CONTRACT NUMBER: W81XWH-16-D-0024-0002

TITLE: Shock, Whole blood and Assessment of TBI (SWAT)

PRINCIPAL INVESTIGATOR: Dr. Jason Sperry, MD

RECIPIENT: University of Pittsburgh
Pittsburgh, Pennsylvania 15213

REPORT DATE: OCT-2020

TYPE OF REPORT: Annual – Year 3

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

REPORT DOCUMENTATION PAGE

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4. TITLE AND SUBTITLE

Shock, Whole blood and Assessment of TBI (SWAT)

1. REPORT DATE OCT-2020	**2. REPORT TYPE** Annual Report	**3. DATES COVERED** 25-SEP-2019 to 24-SEP-2020
		5a. CONTRACT NUMBER
		5b. GRANT NUMBER W81XWH-16-D-0024-0002
		5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S) Jason L. Sperry, Barbara Early, Meghan Buck, Laurie Silfies E-Mail: sperryjl@upmc.edu; earlybj@upmc.edu; buckml@upmc.edu; silfiesl@edc.pitt.edu		**5d. PROJECT NUMBER** **5e. TASK NUMBER** **5f. WORK UNIT NUMBER**
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Pittsburgh Pittsburgh, Pennsylvania 15213		**8. PERFORMING ORGANIZATION REPORT**
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Marvland 21702-5012		**10. SPONSOR/MONITOR'S ACRONYM(S)** **11. SPONSOR/MONITOR'S REPORT NUMBER(S)**

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Task Order 0002 is a multicenter, prospective, observational cohort study over a 4-year period to determine the impact of whole blood resuscitation in trauma patients with hemorrhagic shock at risk of large volume resuscitation with and without TBI. Specific Aim one is to evaluate patient centered outcomes associated with early whole blood resuscitation practice as compared to component resuscitation in poly-trauma patients with hemorrhagic shock and further characterize outcome benefits in those with traumatic brain injury. Specific Aim two is to characterize blood pressure and resuscitation endpoints during the acute resuscitation phase of care and the associated/attributable outcomes for traumatic brain injury in patients with hemorrhagic shock.

15. SUBJECT TERMS
Trauma; whole blood resuscitation; component therapy; traumatic brain injury; hemorrhagic shock

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGE**	**19a. NAME OF RESPONSIBLE PERSON** USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	**14**	

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Task Order 0002 is a multicenter, prospective, observational cohort study over a 4-year period to determine the impact of whole blood resuscitation in trauma patients with hemorrhagic shock at risk of large volume resuscitation with and without TBI. Specific Aim one is to evaluate patient centered outcomes associated with early whole blood resuscitation practice as compared to component resuscitation in poly-trauma patients with hemorrhagic shock and further characterize outcome benefits in those with traumatic brain injury. Specific Aim two is to characterize blood pressure and resuscitation endpoints during the acute resuscitation phase of care and the associated/attributable outcomes for traumatic brain injury in patients with hemorrhagic shock.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Trauma; whole blood resuscitation; component therapy; traumatic brain injury; hemorrhagic shock

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

The purpose of Task Order 0002 to determine the impact of whole blood resuscitation in trauma patients with hemorrhagic shock at risk of large volume resuscitation with and without TBI. Early whole blood resuscitation will be compared to standard component resuscitation. The study will also further characterize blood pressure and resuscitation endpoints in poly-trauma patients with traumatic brain injury.

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

CCC/DCC
- Held monthly site coordinator call.
- Generated and distributed quarterly payment reports.

- Two REDCap forms were updated (TBI and DIT).
  - Updated documents posted in the Document Library on the study website.
- Generated and distributed monthly Data Compliance Reports (DCR) to clinical sites.
  - Automated report of missing forms, data inconsistencies and edits, and issues identified with samples/use of barcode scanner is working well.
- Monitored status of certifications completed and granted appropriate permission for access to study databases.
- Worked on development of MOP and Data Management Manual.
- DCC worked on development of standardized reporting from SecureShare.
- DCC Monitored status of new certifications completed.
  - Granted appropriate permission for access to study databases.
- DCC generated potential list of IDs to be included in the Interim Analyses and is continuing to work with sites to make sure final study status has been determined for all IDs in the list and that any outstanding data is entered so that the interim dataset can be frozen.
- DCC monitored progress of Central Radiologist reading CTs and entering data.

Pitt sIRB & HRPO

- Annual IRB renewal approval for all participating sites was obtained 11-OCT-2019.
- Received HRPO Continuing Review acknowledgement for all participating sites on 04-DEC-2019.
- Due to the COVID-19 pandemic, enrollment across all sites will be limited or stopped based on each site's capabilities.
  - The University of Pittsburgh IRB approved this exception on 17-MAR-2020.
  - This exception allows us to continue the study while protecting the health and safety of research staff and not compromising the primary outcome.
- Annual IRB renewal approval for all participating sites was obtained on 24-SEP-2020.
  - Distributed to external sites on 25-SEP-2020.

Study Start-up

University of Florida – Gainesville

- Received fully executed contract on 19-OCT-2019.
- Initial Pitt IRB approval obtained on 03-FEB-2020.
- Surface tablet and barcode scanner configured and sent to site.
- DataStream installer configured for site and made available to them on study website.
- Site Initiation Visit (SIV) held on 20-FEB-2020.
- Site submitted to HRPO for initial approval on 30-MAR-2020.
  - Site-specific addendum submitted to HRPO 29-MAY-2020.
- On 20-AUG-2020, the CCC and Pitt IRB decided that it would not be feasible to continue to pursue adding University of Florida (Gainesville) as a participating site.
  - Their IRB will not permit the waiver of consent and Dr. Sperry does not want to have a participating site with different data retention/enrollment procedures.
- CCC working with the University of Florida (Gainesville) to finalize invoices.
- DCC confirmed the study-provided Surface Tablet and barcode scanner were returned in SEP-2020.

University of Miami

- Initial Pitt IRB approval obtained on 18-MAR-2020.
- CCC/DCC conducted a remote Site Initiation Visit (SIV) on 24-APR-2020.
- Miami site was submitted to HRPO for initial approval on 29-MAY-2020.

- U of Miami IRB approval of Protocol v5 was submitted to HRPO on 29-JUL-2020.
- U of Miami received initial HRPO approval on 14-SEP-2020.

- CCC continued to work with U of Miami to collect outstanding items for study activation/start-up.

Monitoring

- In-person & remote Interim Monitoring Visits (IMV) were conducted at participating sites. Follow-up meetings/calls to discuss findings with the PI & study team were held.
- In response to COVID-19, CCC/DCC developed a remote-format for Site Initiation Visits (SIV) & Interim Monitoring Visits (IMV).
- CCC conducted quarterly remote consent document review & distributed findings to participating sites.
- CCC/DCC worked with the UTSW site on closeout items: ensuring all data was entered, outstanding edits were addressed, and that consents, and consent documentation were uploaded for review.
  - Close-out visit will be conducted once travel can resume to being held in-person.

DCC distributed Operation Memos to all study personnel.

#14	Remote Consent Monitoring	07-OCT-2019
#15	TBI Participants w/out CT Scans	
#16	Data Collection for Post-waiver Deaths	13-DEC-2019
#17	TBI Scans and Data Issues Tracking forms	
#18	updates about the COVID-19 situation and its impact on TO2/SWAT	12-MAR-2020
#19	updates about the COVID-19 situation and its impact on TO2/SWAT	19-MAR-2020
#20	Funding and Staffing Considerations during COVID-19 Situation	20-MAR-2020
#21	Documenting Missing Blood Samples (under the temporary IRB exception) and recruitment status update RE: the ability to enroll due to loosening (or tightening) of COVID-19 related restrictions at each site.	05-JUN-2020
#22	Request that each site complete two surveys, (1) blood products, including platelets and cryoprecipitate and (2) screening and enrollment status.	26-JUN-2020
#23	Obtaining Consent for COVID or COVID-suspected Participants	08-JUL-2020
#24	Mortality Assessment for Interim Analysis	27-AUG-2020
#25	Enrollment Payments	

- Enrollment: 642 (total eligible not withdrawn as of 30-SEP-2020).

University of Pittsburgh	226
University of Pennsylvania	89
University of Texas Health Science Center at Houston	190
Denver Health & Hospital Authority	63
Oregon Health & Science University	63
University of Texas Southwestern (*closed to enrollment*)	11
University of Miami	*Not yet recruiting*

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- Continue to hold monthly coordinator teleconferences, distribute monthly Data Compliance Reports (DCR), distribute quarterly payment reports, and monitor progress of Central Radiologist reading CTs & entering data.
- Conduct Interim Monitoring Visits (IMV) at the Pitt site.
- Obtain initial HRPO approval for U of Miami.
  - Activate and commence enrollment at Miami.
- Continue working with sites to make sure outstanding data is entered for the interim analysis.

Travel Reporting: no travel is anticipated for the next quarter (OCT-2020 to DEC-2020).

- Due to the COVID-19 pandemic, Site Initiation Visits (SIV) & Interim Monitoring Visits (IMV) will be conducted remotely until we can resume to normal in-person visits.

Cumulative to Billing Period: **30-SEP-2020**	**Travel Funds Budgeted**	**Cumulative Actual Spent**	**Remaining Balance**

	Traveler Name	**Destination/ Purpose**	**Estimated Date of Travel**
OCT-2019 to DEC-2019	Peter Adams Ashley Harner	UTSW (Dallas, TX)/ IMV	15-OCT-2019 to 16-OCT-2019

	Laurie Silfies		
JAN-2020 to MAR-2020	Peter Adams Ashley Harner Laurie Silfies Megan Buhay	UT Houston (Houston, TX)/ IMV	05-FEB-2020 to 06-FEB-2020
	Peter Adams Ashley Harner Laurie Silfies Natalie Rogers Josh Hutton	University of Florida (Gainesville, FL). SIV	19-FEB-2020 to 20-FEB-2020
	Peter Adams Ashley Harner Laurie Silfies Ali Merti	UPenn (Philadelphia, PA)/ IMV	05-MAR-2020
APR-2020 to JUN-2020	Due to the COVID-19 pandemic, Site Initiation Visits (SIV) & Interim Monitoring Visits (IMV) will be conducted remotely until we can resume to normal in-person visits.		
Upcoming Travel for Quarter: **OCT-2020 to DEC-2020**	n/a	n/a	n/a

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:
- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. **CHANGES/PROBLEMS:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

- Due to the COVID-19 pandemic, various jurisdictions around the country are imposing limits and restrictions on workplaces and healthcare facilities.
  - Staffing restrictions and enrollment hours across all sites have been limited (or stopped) based on each site's capabilities.
  - Sites that are enrolling are either collecting limited blood samples or no blood samples at any timepoint depending on the subject status, site facility limitations, and staffing limitations.
- The COVID-19 pandemic has significantly impacted the ability of each site to enroll. This led to decreased enrollment since MAR-2020 and is likely to continue for the near term until restrictions are lifted.
- Failure to meet enrollment goals at component sites requiring addition of new site(s).
- Component sites may transition to whole blood if their standard of care changes (possibly add more sites if enrollment goals are not on target).
- Houston site has not shipped any samples. Site had been notified to ship shortly before COVID-19 restriction were implemented and sample shipments were put on temporary

hold. Shipping will resume in OCT-2020.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

Not applicable to TO 0002

Significant changes in use of biohazards and/or select agents

Not applicable to TO 0002

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to Report.

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable;*

bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Nothing to Report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*

- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Personnel Listing: see page 14

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have

provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

Year 3 Quad Chart: see page 14

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Annual and final reports are submitted to: https://ers.amedd.army.mil/

AND
One Copy: Contract Specialist, Mr. Paul Martha
Email: paul.m.martha.civ@mail.mil

One e-Copy: Contracting Officer's Representative (COR), Wilbur Malloy
Email: wilbur.w.malloy.civ@mail.mil

Personnel Listing (as of 05-OCT-2020)

Department	Last Name	First Name	Government Used Labor Category	UPitt Role	SWAT/2
Surgery	Neal	Matthew	Clinical Research Director	Co-PI	2%
Epidemiology (GSPH)	Wisniewski	Stephen	Epidemologist	Co-PI	2.50%
Neurosurgery	Okonkwo	David	Clinical Research Director	CO-Investigator	2.50%
Emergency Medicine	Guyette	Francis	Clinical Research Director	Co-PI	3.00%
Surgery	Sperry	Jason	Clinical Research Director	PI	7.50%
Epidemiology (GSPH)	Luther	James	Biostatistican IV	Biostatistican IV	10%
Epidemiology (GSPH)	Silfies	Laurie	Systems Engineer IV	Systems Engineer IV	20%
Epidemiology (GSPH)	O'Donnell	Jefferey	Systems Developer III	Systems/Programmer IV	50%
Neurosurgery	Borrasso	Allison	Research Scientist (Research and Development Associate I)	Health Professional II	50%
Epidemiology (GSPH)	Pattison	Angela	Database Adminstrator III	Research IV	80%
Epidemiology (GSPH)	Over	Lisa	Database Administration Manager	Research IV	100%

YEAR 3 QUAD CHART

Linking Investigations in Trauma and Emergency Services – TO2

17052001-TO2/W81XWH-16-D-0024-0002 LITES Task Order 0002
Shock, Whole blood and Assessment of TBI (SWAT)

PI: Jason Sperry MD MPH **Org:** University of Pittsburgh **Award Amount:** $$7,452,420.12

STUDY AIMS

I. Evaluate patient centered outcomes associated with early whole blood resuscitation practice as compared to component resuscitation in poly-trauma patients with hemorrhagic shock and further characterize outcome benefits in those with traumatic brain injury. Whole blood Clinical Practice Guidelines will be prepared, including staff training resources, and provided for use by the Government.

II. Characterize blood pressure and resuscitation endpoints during the acute resuscitation phase of care and the associated/attributable outcomes for traumatic brain injury in patients with hemorrhagic shock.

APPROACH

Task Order 0002 is a multicenter, prospective, observational cohort study over a 4-year period to determine the impact of whole blood resuscitation in trauma patients with hemorrhagic shock at risk of large volume resuscitation with and without TBI.

Determine if whole blood resuscitation is associated with improved mortality and morbidity outcomes following hemorrhagic shock with and without TBI.

N = 642
(total eligible not withdrawn as of 30-SEP-2020)

ACCOMPLISHMENTS

- ✓ CCC/DCC continued to work with the University of Miami for study start-up & received initial HRPO approval.
- ✓ Distributed monthly Data Compliance Reports (DCR) to clinical sites.
- ✓ CCC/DCC conducted remote Interim Monitoring Visits (IMV) at Denver Health and OHSU.
- ✓ Annual IRB renewal approval for all participating sites was obtained!

Timeline and Cost

Activities / CY	18	19	20	21
Startup, Hiring, IRB approval, Contracts, Central IRB organization, Database creation				
1 year thru 4 year enrollment, 1050 patients; interim analysis at 50 % enrolled				
Characterize for variation of patient centered outcomes related to whole blood vs component therapy				
Characterization of bp and resusc endpoints for TBI in hemorrhagic shock ; prepare WB clinical practice guidelines				
Estimated Budget ($K)	**$1M**	**$2.5M**	**$2.5M**	**$1.5M**

Updated: (University of Pittsburgh 06-OCT-2020)

Goals/Milestones

CY18 Goal – Network Startup and Data procurement/extraction
- ✓ Base Hiring; IRB approval; Central IRB organization, Sub-Contract organization
- ✓ Data base creation and CRF completion, data dictionary
- ✓ Begin Patient enrollment 200-30

CY19 Goal – Patient enrollment 300-400
- ✓ Begin Characterization of variation of patient centered outcomes related to whole blood vs. component therapy

CY20 Goal – Patient enrollment 300-400
- ❑ Begin Characterization of blood pressure and resuscitation endpoints for TBI subjects in hemorrhagic shock
- ❑ Prepare whole blood administration clinical guidelines

Comments/Challenges/Issues/Concerns
- Failure to meet enrollment goals at component sites requiring addition of new site(s).
- Component sites may transition to whole blood if their standard of care changes (possibly add more sites if enrollment goals are not on target)
- The COVID-19 pandemic has significantly impacted the ability of each site to enroll. This led to decreased enrollment for MAR-2020 and is likely to continue for the near term until restrictions are lifted.

Budget Expenditure to Date
- Actual Expenditures To-Date: **$3,082,388.44** (reflected level reports up to 31-AUG-20)
- Projected Expenditures: $52,482 (*reflects current projections on account for AUG2020 period*).