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

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

PRINCIPAL INVESTIGATOR: Jason Sperry

RECIPIENT: University of Pittsburgh

REPORT DATE: OCT-2019

TYPE OF REPORT: Annual

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

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
OCT-2019	Annual Report	25-SEP-2018 to 24-SEP-2019

4. TITLE AND SUBTITLE

Shock, Whole blood and Assessment of TBI (SWAT)

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-16-D-0024-0002

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Pittsburgh
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 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 PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified		19b. TELEPHONE NUMBER *(include area code)*

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

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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/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.

Task Order 0002

- CCC/DCC continued to hold monthly site teleconferences.

- All 6 participating Network sites received initial HRPO approval by 16-OCT-2018.
- Conducted the final Site Initiation Visit at UTSW on 15-OCT-2018.
- University of Pittsburgh received Annual IRB Renewal approval for all participating sites on 31-OCT-2018.
- University of Pittsburgh received HRPO Continuing Review Acknowledgment for all participating sites on 19-DEC-2018.
- All 6 participating Network sites were activated by 10-JAN-2019.
- The University of Pittsburgh received IRB approval for protocol modification V3 on 30-JAN-2019.
- All 6 participating Network site commenced enrollment by 04-FEB-2019.
- Received approval to reallocate funds to establish a new research site, the University of Florida on 27-JUN-2019.
- Conducted Interim Monitoring Visits at the following sites:
  - University of Texas Health Science Center at Houston on 13-DEC-2018.
  - Denver Health on 22-FEB-2019.
  - University of Pennsylvania on 26-FEB-2019.
  - Oregon on 05-APR-2019.
- DCC worked with the University of Pittsburgh's IT department to certify use of the LITES website for secure upload of Consent Forms for remote review.
  - Reviewed SecureShare to be used for remote consent monitoring.
  - Prepared Op Memo and updated appropriate MOP sections.
- DCC continued to monitor the status of certifications completed and granted appropriate permissions for access to study databases.
- Generated and distributed monthly Data Compliance Reports (DCR) to clinical sites.
  - DCC continued to work with the clinical site personnel to address any data entry/management issues and assure that all queries have been addressed.
  - Incorporated and verified new edits.
  - Automated report of missing forms, data inconsistencies and edits, and issues identified with samples/use of barcode scanner is working well.
  - Bypass functionality added.
- Generated and distributed quarterly payment reports.
- Identified and worked on additional modifications to Labs form reporting based on site input.
  - Adding unit fields, adding two fields to ABG panel.
  - Updating REDCap, hard-copy forms, QxQ, Variable Reference, DM Manual, generating OP Memo.
- Worked on developing a process which allows clinical sites to copy sample processing data already being collected locally and upload to the DCC rather than having the site duplicate work by hand-entering the data into REDCap.
  - DCC worked with Denver Health to develop the process for their site.
- Modified sample shipment process to allow for entry of shipment documentation via a link to the form rather than having to go through REDCap.
- Reporting:
  - Finalized Clinical Monitoring Report.
  - Finalized report for IRB reporting/tracking.
  - Working through PI signoff process.

Central Radiologist & CT Scans

- Worked with central Radiologist to finalize updates to Scan Interpretations form and user interface for accessing CTs via DataStream.

- Finalized & released Scan Interpretations form, variable reference and QxQ document for use by central Radiologist.
- Radiologist trained in REDCap and Data Stream Monitor.
- Radiologist began reading the CT scans in AUG-2019.
  - Identified issues in the upload/read process & addressed with site personnel.
- Worked with Oregon to finalize DataStream set up for CT transfers.
  - Received and loaded de-identified CTs on disks while working on the above.

DCC distributed 11 Operation Memos to all study personnel.

- Op Memo (2) - Modifications made to the Closeout Discharge Form was sent on 29-OCT-2018.
- Op Memo (3) - Changes to Sample Shipment Process was sent on 30-NOV-2018.
- Op Memo (4) - Revision to the GOAT Form was sent on 13-DEC-2018.
- Op Memo (5) - Process for Collecting Lab Values was sent on 11-JAN-2019.
- Op Memo (6) - Protocol Update and Inclusion Criteria Clarification was sent on 08-FEB-2019.
- Op Memo (7) - Guidance from the Central IRB; (8) - Monitoring Requirements Checklist; (9) - Updates to Data Collection Forms was sent on 25-FEB-2019.
- Op Memo (10) - Forms Changes and Enrollment Flowchart was sent on 22-MAR-2019.
- Op Memo (11) - LABS Form Upgrade & ICP Form QxQ update was sent on 13-MAY-2019.
- Op Memo (12) - Manual of Operations Modifications was sent on 22-JUL-2019.

- Enrollment: 342 (total eligible not withdrawn as of 30-SEP-2019).

SITE	ENROLLMENT THROUGH 30-SEP-2019
University of Pittsburgh	122
UPenn	56
UT Houston	95
Denver	37
Oregon	28
UTSW	4

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.
- CCC to decide if dropping a low performance site & including another is feasible.

Travel Reporting:

- The first Interim Monitoring Visit (IMV) at UTSW is to be conducted by members of the CCC & DCC in the upcoming quarter (see table below).
- We anticipate the second round of IMVs to be scheduled in the first and second quarters of 2020.
- We anticipate a Site Initiation Visit (SIV) will be conducted at the University of Florida in the first quarter of 2020 but nothing is currently scheduled.

Cumulative to Billing Period: **30-SEP-2019**	Travel Funds Budgeted	Cumulative Actual Spent	Remaining Balance
	$47,525.88	$24,362	$23,163.88

Upcoming Travel for Quarter: **OCT-2019 to DEC-2019**			Traveler Name	Destination/ Purpose	Estimated Date of Travel
		1	Peter Adams	UTSW (Dallas, TX)/ IMV	15-OCT-2019 to 16-OCT-2019
		2	Ashley (Ryman) Harner	UTSW (Dallas, TX)/ IMV	15-OCT-2019 to 16-OCT-2019
		3	Laurie Silfies	UTSW (Dallas, TX)/ IMV	15-OCT-2019 to 16-OCT-2019

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.

- Component sites may transition to whole blood if their standard of care changes (possibly add more sites if enrollment goals are not on target).
  - CCC will need to decide if dropping a low performance site & including another is feasible.
- Failure to address Data Compliance Reports (DCR) in a timely manner.
- Ongoing issues with getting Oregon set up to transfer CTs.
- Working through inconsistencies in units reported for LABS across sites took longer than anticipated.
- Many sites had not worked with a central IRB previously so, the process took longer than anticipated.

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.)*

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.

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.

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

LITES Project Personnel - Task Order 0002

	Department	Last Name	First Name	Middle Initial	Role	Account #413531/2	Other Department Subaccounts
1	Emergency Medicine	Guyette	Francis	X	PI		7.5%
2	Epidemiology (GSPH)	Fabio	Anthony		CO-Investigator		5.0%
3	Epidemiology (GSPH)	Luther	James	F	Biostatistican IV		10.0%
4	Epidemiology (GSPH)	Silfies	Laurie	N	Systems Engineer IV		40.0%
5	Epidemiology (GSPH)	Wisniewski	Stephen	R	PI		2.5%
6	Epidemiology (GSPH)	O'Donnell	Jefferey		Systems/Programmer IV		100.0%
7	Epidemiology (GSPH)	Over	Lisa	A	Research IV		100.0%
8	Epidemiology (GSPH)	Pattison	Angela	D	Research IV		25.0%
9	Neurosurgery	Borrasso	Allison	J.H.	Health Professional II		50.0%
10	Neurosurgery	Okonkwo	David	O	CO-Investigator		5.0%
11	Surgery	Sperry	Jason	L	PI	7.5%	
12	Surgery	Neal	Matthew		PI	2.0%	
13	Surgery	Hutton	Joshua		TBN Project Manager ($60K)	50.0%	

Personnel named directly in budgets. Does not include MACRO personnel.

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 = 342
(total eligible not withdrawn as of 30-SEP-2019)

ACCOMPLISHMENTS

- ✓ All 6 participating Network site commenced enrollment by 04-FEB-2019.
- ✓ Distributed monthly Data Compliance Reports (DCR) and quarterly Payment Reports to clinical sites.
- ✓ CCC/DCC conducted several Interim Monitoring Visits (IMV).

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 22-OCT-2019)

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 address Data Compliance Reports (DCR) in a timely manner.
- Some component sites may transition to whole blood if their standard of care changes.

Budget Expenditure to Date
- Actual Expenditures To-Date: $1,901,657.88 (*reflected level reports up to 30-SEP-19*).
- Projected Expenditures: $119,000.00 (*reflects current projections as of OCT-2019)*