenue, New Orleans, LA, (504) 568-4970. The contact person for answers to questions about the research and whom to contact in the event of a research related injury is Michael E. Carey, M.D.; Principal Investigator; Department of Neurosurgery; Louisiana State University Medical Center; 1542 Tulane Avenue; New Orleans, LA 70112; (504) 568-6123.

SIGNATURES:

I agree to voluntarily participate in this project or to have my relative or guardee participate in this project:

_____	_____
Patient age 15-18yrs	Date
_____	_____
Patient age 19 or older	Date
_____	_____
Relative or Legal Guardian	Date
_____	_____
Witness	Date

I am unable to read, but this consent form has been explained to me by _____. I understand the information stated above and I willingly sign this consent form.

_____	_____
Patient age 15-18yrs	Date
_____	_____
Patient age 19 or older	Date
_____	_____
Relative or Legal Guardian	Date
_____	_____
Witness	Date

Questions:

1. I have been given an opportunity to ask all questions and all questions have been answered to my satisfaction.
2. I have been assured that all future questions arising in the course of this study will be answered.

_____ _____

Patient, Relative or Legal Guardian — Date

I have been given a copy of this consent form.

_____ _____

Patient, Relative or Legal Guardian — Date

VOLUNTEER INFORMED CONSENT FORM SOD1 (GCS 3-5)
for the
ARMY PENETRATING HEAD INJURY PROJECT

LSU MEDICAL CENTER, CHNO, TULANE UNIV. MEDICAL CENTER

MICHAEL E. CAREY, M.D. 568-6123 (B)
NANCY L. ROGERS, M.D. 568-6120 (B)
JUDITH HICKEY, R.N. 568-6120 (B)
Any of the above may be contacted for questions related to this study

BACKGROUND AND OBJECTIVES:

You or your next of kin are being asked to participate in a multicenter research study with two objectives: 1) to determine the value of early surgery in the treatment of brain wounds and 2) to determine the value of low glucose treatment and the experimental drug Superoxide Dismutase(PEG-SOD) in the treatment of brain wounds. A copy of this consent form will be given to me/ my next of kin.

Although a brain operation is often the recommended treatment for patients with brain wounds, experience has suggested to us that patients with extremely severe wounds, such as your next of kin, may not able to tolerate extensive surgery well and may be more effectively treated with intensive supportive care and medications in the first few days after their injury as long as we can be sure that they do not have any large blood clots pressing on their brain. In this study, once we are certain that you or your of kin does not have such a blood clot, we will randomly select extremely severely injured patients to be treated with surgery within 24 hours or with intensive non-surgical care and drugs.

Recent research has also suggested that the brain's reaction to the injury, including inflammation and swelling, may be excessive and cause more damage over the first few days after the injury. Superoxide dismutase (SOD) is a normal enzyme or protein which helps to break down some of the harmful chemicals produced by injured tissue. In this study we will test the effects of providing extra amounts of this enzyme to the body to help reduce inflamation and swelling. Although SOD is a normal body protein, it is considered an experimental drug by the Food and Drug Administration. To help the SOD work it has been chemically attached to polyethylene glycol(PEG) and thus is known as PEG-SOD.

There is also some evidence that high levels of blood sugar may also be harmful to the injured brain. In this study we will specifically limit the administration of sugar

solutions.

INCLUSION AND EXCLUSION CRITERIA:

Those included in the study: patients who have sustained a gunshot wound to the brain within 24 hours of admission and are not brain dead.

Those excluded from the study: women of childbearing potential; individuals with known severe heart disease or other serious illness.

PROCEDURES TO BE FOLLOWED:

After emergency room entry, you or your next of kin will be randomly divided into two groups. You or your next of kin will receive either an intravenous infusion with PEG-SOD or a normal saline (salt water) infusion. You or your next of kin will also receive a second infusion of PEG-SOD or saline four days later. Unless it is absolutely necessary in the judgement of your doctors, neither you nor your doctor will know which group your next of kin is in. However, since we do not know the effect of extra amounts of this drug on the unborn child, women of child-bearing age will not be given PEG-SOD.

You or your next of kin will also receive a CAT scan as soon as possible. If you or your next of kin has a large blood clot pressing on the brain he (she) will receive an operation if recommended by their doctor. If you or your next of kin does not have a large blood clot he (she) will be placed in one of two groups by a randomization procedure. One group will undergo an immediate brain operation (within 24 hours after the injury), and the second group will undergo a simple superficial cleaning and closing of the wound. In the second group the brain operation will be delayed until 120 hours after the injury. You or your next of kin will then receive intensive care in the Neurosurgery Intensive Care Unit including antibiotics, monitoring, and low sugar solutions. At the end of five days, patients in the second group may undergo a brain operation if recommended by their doctors. If a large blood clot develops in you or your next of kin at any time after injury, he (she) will undergo an operation for its removal as recommended by his (her) doctor.

To our knowledge, no other experimental studies have been done to test the effectiveness of PEG-SOD or of deep brain operations in the treatment of severe brain wounds.

Your next of kin's condition will be carefully monitored and recorded throughout his or her hospitalization.

including specific blood tests, CAT scans, and other examinations which are standard in the care of such patients. The evaluation in the hospital and at followup include neurologic examination, tests concerning memory, speech, the ability to put things together, pay attention, solve problems, name objects, carry out requests to move small objects, and remember pictures and words. You (he/ she) will be asked to answer questions concerning the injury and its effect on your (his/ her) daily living. you (he/ she) will have the choice of answering or not answering any questions. They will be invited to return for followup visits at 1,3,6, and 12 months after injury.

BLOOD DRAWING STATEMENT:

In addition to the usual blood samples required for daily patient management, 23 additional blood samples will be taken to measure the level of PEG-SOD in the blood. Only 5 milliliters (a teaspoon) of blood will be required for each sample. When possible, the blood will be taken without "sticking" the patient in a vein. Blood samples will be taken prior to each treatment of PEG-SOD and every 8 hours for 2 days following each treatment. One sample per day will be collected on days 3 and 7 to 14 after the injury.

CEREBROSPINAL FLUID SAMPLE STATEMENT:

Brain or spinal fluid will periodically be withdrawn for analysis of brain or spinal fluid chemicals. When possible this fluid will be obtained from tubes already placed in the brain. 5 milliliters (teaspoon) of spinal fluid will be needed for each sample. When possible, samples will be collected at the time of surgery and every 12 hours following each treatment of PEG-SOD. If possible, one sample per day will be collected on days 3,7, and 8 after the injury. These samples will be collected from tubes already placed in the brain.

DURATION OF PARTICIPATION:

You or your next of kin will remain in the study for as long as he (she) is hospitalized and will be invited to return for followup at about 1,3,6, and 12 months after injury. Participation in the study will not change the period of hospitalization.

Treatment with PEG-SOD will be given in two intravenous infusions lasting about an hour each.

If you or your next of kin withdraws or is withdrawn from the study the he (she) will not be penalized and medical care will not be compromised.

FORSEEABLE RISKS OR DISCOMFORTS:

PEG-SOD has not produced any side effects in animals at doses 100 times higher than those planned for the study, or in normal human volunteers at the doses planned for the study. However unexpected problems such as an allergic reaction could possibly occur and will be treated appropriately. Complications relating to surgery are the same as would occur with the surgical procedure irrespective of this study. These include infection, rebleeding, paralysis, and even death, among others. Other discomforts or risks associated with routine intensive care include localized discomfort or hematoma with needle sticks or insertions of catheters.

YOU MUST UNDERSTAND THAT YOUR NEXT OF KIN HAS SUFFERED AN EXTREMELY SEVERE BRAIN WOUND, AND THAT HIS OR HER CHANCES FOR SURVIVAL WITH THE STANDARD TREATMENTS NOW AVAILABLE ARE VERY LOW. Regardless of the treatment rendered, there is always the possibility of long term survival in a severely disabled or vegetative state as a result of the brain injury.

POTENTIAL BENEFITS:

ONE INTENT OF THIS STUDY IS TO PROVIDE SOME TREATMENT BENEFIT TO ALL PATIENTS PARTICIPATING. WE EXPECT TO SEE THIS BENEFIT AS AN INCREASE IN THE PERCENTAGE OF PARTICIPANTS WHO SURVIVE THEIR INJURY. THERE CAN BE NO GUARANTEE THAT PARTICIPATION IN THIS STUDY WILL PROVIDE TREATMENT BENEFIT ESPECIALLY FOR THOSE HAVE RECEIVED AN EXTREMELY SEVERE BRAIN WOUND.

THE CHANCES FOR SURVIVAL AFTER AN EXTREMELY SEVERE BRAIN WOUND ARE STILL LOW.

CONFIDENTIALITY:

Research records of your participation in this study will be maintained by the principal investigator. These records may be reviewed by the Hospital Department of Clinical Investigation and the Institutional Review Board as well as the Food & Drug Administration, Department of Defense, or Enzon Inc. representatives as part of their responsibilities for insuring the protection of research volunteers. However confidentiality will be strictly maintained. You will not be identified by name in any publication or presentation resulting from this study.

CIRCUMSTANCES UNDER WHICH PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT:

Your participation may be terminated without your consent if health conditions or other conditions occur that might be dangerous or detrimental to you or your health or if military contingency requires it. Your participation will be terminated without your consent if the drug becomes unavailable from the drug study sponsor or if the study is cancelled by the sponsor.

SAFEGUARDS:

The condition of all study participants will be closely monitored and recorded. Most patients will be in the intensive care unit at the time that they receive the experimental drug. If there is any unusual reaction to the experimental treatment, the treatment will be stopped if recommended by your doctor.

In addition, the ongoing results of the study will be monitored by the company providing the drug and by the project monitoring committee. If there is any significant difference between treatments, and particularly if there is any evidence of an unsuspected harmful effect of the drug, the study may be stopped.

APPROXIMATE NUMBER OF SUBJECTS IN THE STUDY:

About 22 patients will be entered in this study at each of four University Medical Centers, for a total of 88 patients overall.

ALTERNATIVE PROCEDURES OR TREATMENTS:

Participation in this study is voluntary; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you are free to withdraw from this study at anytime without prejudice to your (or the patients') future medical care. If you decide not to participate in this study you will receive the standard surgical and/or intensive care treatment for penetrating head injured patients at this hospital.

UNFORSEEABLE RISKS TO SUBJECT:

Because the effect of PEG-SOD on the unborn child is unknown, women of childbearing age cannot receive this treatment.

ADDITIONAL COSTS THAT MAY RESULT FROM PARTICIPATION:

There is no additional cost to you for participation in this study. You will receive $50 per followup visit to compensate you for your participation in this study. Participation in this study will not result in any extra charges above and beyond those routinely incurred by patients with similar illnesses. In the unlikely event of any injury occuring as a result of this study, I understand that neither Tulane University, Charity Hospital, Orleans parish, Enzon Inc., nor the United States Department of Defense will be able to offer any financial compensation. However, you are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. By signing this consent form and participating in this study, the patient is not waiving or giving up any right he/ she might have to seek recovery for damages caused by negligence or intentional misconduct of those conducting this program.

SIGNIFICANT NEW FINDINGS:

Any significant new findings that develop during the study which could affect your willingness to continue participation will be made available to you. The results of the research will be made available to you if you so desire.

INVESTIGATIONAL DRUG:

This study involves the use of an investigational drug called Superoxide dismutase(PEG-SOD). This means that the drug has not been approved by the Food and Drug Administration for commercial use, but has been approved for use in this study to determine its safety and effectiveness in the treatment of head injury.

WAIVER OF COMPENSATION FOR PRIVATE CITIZENS:

You agree that you will not be entitled to any compensation for your participation in the study (other than the $50 for each followup visit).

INFORMATION:

I understand that full information concerning the availability of compensation, treatment, or patient's rights can be obtained from the Office of the Dean, 1430 Tulane Avenue, New Orleans, Louisiana, (504) 588-5462.

The contact person for answers to questions about research and whom to contact in the event of a research related injury is Michael E. Carey, M.D., Principal Investigator; Department of Neurosurgery; Louisiana State University Medical Center; 1542 Tulane Avenue; New Orleans, LA 70112; (504) 568-6123.

SIGNATURES:

I agree to voluntarily participate in this project or to have my relative or guardee participate in this project:

Patient age 15-18yrs	Date
Patient age 19 or older	Date
Relative or Legal Guardian	Date
Witness	Date

I am unable to read, but this consent form has been explained to me by _____. I understand the information stated above and I willingly sign this consent form.

Patient age 15-18yrs	Date
Patient age 19 or older	Date
Relative or Legal Guardian	Date
Witness	Date

Questions:

1. I have been given an opportunity to ask all questions and all questions have been answered to my satisfaction.

2. I have been assured that all future questions arising in the course of this study will be answered.

_____ _____

Patient, Relative or Legal Guardian — Date

I have been given a copy of this consent form.

_____ _____

Patient, Relative or Legal Guardian — Date

VOLUNTEER INFORMED CONSENT FORM SOD2 (GCS 6-15)
for the
ARMY PENETRATING HEAD INJURY PROJECT

LSU MEDICAL CENTER, CHNO, TULANE UNIV. MEDICAL CENTER

MICHAEL E. CAREY, M.D. 568-6123 (B)
NANCY L. ROGERS, M.D. 568-6120 (B)
JUDITH HICKEY, R.N. 568-6120 (B)
Any of the above may be contacted for questions related to this study

BACKGROUND AND OBJECTIVES:

You or your next of kin are being asked to participate in a multicenter research study to determine the value of low glucose treatment and the experimental drug Superoxide Dismutase(PEG-SOD) in the treatment of brain wounds. A copy of this consent form will be given to me/ my next of kin.

Recent research has also suggested that the brain's reaction to the injury, including inflamation and swelling, may be excessive and cause more damage over the first few days after the injury. Superoxide dismutase (SOD) is a normal enzyme or protein which helps to break down some of the harmful chemicals produced by injured tissue. In this study we will test the effects of providing extra amounts of this enzyme to the body to help reduce inflamation and swelling. Although SOD is a normal body protein, it is considered an experimental drug by the Food and Drug Administration. To help the SOD work it has been chemically attached to polyethylene glycol(PEG) and thus is known as PEG-SOD.

There is also some evidence that high levels of blood sugar may also be harmful to the injured brain. In this study we will specifically limit the administration of sugar solutions.

INCLUSION AND EXCLUSION CRITERIA:

Those included in the study: patients who have sustained a gunshot wound to the brain within 24 hours of admission and are not brain dead.

Those excluded from the study: women of childbearing potential; individuals with known severe heart disease or other serious illness.

PROCEDURES TO BE FOLLOWED:

After emergency room entry, you or your next of kin will be randomly divided into two groups. You or your next of kin will receive either an intravenous infusion with PEG-SOD or a normal saline (salt water) infusion. You or your next of kin will also receive a second infusion of PEG-SOD or saline four days later. Unless it is absolutely necessary in the judgement of your doctors, neither you nor your doctor will know which group your next of kin is in. However, since we do not know the effect of extra amounts of this drug on the unborn child, women of child-bearing age will not be given PEG-SOD.

You or your next of kin will also receive a CAT scan as soon as possible. You or your next of kin may receive a brain operation to clean out the wound as recommended by their doctor. You or your next of kin will then receive intensive care in the Neurosurgery Intensive Care Unit including antibiotics, monitoring, and low sugar solutions. If a large blood clot develops in you or your next of kin at any time after injury, he (she) may undergo an operation for its removal as recommended by their doctor.

To our knowledge, no other experimental studies have been done to test the effectiveness of PEG-SOD in the treatment of head injury in humans.

Your next of kin's condition will be carefully monitored and recorded throughout his or her hospitalization, including specific blood tests, CAT scans, and other examinations which are standard in the care of such patients. The evaluation in the hospital and at follow up includes neurologic examination, tests concerning memory, speech, the ability to put things together, pay attention, solve problems, name objects, carry out requests to move small objects, and remember pictures and words. You (he/ she) will be asked to answer questions concerning the injury and its effect on your (his/ her) daily living. You (he/ she) will have the choice of answering or not answering any question. They will be invited to return for followup visits at 1,3,6, and 12 months after injury.

BLOOD DRAWING STATEMENT:

In addition to the usual blood samples required for daily patient management, 23 additional blood samples will be taken to measure the level of PEG-SOD in the blood. Only 5 milliliters (a teaspoon) of blood will be required for each sample. When possible, the blood will be taken without "sticking" the patient in a vein. Blood samples will be taken prior to each treatment of PEG-SOD and every 8 hours for 2 days following each treatment. One sample per day will be collected on days 3 and 7 to 14 after the injury.

CEREBROSPINAL FLUID SAMPLE STATEMENT:

Brain or spinal fluid will periodically be withdrawn for analysis of brain or spinal fluid chemicals. When possible this fluid will be obtained from tubes already placed in the brain. 5 milliliters (a teaspoon) of spinal fluid will be needed for each sample. When possible, samples will be collected at the time of surgery and every 12 hours following each treatment with PEG-SOD. If possible, one sample per day will be collected on days 3,7, and 8 after the injury. These samples will be collected from tubes already placed in the brain.

DURATION OF PARTICIPATION:

You or your next of kin will remain in the study for as long as he (she) is hospitalized and will be invited to return for followup at about 1,3,6, and 12 months after injury. Participation in the study will not change the period of hospitalization.

Treatment with PEG-SOD will be given in two intravenous infusions lasting about an hour each.

If you or your next of kin withdraws or is withdrawn from the study he (she) will not be penalized and medical care will not be compromised.

FORSEEABLE RISKS OR DISCOMFORTS:

PEG-SOD has not produced any side effects in animals at doses 100 times higher than those planned for the study, or in normal human volunteers at the doses planned for the study. We do not forsee any major adverse effects. However, PEG-SOD is an experimental drug and has not been used to treat brain injured persons before. However, unexpected problems such as an allergic reaction could possibly occur and will be treated appropriately. Complication relating to surgery are the same as would occur with the surgical procedure irrespective of this study. These include infection, rebleeding, paralysis, and even death, among others. Other discomforts or risks associated with routine intensive care include localized discomfort or hematoma with needle sticks or insertion of catheters.

POTENTIAL BENEFITS:

ONE INTENT OF THIS STUDY IS TO PROVIDE SOME TREATMENT BENEFIT TO ALL PATIENTS PARTICIPATING. WE EXPECT TO SEE THIS BENEFIT AS AN INCREASE IN THE PERCENTAGE OF PARTICIPANTS WHO SURVIVE THEIR INJURY. THERE CAN BE NO GUARANTEE THAT

PARTICIPATION IN THIS STUDY WILL PROVIDE TREATMENT BENEFIT ESPECIALLY FOR THOSE HAVE RECEIVED AN EXTREMELY SEVERE BRAIN WOUND. Regardless of the treatment rendered, there is always the possibility of long term survival in a severely disabled or vegetative state as a result of the brain injury.

CONFIDENTIALITY:

Research records of your participation in this study will be maintained by the principal investigator. These records may be reviewed by the Hospital Department of Clinical Investigation and the Institutional Review Board as well as the Food & Drug Administration, Department of Defense, or Enzon Inc. representatives as part of their responsibilities for insuring the protection of research volunteers. However confidentiality will be strictly maintained. You will not be identified by name in any publication or presentation resulting from this study.

CIRCUMSTANCES UNDER WHICH PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT:

Your participation may be terminated without your consent if health conditions or other conditions occur that might be dangerous or detrimental to you or your health or if military contingency requires it. Your participation will be terminated without your consent if the drug becomes unavailable from the drug study sponsor or if the study is cancelled by the sponsor.

SAFEGUARDS:

The condition of all study participants will be closely monitored and recorded. Most patients will be in the intensive care unit at the time that they receive the experimental drug. If there is any unusual reaction to the experimental treatment, the treatment will be stopped if recommended by your doctor.

In addition, the ongoing results of the study will be monitored by the company providing the drug and by the project monitoring committee. If there is any significant difference between treatments, and particularly if there is any evidence of an unsuspected harmful effect of the drug, the study may be stopped.

APPROXIMATE NUMBER OF SUBJECTS IN THE STUDY:

About 26 patients will be entered in this study at each of four University Medical Centers, for a total of 104 patients overall.

ALTERNATIVE PROCEDURES OR TREATMENTS:

Participation in this study is voluntary; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you are free to withdraw from this study at anytime without prejudice to your (or the patients') future medical care. If you decide not to participate in this study you will receive the standard surgical and/or intensive care treatment for penetrating head injured patients at this hospital.

UNFORSEEABLE RISKS TO SUBJECT:

Because the effect of PEG-SOD on the unborn child is unknown, women of childbearing age cannot receive this treatment.

ADDITIONAL COSTS THAT MAY RESULT FROM PARTICIPATION:

There is no additional cost to you for participation in this study. You will receive $50 per followup visit to compensate you for your participation in this study. Participation in this study will not result in any extra charges above and beyond those routinely incurred by patients with similar illnesses. In the unlikely event of any injury occuring as a result of this study, I understand that neither Tulane University, Charity Hospital, Orleans parish, Enzon Inc., nor the United States Department of Defense will be able to offer any financial compensation. However, you are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. By signing this consent form and participating in this study, the patient is not waiving or giving up any right he/ she might have to seek recovery for damages caused by negligence or intentional misconduct of those conducting this program.

SIGNIFICANT NEW FINDINGS:

Any significant new findings that develop during the study which could affect your willingness to continue particpation will be made available to you. The results of the research will be made available to you if you so desire.

INVESTIGATIONAL DRUG:

This study involves the use of an investigational drug called Superoxide dismutase(PEG-SOD). This means that the drug has not been approved by the Food and Drug Administration for commercial use, but has been approved for use in this study to determine its safety and effectiveness in the treatment of head injury.

WAIVER OF COMPENSATION FOR PRIVATE CITIZENS:

You agree that you will not be entitled to any compensation for your participation in the study (other than the $50 for each followup visit).

INFORMATION:

I understand that full information concerning the availability of compensation, treatment, or patient's rights can be obtained from the Office of the Dean, 1430 Tulane Avenue, New Orleans, Louisiana 70112, (504) 588-5462.

The contact person for answers to questions about the research and whom to contact in the event of a research related injury is Michael E. Carey, M.D.; Principal Investigator; Department of Neurosurgery; Louisiana State University Medical Center; 1542 Tulane Avenue; New Orleans, LA 70112; (504) 568-6123.

SIGNATURES:

I agree to voluntarily participate in this project or to have my relative or guardee participate in this project:

_____	_____
Patient age 15-18yrs	Date
_____	_____
Patient age 19 or older	Date
_____	_____
Relative or Legal Guardian	Date
_____	_____
Witness	Date

I am unable to read, but this consent form has been explained to me by _____. I understand the information stated above and I willingly sign this consent form.

_____	_____
Patient age 15-18yrs	Date
_____	_____
Patient age 19 or older	Date
_____	_____
Relative or Legal Guardian	Date
_____	_____
Witness	Date

Questions:

1. I have been given an opportunity to ask all questions and all questions have been answered to my satisfaction.
2. I have been assured that all future questions arising in the course of this study will be answered.

_____ _____

Patient, Relative or Legal Guardian — Date

I have been given a copy of this consent form.

_____ _____

Patient, Relative or Legal Guardian — Date

Virginia Commonwealth University

COMMITTEE ON THE CONDUCT OF HUMAN RESEARCH
Sanger Hall 1-020 Box 568 786-0868

Date: March 23, 1988

To: Harold Young, M.D.
Neurosurgery
Box 631

From: Robert L. Campbell, DDS, Chairman
Committee on the Conduct of Human Research

Re: CCHR Protocol: 8803-2I
PEG-Superoxide Dismutase in the mangement of moderate penetrating head injury (SOD-606).

Approval Date: March 23, 1988

The Committee on the Conduct of Human Research of VCU reviewed and approved the subject investigation and the appropriate consent form.

PLEASE NOTE:

1. Informed, written consent is required of each human subject or his legally qualified guardian or next-of-kin, unless specifically excluded.

2. Any deviation from the above named protocol, or the identification of unanticipated problems which may involve risk to subjects, must be reported to this Committee for review and approval.

3. Your study is subject to continued surveillance by this Committee, and it will be reviewed periodically. The next review is scheduled for March 1, 1989. At that time you must make available to the Committee a roster of all subjects, a copy of the most recent consent form and a summary of the results obtained, especially any adverse or unexpected effects.

4. All requests for information related to this investigation must include the exact title and the investigator's name(s).

5. If this protocol is used in a sponsored program proposal, the approval date and protocol number should be written on the Sponsored Programs internal approval form.

6. If this protocol is a drug study, all drugs are to be dispensed by the Investigational Drug Pharmacy. A copy of the CCHR approved protocol must be submitted to the Pharmacy. Contact the Investigational Drug Pharmacy at extension 6-0854.

PEG-SUPEROXIDE DISMUTASE IN THE MANAGEMENT OF MODERATE PENETRATING HEAD INJURY

Principal Investigator:	Harold F. Young, M. D.
Co-Investigators:	John D. Ward, M. D.
	Anthony Marmarou, Ph.D.
Department:	Neurosurgery
Sponsors:	U.S. Army Medical Research and Development Command
	Enzon, Inc., Plainfield, New Jersey
Period of Study:	2/1/88 to 2/1/91
Hospital Involved:	Medical College of Virginia Virginia Commonwealth University
Outline of Proposal:	Please refer to next page

Harold F. Young
Principal Investigator

May 4, 1988
Date

Harold F. Young
Division Chairman

May 4 1988
Date

Virginia Commonwealth University

Committee on the Conduct of Human Research
Sanger 1 - 020 786-0868 Box 568

Date: March 23, 1988

To: Harold Young, M.D.
Neurosurgery
Box 631

From: Robert L. Campbell, DDS, Chairman
Committee on the Conduct of Human Research

CCHR Protocol # 8803-2H
Surgery and PEG-Superoxide Dismutase in the management of very severe penetrating head injury. (SOD-605)

Approval Date: March 23, 1988

The Committee on the Conduct of Human Research of Virginia Commonwealth University reviewed and approved the subject investigation and the appropriate consent form.

PLEASE NOTE:

1. Informed, written consent is required of each human subject or his legally qualified guardian or next-of-kin, unless specifically excluded.

2. Any deviation from the above named protocol, or the identification of unanticipated problems which may involve risk to subjects, must be reported to this Committee for review and approval.

3. Your study is subject to continued surveillance by this Committee, and it will be reviewed periodically. The next review is scheduled for March 1, 1989. At that time you must make available to the Committee a roster of all subjects, a copy of the most recent consent form and a summary of the results obtained, especially any adverse or unexpected effects.

4. All requests for information related to this investigation must include the exact title and the investigator's name(s).

5. If this protocol is used in a sponsored program proposal, the approval date and protocol number should be written on the Sponsored Programs internal approval form.

6. If this protocol is a drug study, all drugs are to be dispensed by the Investigational Drug Pharmacy. A copy of the CCHR approved protocol must be submitted to the Pharmacy. Contact the Investigational Drug Pharmacy at extension 6-0854.

PEG-SUPEROXIDE DISMUTASE IN THE MANAGEMENT OF

VERY SEVERE PENETRATING HEAD INJURY

Principal Investigator:	Harold F. Young, M. D.
Co-Investigators:	John D. Ward, M. D.
	Anthony Marmarou, Ph.D.
Department:	Neurosurgery
Sponsors:	U.S. Army Medical Research and Development Command
	Enzon, Inc., Plainfield, New Jersey
Period of Study:	2/1/88 to 2/1/91
Hospital Involved:	Medical College of Virginia Virginia Commonwealth University
Outline of Proposal:	Please refer to next page

Harold F. Young
Principal Investigator

May 4 1988
Date

Harold F. Young
Division Chairman

May 4 1988
Date

ARMY PENETRATING HEAD INJURY PROJECT

SUPEROXIDE DISMUTASE AND SURGERY IN VERY SEVERE PENETRATING HEAD INJURY

CONSENT FOR PARTICIPATION IN A RESEARCH STUDY
Medical College of Virginia/Virginia Commonwealth University

My next-of-kin, _____, has suffered a very severe penetrating injury of the brain. I understand that at present there are no specific therapies that have been proven to improve outcome from such injuries. In fact, data from various major trauma centers has shown that virtually all patients with such serious brain injuries die, and the few that survive are usually severely disabled or vegetative. The physicians at this hospital are conducting a study in collaboration with the U.S. Department of Defense, Enzon, Incoprorated, and three other major university hospitals, to try and develop better treatments for this almost uniformly fatal condition. I am being asked to enroll my _____ (relationship) in this study. A copy of this consent form will be given to me/my next of kin.

The Drug: After suffering a penetrating head injury, the brain can develop inflammation and swelling, resulting in further damage. A drug known as Superoxide Dismutase (PEG-SOD), which is a normal body protein has been shown in animal studies to effectively limit such damage. PEG (monomethoxy-polyethylene glycol) is a nontoxic substance used to prolong the effects of SOD. This drug has now become available to a few select trauma centers (including this hospital) for clinical trials, to assess its usefulness in humans. Although SOD is a normal body protein, it is categorized as an experimental drug by the Food and Drug Administration.

Surgery: There is no evidence that immediate surgery makes any difference to the outcome in patients with such severe penetrating brain injuries, unless there is a large blood clot in the head. Patients in this study will undergo immediate CT scans of the head. If a large blood clot is found along the bullet tract, the patient will be operated upon for removal of the blood clot.

Risks, Inconveniences and Discomforts

Possible Risks: PEG-SOD has not produced any side effects in animals at doses 100 times higher than those planned for this study. Doses equal to those used in this study have been given to normal human volunteers with no adverse effects. No complications are therefore anticipated. However, unexpected problems such as allergic reactions could possibly occur and will be treated appropriately. Complications relating to surgery are the same as would occur with the surgical procedure irrespective of this study. These include infection, re-bleeding, paralysis and even death. Regardless of treatment rendered, there is always the possibility of long-term survival in a severely disabled or vegetative state as a result of the brain injury.

Randomization: My relative will be randomly assigned to receive either PEG-SOD or a placebo (an inactive substance). Neither I, nor the physicians, will know whether the patient is receiving the drug or the placebo. In the unlikely event of an adverse reaction, the code can be broken to get this information. The patient will receive two doses of the drug or placebo intravenously on the first and fourth day after injury. It is important that the treatment is started as soon

after the injury as possible. Once the CT scan has been read if no significant clot is seen, the patient will be randomly assigned to have either surgery within 24 hours of injury, or simple closure of the scalp wound. Both groups will have intracranial pressure monitors placed to allow for early treatment of increased pressure and will receive postoperative intensive care. Patients who were initially treated without extensive surgery may be operated upon at a later time if, in the judgement of the attending physician, there is a clear reason for doing so.

Intensive Care: The Neurosurgical Intensive Care Unit at the Medical College of Virginia is one of the most advanced neurotrauma units in the country. In the NSICU the patient will be carefully monitored and the best possible medical care will be rendered. Blood tests, CT scans and spinal fluid examinations will be done as part of standard care. A ventricular catheter or an alternate device will be inserted for monitoring intracranial pressure. Small samples of blood and spinal fluid (less than a total of 3 tablespoons per day) will be collected for a few days for special tests. These special tests are for determination of SOD level within the body. Blood samples will be done every eight hours for two days following each injection, one sample per day will be required on Day 3 and Days 7 to 14. Other discomforts or risks associated with routine intensive care include localized discomfort or hematoma with needle sticks or insertion of catheters. However, because of indwelling catheters, additional needle sticks will generally not be necessary to obtain these samples.

Follow-up: As part of this study, patients who are discharged from the hospital will be seen in follow-up in the Neurosurgery Clinic approximately once every three months for up to a year. These evaluations include neurologic examination, tests concerning memory, speech, the ability to put things together, pay attention, solve problems, name objects, carry out requests to move small objects, remember pictures and words. He/she will be asked to answer questions concerning the injury and of its effects on his/her daily living. He/she will have the choice of answering or not answering any questions. This follow-up may represent some inconvenience to the patient. All attempts will be made to work around the patient's schedule.

Pregnancy: Not applicable. All females of childbearing potential are excluded, unless they are surgically sterile or postmenopausal.

Possible Benefits: As stated earlier, very few patients with such severe head injuries survive. This study is an effort to improve upon this otherwise dismal prognosis. Since every patient entering this study will be receiving at least one (1) special therapy, it is hoped that the survival rates can be improved upon and the extent of neurological recovery improved.

Alternative Therapy: If you do not wish to have the patient participate, routine care normally administered to head injured patients will be carried out, without being entered in this drug study.

Research Related Injury and Cost of Participation: All the medical costs will still be the patient's responsibility and be billed in a routine fashion, but there will be no additional cost to the patient as a result of participating in this study. I understand that in the unlikely event of any physical and/or mental injury resulting from my participation of this research project, Virginia Commonwealth University, Enzon, Incorporated, or the U.S. Department of Defense will not be able to offer any financial compensation. However, my relative is authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. A payment of $50.00 will be offered for each visit to those patients returning for follow-up neuropsychological testing.

Confidentiality: Careful records of this study will be maintained and may be reviewed by the Medical College of Virginia, the Food and Drug Administration, the Department of Defense, and Enzon, Incorporated, to ensure patient protection. All confidentiality will be maintained within the legal limits of the investigators. Patient's names will not be used in any public presentations or publications.

Withdrawal: Participation in this study is voluntary; refusal to participate will involve no penalty or loss of benefit to which my relative is entitled and I am free to withdraw from this study at any time without prejudice to the future medical care of the patient. I can contact Harold F. Young, M.D. (principal investigator), or John D. Ward, M.D. (associate investigator) at (804) 786-9165 or Box 631, MCV Station, Richmond, Virginia 23298-0631 for further information and research related injuries concerning this study. I may contact them after regular hours by calling the hospital at (804) 786-0951 and asking for the neurosurgery resident on call. Robert Campbell, M.D. may be reached at (804) 786-0868 for any questions concerning the rights of the research subject.

By signing this consent form and participating in this study, my relative is not waiving or giving up any rights that he/she might have to seek recovery for damages caused by negligence or intentional misconduct of those conducting this program.

Signature of Patient's Next-of-Kin	Signature and name of witness
Relationship	Date and Time
Date and Time	

ARMY PENETRATING HEAD INJURY PROJECT

SUPEROXIDE DISMUTASE IN MODERATE PENETRATING HEAD INJURIES

CONSENT FOR PARTICIPATION IN RESEARCH STUDY
Medical College of Virginia/Virginia Commonwealth University

I (or my next-of-kin) _____ have (has) suffered a serious penetrating head injury of the brain. I understand that at present there are no specific therapies that have been proven to improve outcome from such injuries. My physicians are conducting a study in collaboration with the U.S. Department of Defense, Enzon, Incorporated and three other major university hospitals, to try and develop better treatments for the condition. I am being asked to participate in this study. A copy of this consent form will be given to me/my next of kin.

The drug: After suffering a penetrating head injury, the brain can develop inflammation and swelling, resulting in further damage. A drug known as Superoxide Dismutase (PEG-SOD), which is a normal body protein, has been shown in animal studies to effectively limit such damage. PEG (monomethoxy-polyethylene glycol) is a non-toxic substance used to prolong the effects of SOD. This drug has now become available to four major trauma centers (including this hospital) for clinical trials, to assess its usefulness in humans. Although SOD is a normal body protein, it is categorized as an experimental drug by the Food and Drug Administration.

Surgery: All patients in this study will undergo immediate CT scans of the head and the appropriate operation will be performed for debridement of the bullet tract and closure of the scalp wound. Patients who are unable to follow simple commands as a result of their injuries will also receive intracranial pressure monitors. These will be left in place for a few days in order to guide treatment of the intracranial pressure.

Risks, Inconveniences and Discomforts

Possible risks: PEG-SOD has not produced any side effects in animals at doses 100 times higher than those planned for this study. Doses equal to those used in this study have been given to normal human volunteers with no adverse effects. No complications are therefore anticipated as a result of the use of this drug. However unexpected problems such as allergic reactions could possibly occur and will be treated appropriately.

Randomization: I (or my injured relative) have (has) been assigned to receive either PEG-SOD or a placebo (an inactive substance) based on random selection. Neither I, nor my physicians, will know whether the patient is receiving the drug or the placebo. In the unlikely event of an adverse reaction, the code can be broken in order to obtain this information. The patient will receive two doses of the drug or placebo intravenously on the first and fourth day after injury. It is important that the treatment is started as soon after the injury as possible. Complications relating to surgery are the same as would occur with any neurosurgical procedure irrespective of this study. These include infection, re-bleeding, paralysis and even death. Regardless of treatment rendered, there is always the possibility of long-term survival in a severely disabled or vegetative state as a result of the brain injury.

Intensive Care: The Neurosurgical Intensive Care Unit at the Medical College of Virginia is one of the most advanced neurotrauma units in the country. In the NSICU the patient will be carefully monitored and the best possible medical care will be rendered. Blood tests, CT scans and spinal fluid examinations will be done as part of standard care. Small samples of blood and spinal fluid (less than a total of three tablespoons per day) will be collected for a few days for special tests. These special tests are for determination of SOD levels within the body. Blood samples will be done every eight hours for two days following each injection, one sample per day will be required on Day 3 and Days 7 to 14. Other discomforts or risks associated with routine intensive care include localized discomfort or hematoma with needle sticks or insertion of catheters. However, because of indwelling catheters, additional needle sticks or procedures will generally not be necessary to obtain these samples.

Follow-up: As a part of this study, all patients discharged from the hospital will be followed up in the Neurosurgery Clinic approximately once every three months for up to one (1) year. These evaluations include neurologic examination, tests concurring memory, speech, the ability to put things together, pay attention, solve problems, name objects, carry out requests to move small objects, remember pictures and words. You (he/she) will be asked to answer questions concerning the injury and of its effect on your (his/her) daily living. You (he/she) will have the choice of answering or not answering any questions. This follow-up may represent some inconvenience to the patient. All attempts will be made to work around the patient's schedule.

Pregnancy: Not applicable. All females of child-bearing potential are excluded, unless they are surgically sterile or post-menopausal.

Possible Benefits: As stated earlier, this study is an effort to improve the results from a very serious injury. Every patient entering this study will be receiving at least one (1) special therapy and it is hoped that the survival rate and the extent of neurological recovery can be improved upon over what has been previously possible.

Alternative Therapy: If you do not wish to participate, routine care normally administered to head injured patients will be given without being entered in this drug study.

Research Related Injury and Cost of Participation: All the medical costs will still be my (the patient's) responsibility and be billed in a routine fashion, but there will be no additional cost to the patient as a result of participating in this study. I understand that in the unlikely event of any physical and/or mental injury resulting from my participation in this research project, Virginia Commonwealth University, Enzon, Incorporated or the U.S. Department of Defense will not be able to offer any financial compensation. However, you (the patient) are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. A payment of $50.00 will be offered for each visit to those patients returning for follow-up neuropsychological testing.

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Withdrawal: Participation in this study is voluntary; refusal to participate will involve no penalty or loss of benefit to which you (the patient) are otherwise entitled and I am free to withdraw from this study at any time without prejudice to my (the patient's) future medical care. I can contact Harold F. Young, M.D. (principal investigator), or John D. Ward, M.D. (associate investigator) at (804) 786-9165 or Box 631, MCV Station, Richmond, VA 23298-0631 for further information and research related injuries concerning this study. I may contact them after regular hours by calling the hospital at (804) 786-0951 and asking for the neurosurgery resident on call. Robert Campbell, M.D. may be reached at (804) 786-0868 for any questions concerning the rights of the research subject.

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Signature of Patient or Next-of-Kin	Signature and name of witness
Relationship	Date and time
Date and time	