

**CONTRACT NUMBER:** W81XWH-16-D-0024-0002  
**LOG NUMBER:** 17052001-TO2

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

**PRINCIPAL INVESTIGATOR:** Jason Sperry

**CONTRACTING ORGANIZATION:** University of Pittsburgh  
Pittsburgh, Pennsylvania 15213

**REPORT DATE:** OCT-2021

**TYPE OF REPORT:** Annual – Year 4

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

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<b>1. REPORT DATE</b> OCT-2021		<b>2. REPORT TYPE</b> Annual Report		<b>3. DATES COVERED</b> 25-SEP-2020 to 24-SEP-2021	
<b>4. TITLE AND SUBTITLE</b>  Shock, Whole blood and Assessment of TBI (SWAT)			<b>5a. CONTRACT NUMBER</b>		
			<b>5b. GRANT NUMBER</b> W81XWH-16-D-0024-0002		
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			<b>5e. TASK NUMBER</b>		
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<b>14. ABSTRACT</b>  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/attribution outcomes for traumatic brain injury in patients with hemorrhagic shock.					
<b>15. SUBJECT TERMS</b> Trauma; whole blood resuscitation; component therapy; traumatic brain injury; hemorrhagic shock					
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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/attributionable 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.*

- Successful virtual In Progress Review (IPR) meeting held on 01-DEC-2020!
- CCC/DCC continued to hold monthly site coordinator call
- Interim dataset was frozen on 23-OCT-2020!
- DCC performed analyses and created tables for Interim Analysis report
- Interim Analysis Report (initial 446 enrollments) was sent to the DoD on 10-APR-2021
- DCC generated & distributed monthly Data Compliance Reports (DCR) to sites
- CCC/DCC continued to hold calls with individual sites to work through edit error log
- DCC monitored status of new certifications completed
- DCC monitored progress of Central Radiologist reading CTs and entering data
- Miami was activated on 13-OCT-2020 and commenced enrollment on 14-DEC-2020
- CCC/DCC conducted a virtual closeout for UTSW on 11-NOV-2020
  - Closeout letter issued on 28-JAN-2020
- Miami's standard care switched to Whole Blood on 27-MAR-2021
- Denver's standard care switched to Whole Blood on 26-MAY-2021 (through their Massive Transfusion Protocol only)
- sIRB application was transitioned to the University of Pittsburgh's new platform called PittPRO (previously known as OSIRIS)
- Annual IRB renewal approval for all participating sites was obtained 08-SEP-2021
- HRPO CR documents were submitted for E00053 Series on 23-SEP-2021
- Enrollment wind-down & notification process was communicated to sites:
  - To prevent over-enrollment, enrollment will stop at all sites except Pittsburgh when there are approximately three patients left to enroll. The final patients will be enrolled at the Pittsburgh where enrollments can be strictly controlled
  - CCC collected two contacts from each site to notify them to stop enrollment
  - Sites provided their plan for communicating end of enrollment to their local study team
- Enrollment goal (1050) reached on 17-SEP-2021!
- Sites have shifted efforts to data entry & resolving queries
  - PM will monitor sites data entry progress & data completion forms
- To assist with REDCap data entry, the import tool will be made available for certain study forms. The following tools have been distributed to sites:
  - Import tool for 24 hr. infusions & transfusions
  - AIS tool
- CCC/DCC provided each site with a list of specific sample IDs we expect to be shipped.

**Enrollment goal (1050) reached on 17-SEP-2021!**

University of Pittsburgh	318
University of Pennsylvania	142
University of Texas Health Science Center at Houston	324
Denver Health & Hospital Authority	111
Oregon Health & Science University	110
University of Miami	34
University of Texas Southwestern (closed to enrollment)	11

**2021 Remote Interim Monitoring Visit (IMV)**

Instead of monitoring visits in 2022, the CCC/DCC will conduct close-out visits with all sites

Pittsburgh	IMV-02	NOV/DEC-2020	IMV-03 to be scheduled in Quarter 4 2021
UPenn	IMV-03	APR-2021	Executed report & monitoring log received
UT Houston	IMV-03	APR-2021	Executed report & monitoring log received
Denver	IMV-03	JUN-2021	Executed report & monitoring log received

OHSU	IMV-03	JUL-2021	Executed report & monitoring log received
Miami	IMV-01	MAR-2021	Executed report & monitoring log received
<b>Remote Consent Monitoring [conducted quarterly]</b>			
	<b>2021 Q1 (JAN-MAR-2021)</b>		<b>Q2 2021 (APR-JUN 2021)</b>
Pittsburgh	Consents monitoring for 2021 Q1 & Q2 to be conducted in-person		
UPenn	CCC distributed report of Q1 ICFs uploaded by site. All outstanding ICF query responses to be addressed with Q2 review.	2021 Q2 and comprehensive report furnished to site in SEP-2021. Response to queries due OCT-2021.	
UT Houston	CCC distributed report of Q1 ICFs uploaded by site.	2021 Q2 and comprehensive report furnished to site in SEP-2021. Response to queries due OCT-2021.	
Denver	No consents expected for upload this quarter.	2021 Q2 and comprehensive report forthcoming in OCT-2021.	
OHSU	CCC reviewed uploaded documents with 2021Q2 reporting.	2021 Q2 and comprehensive report furnished to site in SEP-2021. Response to queries due OCT-2021.	
Miami	CCC distributed report of Q1 ICFs uploaded by site.	2021 Q2 and comprehensive report furnished to site in SEP-2021. Response to queries due OCT-2021.	
UTSW	Consent review completed during the close-out visit		
<b>DCC distributed Operation Memos and two reference documents to all study personnel</b>			
#26	New Data Field - Unknown for Nosocomial Infections and Complications End Date.		06-NOV-2020
#27	Updates to the Certification Quizzes		01-FEB-2021
	Updates to two Data Collection Forms: Closeout/Discharge Form & Data Issues Tracking (DIT) Form)		
#28	Notification of citrate tube shortage		23-APR-2021
Data Collection Guidance document (specific to Pittsburgh EHR – Cerner)			02-FEB-2021
Tips for Resolving Edits (summarizes ways to avoid/resolve edits in monthly Data Compliance Report)			

**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 as needed
- Continue working with sites to make sure outstanding data is entered & queries are resolved for the final analysis.
  - Monitor site’s data entry progress & query resolution
- Continue to hold calls with individual clinical sites to work through edit error log.
- CCC will resume discussions with sites regarding shipping patient samples
- Pittsburgh’s IMV-03 will be held in Q4 2021.
- Monitor progress of Central Radiologist reading CTs & entering data.

**Travel Reporting:** no travel is anticipated for the next quarter (OCT-2021 to DEC-2021).

Cumulative to Billing Period: <b>30-SEP-2021</b>	<b>Travel Funds Budgeted</b>	<b>Cumulative Actual Spent</b>	<b>Remaining Balance</b>
	\$47,525.88	\$38,775.34	\$8,750.54
<b>Traveler Name</b>			
<b>Destination/Purpose</b>		<b>Estimated Date of Travel</b>	
Upcoming Travel for Quarter: <b>OCT-2021 to DEC-2021</b>	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.*

Unbalanced comparison groups because the last remaining component site transitioned to using whole blood as part of their resuscitative strategy.

**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.*

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 13

### 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.
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## 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 4 Quad Chart: see page 13
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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](mailto:paul.m.martha.civ@mail.mil)

One e-Copy: Contracting Officer’s Representative (COR), Sandy Snyder

Email: [sandy.j.snyder.civ@mail.mil](mailto:sandy.j.snyder.civ@mail.mil)

## Personnel Listing (as of 31-AUG-2021)

Department	Pesonnal Name	Government Used Labor Category	UPitt Role	T0 % Effort
Neurosurgery	Battistella, Cara	Health Professional I	Health Professional I	50%
Surgery	Blandon, Stephanie	FICA-Paying Student	FICA-Paying Student	100%
Neurosurgery	Borrasso, Allison Jean Hr	Research Scientist (Research & Development Asso	Health Professional II	40%
Emergency Medicine	Guyette, Francis X III	Clinical Research Director	Co-PI	11%
Surgery	Hayes, Hannah E	Clinical Researcher II	Clinical Researcher II	30%
Epidemiology (GSPH)	Luther, James Francis	Biostatistician IV	Biostatistician IV	10%
Epidemiology (GSPH)	Odonnell, Jeffrey H	Systems Developer III	Systems Programer IV	50%
Neurosurgery	Okonkwo, David O	Clinical Research Director	CO-Investigator	3%
Surgery	Phillips, Kaitlin Nicole	FICA-Paying Student	FICA-Paying Student	50%
Surgery	Rayman, MaryAnne	Research II	Research II	100%
Epidemiology (GSPH)	Silfies, Laurie N	Systems Engineer IV	Systems Engineer IV	20%
Surgery	Skroczyk, Hunter L	Health Professional III	Health Professional III	80%
Surgery	Sperry, Jason L	Clinical Research Director	PI	0%
Surgery	Sperry, Jason L	Clinical Research Director	PI	8%
Epidemiology (GSPH)	Wisniewski, Stephen R	Epidemiologist	Co-PI	3%


## YEAR 4 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**





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**STUDY AIMS**

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

- 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.

*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.*

**ACCOMPLISHMENTS**

✓ Enrollment goal (1050) reached on 17-SEP-2021!

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**Timeline and Cost**

Activities	CY	SEP-17	18	19	20	21	22	23
Startup, Hiring, IRB approval, Contracts, Single IRB organization, Database creation, site selection								
1 year thru 4-year enrollment								
Interim analysis at 50 % enrolled								
Reach Enrollment Goal (1050 pts.)								
Data analysis and publication								
Estimated Budget		933K	933K	933K	933K	933K	1.4 M	1.4 M

Updated: (University of Pittsburgh 06-OCT-2021)

**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

- ✓ Begin Characterization of variation of patient centered outcomes related to whole blood vs. component therapy

FY20 Goal

- ✓ Interim analysis reached

CY21 Goal

- ✓ Interim Data Tables and Exec Summary
- ✓ Reach enrollment goal

CY22 | CY23 Goal

- Data analysis and publication
- Begin Characterization of blood pressure and resuscitation endpoints for TBI subjects in hemorrhagic shock
- Prepare whole blood administration clinical guidelines

**Budget Expenditure to Date**

- Actual Expenditures To-Date: \$4,667,288 (reflected level reports up to 31-AUG-2021)
- Current Month Expenses: \$63,276 (reflects account through AUG-2021 period).