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OPERATIONS MEMOS

Thirteen new Operations Memos have been sent since the last Quarterly Update.

- ▶ **T05 #34 distributed 11/14/24**
notifying sites that changes have been made to the AIS form.
- ▶ **T06 #14 distributed 10/30/24**
notifying sites that changes have been made to the AIS, EVT and AER forms.
- ▶ **T06 #15 distributed, 12/4/24**
notifying sites that changes have been made to the NON and TRCK forms and Protocol V11.0 was available.
- ▶ **T06 #16 distributed 12/20/24**
notifying sites that changes have been made to the SCR and DEV forms and Protocol V12.0 and MOP V7.0 were available.
- ▶ **T07 #9 distributed 10/16/24**
notifying sites that instruction changes have been made to the EDS Form.
- ▶ **T07 #10 distributed 10/21/24**
notifying sites that the annual continuing IRB review was approved and that the latest informed consent forms were uploaded to the LITES website.
- ▶ **T07 #11 distributed 10/23/24**
notifying sites that changes have been made to the AIS form.
- ▶ **T010 #8 distributed 10/9/24**
notifying sites that changes have been made to the REGPH and SCRPH forms and only QxQs for EVT and INJ forms.
- ▶ **T010 #9 distributed 10/23/24**
notifying sites that changes have been made to the AIS form.
- ▶ **T010 #10 distributed 11/11/24**
notifying sites that MOP V4.0 was available.
- ▶ **T010 #11 distributed 11/13/24**
notifying sites that changes have been made to the DEV and PDR forms.
- ▶ **T010 #12 distributed 11/21/24**
notifying sites that the Data Management Manual was updated.
- ▶ **T10 #13 distributed 12/20/24**
notifying sites that Protocol V8.0 and MOP V5.0 were available.

As with all Operations Memos, please ensure that they have been read by anyone who needs the information and that copies are stored with the MOP and/or Regulatory Binder. Operations Memos can be found in the Documents Library area of the LITES website.



TASK ORDER 001 UPDATE

We truly appreciate all the time and dedication each site has exerted towards this project, and we look forward to collaborating with you on papers and presentations! Please use this link to submit your Publication Requests. <https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=3LANCM7TH8>

The coordinating center continues to prioritize manuscript proposals submitted by Co-Investigators.

As the DCC continues to curate and analyze the data, we ask that IRBs remain open at sites until closure memos are issued.

TASK ORDER 002 / SWAT UPDATE

The big news for the SWAT (Shock, Whole Blood, and Assessment of TBI) study is that LITES will be making the SWAT dataset available to all LITES PIs in Q1 of 2025. This observational study was done at seven U.S. trauma centers and has data on 1,051 patients at risk of hemorrhagic shock (70% of which received massive transfusion). It is a robust dataset (just ask the CRCs!) that can be used for secondary analyses. If you would like access to the data, please contact Laurie Silfies (silfies@pitt.edu) at the LITES Data Coordinating Center.

When working on secondary analyses, please remember;

- 1. Sites must notify LITES when they are pursuing analyses for presentation or publication**
- 2. Sites must notify LITES before submitting a project for presentation or publication – the DoD requires that we notify them of submissions that use LITES data.**
- 3. Presentations that use SWAT data must include the following:** *This work is supported by the US Army Medical Research and Materiel Command under Contract No. W81XWH-16-D-0024-0002. The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.*
- 4. Publications in peer-reviewed journals must include the following:** *This work is supported by the US Army Medical Research and Materiel Command under Contract No. W81XWH-16-D-0024-0002.*



TASK ORDER 004 / CriSP UPDATE

CriSP-HS

We would like to remind everyone that the publication request form has been updated to include requests for CriSP-HS (Cold-Stored Platelet Early Intervention in Hemorrhagic Shock) data. You can access the request form using the following URL: <https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=3LANCM7TH8>.

Although the request form is publicly available, we will prioritize manuscript proposals submitted by CriSP site Investigators. In addition to the request form, the DCC plans to release the CriSP-HS dataset to all CriSP site Principal Investigators in Q1 of 2025. We look forward to collaborating with you on your proposed secondary analyses!

CriSP-TBI

We have responded to reviewers' comments on the primary manuscript for CriSP-TBI (Cold-Stored Platelet Early Intervention in TBI) at a high-impact journal and we anticipate acceptance soon. Submission of the dataset to FITBIR is ongoing.



TASK ORDER 005 / PACT UPDATE

PACT (Prehospital Airway Control Trial) is a randomized, multi-center trial of prehospital trauma airway management. This study is designed to determine the best strategy for airway management in prehospital patients and compares a strategy of standard airway management to a strategy of supraglottic airway first. On the SGA-first arm, the first airway attempt is dictated by the research protocol. As a step-wedge design, EMS services were randomly chosen to 'step' from standard airway management to the SGA-first airway management strategy each time we reached 287 enrollments. After an agency has 'stepped,' they remain in the SGA-first strategy until enrollment is completed.

As of 1/2/25, we are at 1678 enrollments which is only 44 away from our final step at 1722 enrollments when all sites/services will be on the SGA-first arm as we approach the 2009 needed to complete enrollment!

	Approx. time	Year 1		Year 2		Year 3		Year 4
Step	Enrollment period → Step number	287 subjects	574 subjects	861 subjects	1,148 subjects	1,435 subjects	1,722 subjects	2,009 subjects
1	St. Louis Fire, MO EmergyCare, PA St. Matthews Fire, KY							
2	OHSU EMS services, OR Vidant Eastcare EMS, NC							
3	STAT MedEvac, PA AirEvac, MO Chicago Fire, IL Susquehanna Regional EMS, PA							
4	Grady EMS, GA Lenoir County EMS, NC City of Pittsburgh EMS, PA							
5	Wilson County EMS, NC Louisville Metro EMS, KY							
6	New Orleans EMS, LA Nashville Fire, TN Pitt County EMS, NC							
	END ENROLLMENT - 2009							

	Standard care (control arm)
	Initial SGA (intervention arm)

We were able to host a booth at the National EMS Physician (NAEMSP) conference in San Diego January 8 – 10th. We appreciate everyone from LITES who was able to swing by and visit us!

Monitoring Committee/All-Site calls continue the 2nd Friday of each month at 10am (ET). The next calls will be on Feb 14th and Mar 14th. This once-a-month call provides all the details of how the study is progressing and distributes the Study Monitoring Committee tables for all sites to follow on our progress. It also provides updates on the project and for starting the process of study completion.

As we have already completed 83% of our enrollments, over the next several months, we will be able to finish one of the largest prehospital airway trials ever implemented. Airway emergencies in trauma account for 15 – 20% of preventable deaths in the trauma population. With this study, we will be able to definitively answer the question about airway management for both military and civilian EMS systems. It is important to pay attention to the trial so we can complete the study as our outcomes will help providers decide on the best airway strategy for trauma patients and to save lives.

TASK ORDER 006 / PAIN UPDATE

As of 1/2/25, we are at 55 of our 994 enrollments needed for the PAIN (Prehospital Analgesia Intervention) study. We have just received IRB approval for protocol version 12 and updated our MOP. Please make sure you are following the most current guidelines by accessing these documents via the LITES library.

Four sites are currently enrolling (AGH, UPMC, Cooper, and Milwaukee). Sites who have IRB approval and anticipate starting enrollments within the first quarter of 2025 are: University of Cincinnati Medical Center, University of California San Diego, University of California San Francisco, Atrium Health Carolina Medical Center, University of Utah, and the Guthrie Foundation. The University of Vermont Medical Center will be finalizing their CC/PD efforts within Q1 of 2025 and LITES is currently reaching out to two potential additional sites.

Thank you to those who attended our investigator dinner at NAEMSP in San Diego on January 9th. We appreciate everyone's attendance and hope everyone got the most out of our meeting.

Pine Pharmaceuticals provided Winter Study Drug to enrolling sites which will require replacement on February 12, 2025. EMS training slide decks and reminder materials are available on the EMS Resource tab on the LITES network website using the passcode **ems2021**.

Monthly all site calls are held on the first Wednesday of each month at 2pm (ET). The next all-site calls will be February 5th and March 5th. Quarterly consent uploads and data payout lock will occur on February 28th for all enrollments in November, December, and January.



TASK ORDER 007 / TOWAR UPDATE

The 2nd interim TOWAR (Type O Whole Blood and Assessment of Age during Prehospital Resuscitation) DSMB review was held on December 20, 2024. The official outcome letter will be uploaded to the LITES Document Library as soon as it is available.

The University of Manitoba is expected to commence enrollment in early Q1 of 2025.

Monthly all-site calls are ongoing and are scheduled for the first Wednesday of the month at 12:00pm. Please make all reasonable attempts to have at least one representative from your site available to provide updates.

Enrollment as of January 2nd is as follows:

Pitt	UW	Vandy	UMMC	UC	UT Hou	Knox	Metro	Lou	UAB	TOTAL
129	121	70	96	54	202	95	35	27	12	841

The Clinical and Data Coordinating Centers thank all participating sites for their ongoing efforts on the study.

TASK ORDER 008 / DEEP UPDATE

DSUVIA Early Evaluation of Pain (DEEP) is an open-label, prospective, randomized, interventional trial comparing standard pain medication to DSUVIA (sublingual sufentanil) for adult trauma patients with moderate to severe pain in the emergency department.

We eagerly await publication of the primary manuscript in Anesthesia and Analgesia while our co-investigators explore potential secondary analyses of this dataset.

TASK ORDER 010 / CAVALIER UPDATE

CALcium and VAsopressin following Injury Early Resuscitation trial (CAVALIER), or Task Order 10, is a double blind, randomized multicenter trial designed to determine if prehospital calcium, early in-hospital vasopressin, or a combination improves outcomes in injured patients at risk of hemorrhagic shock.

In-hospital enrollment at Pitt has kept a rapid pace with 26 as of January 2, 2025. The Allegheny General Hospital (AGH) team is preparing to open to enrollment, beginning with the prehospital phase with Allegheny Health Network Critical Care Ground Transport and Allegheny Health Network LifeFlight in January 2025!

CAVALIER sites and services continue to drive community consultation and public disclosure efforts across the country! If you are wrapping up your activities soon, please keep in mind that submission should include OHRO Addendums for your site and services (if applicable) and local informed consent forms.

All-Site updates for January were distributed via email. We will resume our regularly scheduled CAVALIER All-Site calls on Friday, February 7 at 2pm (ET). At least one representative from each site and service should attend each call in this monthly series. Please make every effort to attend.



IMPORTANT DATES

February 5, 2025	12:00 pm ET	TOWAR monthly call
February 5, 2025	2:00 pm ET	PAIN monthly Coordinator call
February 7, 2025	2:00 PM ET	CAVALIER monthly Coordinator call
February 14, 2025	10:00am ET	PACT Study Monitoring Committee and conference call
March 5, 2025	12:00 pm ET	TOWAR monthly call
March 5, 2025	2:00 pm ET	PAIN monthly Coordinator call
March 7, 2025	2:00 PM ET	CAVALIER monthly Coordinator call
March 14, 2025	10:00am ET	PACT Study Monitoring Committee and conference call
April 2, 2025	12:00 pm ET	TOWAR monthly call
April 2, 2025	2:00 pm ET	PAIN monthly Coordinator call
April 4, 2025	2:00 pm ET	CAVALIER monthly Coordinator call
April 11, 2025	10:00am ET	PACT Study Monitoring Committee and conference call



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