RUTGERS UNIVERSITY
Office for Research

Human Research Protection Program (HRPP)
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DHHS Federal Wide Assurance Identifier: FWA00003913

IRB Chair Person(s): Dr. Richard Drachtman, Dr. Jonathan McCoy, & Dr. Kathryn Greene

IRB Director: Swapnali Chaudhari

Effective Date: 10/22/2024

Approval Date: 10/22/2024

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eIRB Notice of Approval with Stipulations

STUDY PROFILE

IRB Number: Pro2024002037

Project Title: Multicenter Trial for Pediatric Intracranial Gunshot Wounds

Principal Investigator: Nina Glass

Co-Investigators:
Antonia Sames

Sponsors:
Department Funded Internal / Institutional Funding

Risk Determination: Minimal Risk

Current Review Type: Exempt 4iii
Records: 20

CURRENT SUBMISSION STATUS

Submission Type: Secondary Data Analysis Only (Exempt)

Submission Status: Approved with Stipulations

Approval Date: 10/22/2024

IRB APPROVAL IS GRANTED SUBJECT TO THE STIPULATION(S) THAT:

All sites contributing data to this study must be added to this eIRB+ submission prior to Rutgers investigators engaging in research activities utilizing this external data. All relevant Data Use Agreements and IRB approvals from the contributing, collaborating site must be provided in this modification to the Rutgers IRB. Where appropriate, the records size should be increased as well to reflect the totality of this multi-center data set.

Retrospective Record Review: If applicable, records may be accessed to review information dating:

From: 1/1/2010

To: 9/1/2024

Study Performance Sites:

University Site
University Hospital New Jersey Medical School

ALL APPROVED INVESTIGATOR(S) MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Amendments/Modifications/Revisions: If you wish to change any aspect of this study, including but not limited to, study procedures, consent form(s), investigators, advertisements, the protocol document, investigator drug brochure, or accrual goals, you are required to obtain IRB review and approval prior to implementation of these changes unless necessary to eliminate apparent immediate hazards to subjects.

3. Unanticipated Problems: Unanticipated problems involving risk to subjects or others must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/hspp-guidance-topics

4. Protocol Deviations and Violations: Deviations from/violations of the approved study protocol must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/hspp-guidance-topics

5. Completion of Study: Notify the IRB when your study has been stopped for any reason. Neither study closure by the sponsor or the investigator removes the obligation for submission of timely continuing review application or final report.

6. eCOI: This IRB approval does not infer other approvals which may be required before this study can begin, such as those provided by the Rutgers Conflict of Interest Committee. If your disclosure requires a management plan with any request to change research document/s (such as consent document/s), then please submit the revised document/s via modification to the IRB for review.

COI The Investigator(s) did not participate in the review, discussion, or vote of this protocol.

Consent/Waiver:

The IRB has reviewed and approved the consent described in this protocol as required by 45 CFR 46 and 21 CFR 50, 56, (if FDA regulated research). Only the versions of the documents included in the approved process may be used to document informed consent; each subject must receive a copy of the approved form(s); and a copy of each signed form must be filed in a secure place in the subject's medical/patient/research record.

Waivers:
Waiver or Alteration of Consent Process
HIPAA Waiver of Authorization

SHIELD Chart Review

Study ID _____

Chart Review

[shield_id]

Pupillary reactivity on arrival

- ☐ reactive bilaterally
- ☐ unreactive unilaterally
- ☐ unreactive bilaterally
- ☐ unilaterally dilated
- ☐ bilaterally dilated
- ☐ unilaterally pinpoint
- ☐ bilaterally pinpoint

Findings from initial head CT

	Yes	No	Other
Presence of visible intracranial pathology	◯	◯	◯
Involvement of deep nuclei and/or 3rd ventricle	◯	◯	◯
Mixed supra-/infratentorial involvement	◯	◯	◯
Transventricular injury	◯	◯	◯
Bihemispheric injury	◯	◯	◯
Midline shift	◯	◯	◯
High or mixed-density mass lesion	◯	◯	◯
Subarachnoid hemorrhage	◯	◯	◯
Intraventricular blood	◯	◯	◯

Size of midline shift (mm) _____

Type of mass lesion

- ☐ Subdural hematoma
- ☐ Intracerebral hematoma
- ☐ Epidural hematoma

Volume of mass lesion

- ◯ ≤ 25 cm^3
- ◯ > 25 cm^3

If subdural hematoma, dual-sided?

- ◯ Yes
- ◯ No

If subdural hematoma, size in mm? _____

If epidural hematoma, dual-sided?

- ◯ Yes
- ◯ No

If epidural hematoma, size in mm?	_____
Location of subarachnoid hemorrhage	☐ Convexities ☐ Basal cisterns
Other findings on initial CT scan (can include any details here; especially if there were "other or unknown findings from above"):	_____
Number of lobes involved	_____
Basal cisterns	◯ Visible ◯ Compressed ◯ Effaced
Diffuse axonal injury (as identified on MRI)?	☐ Yes ☐ No
Location of diffuse axonal injury	☐ Basal ganglia ☐ Splenium ☐ Brain stem

Surgery

Neurosurgical procedures (all; including monitors)	◯ Yes ◯ No
Type of procedure	☐ Decompressive craniectomy (please specify below) ☐ Craniotomy ☐ Cerebral angiography ☐ Ventriculoperitoneal shunt ☐ External ventricular drain ☐ Lumbar drain ☐ Hematoma drainage ☐ Bullet/fragment removal ☐ Cranioplasty ☐ Wound debridement/closure ☐ Skull base repair (for CSF leak) ☐ Other
Other procedure type	_____
ICP monitor placed?	◯ Yes ◯ No
ICP monitor type	◯ EVD ◯ Bolt
Initial ICP	_____
Time to first procedure (hours)	_____

Additional Outcomes

Complications	☐ Seizure ☐ Meningitis ☐ Abscess ☐ CSF leak ☐ Focal neurologic deficit ☐ Endocrine abnormality ☐ Cognitive defect ☐ Neuropsychological deficit ☐ Pneumonia ☐ UTI
Duration of latest follow-up (months)	_____
GOS-E at latest follow-up	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8
3-month mortality	◯ Yes ◯ No
6-month mortality	◯ Yes ◯ No
1-year mortality	◯ Yes ◯ No
10-year mortality	◯ Yes ◯ No
5-year mortality	◯ Yes ◯ No

SHIELD Hospital Characteristics

Study ID _____

Hospital Characteristics

Trauma center level
- ◯ ACS Verified Level 1
- ◯ ACS Verified Level 2
- ◯ ACS Verified Level 3
- ◯ Other

If Trauma center level "Other", please specify: _____

Pediatric trauma center status
- ◯ Not-Pediatric ACS Verified
- ◯ Pediatric ACS Verified Level 1
- ◯ Pediatric ACS Verified Level 2
- ◯ Pediatric ACS Verified Level 3
- ◯ Other

If Pediatric Trauma center level "Other", please specify: _____

State-verified status
- ◯ Yes
- ◯ No
- ◯ Not Available
- ◯ Other

If State Trauma center level "Other", please specify: _____

Number of inpatient adult beds (as of 2025 or most recent year available) _____

Number of inpatient pediatric beds (as of 2025 or most recent year available) _____

Pediatric readiness score (if available) _____

Hospital Setting
- ◯ Urban
- ◯ Surburban
- ◯ Rural
- ◯ Other

If Hospital Setting "Other", please specify: _____

Hospital type	◯ University Teaching Hospital ◯ Community Teaching Hospital ◯ Non-Teaching Hospital ◯ Other

If Hospital Type "Other", please specify:

_____

SHIELD Registry Data

Study ID

_____

SHIELD ID Number

_____

Data generally available from trauma registry (demographics, mechanism of injury, clinical presentation, initial labs if available, and injury severity scores); please use first available data point after presentation unless otherwise noted.

Age

_____

Sex

◯ Male
◯ Female
◯ Other

Race

◯ Asian
◯ Native Hawaiian or Other Pacific Islander
◯ Other Race
◯ American Indian
◯ Black or African American
◯ White

Other race?

_____

Ethnicity

◯ Hispanic or Latino
◯ Not Hispanic or Latino

Height

_____

Weight

_____

Clinical Presentation

Temperature (deg. C)

_____

Injury Incident Date

_____

SBP in ER

_____

HR in ER

_____

RR in ER

_____

Oxygen saturation in ER (%)	_____
Respiratory assistance	◯ Yes ◯ No
Admission GCS	◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 ◯ 11 ◯ 12 ◯ 13 ◯ 14 ◯ 15
Eye-opening	◯ 1 ◯ 2 ◯ 3 ◯ 4
Verbal	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5
Motor	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6

Laboratory Values (first available)

INR	_____
Sodium (mmol/L)	_____
Potassium (mmol/L)	_____
Glucose (mg/dL)	_____
Base excess (mmol/L)	_____
Hemoglobin (g/dL)	_____

Hematocrit (%)	_____
Platelets (x10^9/L)	_____
WBC (x10^9/L)	_____
Cr (mg/dL)	_____
BUN (mg/dL)	_____
ED Discharge Disposition	◯ Floor bed (general admission, non-specialty unit bed) ◯ Observation unit ◯ Telemetry/step-down unit (less acuity than ICU) ◯ Home with services ◯ Deceased/expired ◯ Other (jail, institutional care, mental health, etc.) ◯ Operating Room ◯ ICU ◯ Home without services ◯ Left AMA ◯ Transferred to another hospital
ISS	_____
AIS General	_____
AIS Head & Neck	_____
AIS Abdomen	_____
AIS Extremities & Pelvis	_____
AIS External	_____
Total hospital length of stay	_____
Days on ventilator	_____
Days in ICU	_____

Hospital discharge disposition	◯ Discharged/transferred to short-term general hospital for inpatient care ◯ Discharged/transferred to an intermediate care facility (ICF) ◯ Discharged/transferred to home under care of organized home health service ◯ Left AMA ◯ Decreased/expired ◯ Discharged to home or self-care (routine discharge) ◯ Discharged/transferred to skilled nursing facility (SNF) ◯ Discharged/transferred to hospice care ◯ Discharged/transferred to court/law enforcement ◯ Discharged/transferred to inpatient rehab or designated unit ◯ Discharged/transferred to long term care hospital (LTCH) ◯ Discharged/transferred to a psychiatric hospital or psychiatric distinct part unit of a hospital ◯ Discharged/transferred to another type of institution not defined elsewhere
In-hospital mortality	◯ Yes ◯ No