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OPERATIONS MEMOS

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

- **T05 #35 distributed 5/7/25** notifying sites about the IRB annual renewal effective 5/6/25.
- **T06 #20 distributed, 5/6/25** notifying sites that changes have been made to the SCR and COM forms, updates to Data Management Manual and MATRIX Training slides were available.
- **T06 #21 distributed 5/22/25** notifying sites that MOP v9.0 was available.
- **T010 #21 distributed 4/17/25** notifying sites that changes have been made to the LAB and COM forms.
- **T010 #22 distributed 5/5/25** notifying sites that MOP v8.0, updates to Data Management Manual and MATRIX Training slides were available.
- **T010 #23 distributed 5/30/25** notifying sites that Protocol v9.0, MOP v9.0, and updates to Data Management Manual 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

SWAT (Shock, Whole Blood, and Assessment of TBI) was an observational study conducted at seven U.S. trauma centers with 1,051 patients at risk of hemorrhagic shock (70% of whom received massive transfusion). The SWAT dataset can be used for secondary analyses and was made available to all LITES investigators in February 2025. If you would like access to the data, please contact Laurie Silfies (silfies@pitt.edu) at the LITES Data Coordinating Center.

Please remember;

1. Presentations that use SWAT data must include the following:

"This research is supported by DoD Contract No. W81XWH-16-D-0024, Task Order W81XWH-16-D-0024-0002. Any opinions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the Department of Defense. The views, opinions and/or findings contained in this report are those of the author(s) and are not an official Department of the Army position, policy or decision."

2. Publications in peer-reviewed journals must include the following:

"This research is supported by DoD Contract No. W81XWH-16-D-0024, Task Order W81XWH-16-D-0024-0002."



TASK ORDER 004 / CriSP UPDATE

CriSP-HS

CriSP-HS data remains available for secondary analyses; anyone interested should complete a publication request form here:

<https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=3LANCM7TH8>.

CriSP-TBI

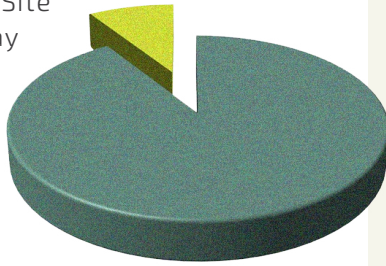
Publication of the TBI dataset on the FITBIR database is nearly complete.

As with CriSP-HS, data for CriSP-TBI remains available for secondary analyses. If interested, please complete a publication request form, found here: <https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=3LANCM7TH8>.

TASK ORDER 005 / PACT UPDATE

As of 6/30/25, we are at 1828 enrollments which means we only need 181 enrollments to complete enrollment!

Monitoring Committee/All-Site calls continue the 2nd Friday of each month at 10am (ET). The next calls will be on July 11th, August 8th, and September 12th. This once-a-month call provides all the details of how the study is progressing and distributes the Study Monitoring Committee tables so that all sites can follow our progress.



All 24 EMS services are in the SGA-first arm and will stay in that arm as we complete the study. We have officially closed the Washington University site in St. Louis, MO and will provide communication of our close-down plan to all other sites once we get closer to our final goal of 2009 enrollments.

The most recent DSMB meeting was held on 4/4/2025. The official DSMB letter is available on the LITES website so please retrieve it from the LITES library and put it into your regulatory binders as necessary.

As a reminder, all consent resolutions for last quarter are due by the end of July.

The next consent uploads will be due at the end of July. These will be for all enrollments that occurred April, May, and June. Also, continue to bill LITES monthly for percent effort and any data payment reports that you receive each month. Any subject with complete data entry and without edits on the last day of the month is eligible for payout at the beginning of next corresponding month.

We have issued new EMS Encouragement posters digitally and will soon be sending them via mail to each EMS service in hopes of keeping our services engaged and eliminating any missed enrollments. If you have any feedback for us, please reach out. Otherwise, we hope to have a robust summer enrollment period!

TASK ORDER 006 / PAIN UPDATE

As of 6/30/25, we are at 101 of our 994 enrollments needed for the PAIN (Prehospital Analgesia Intervention) study.

Ninesites are currently enrolling: AGH, UPMC, Cooper University Hospital, Medical College of Wisconsin (Milwaukee), University of California San Diego, University of Cincinnati, University of Utah, Donald Guthrie Foundation, and Atrium Health.

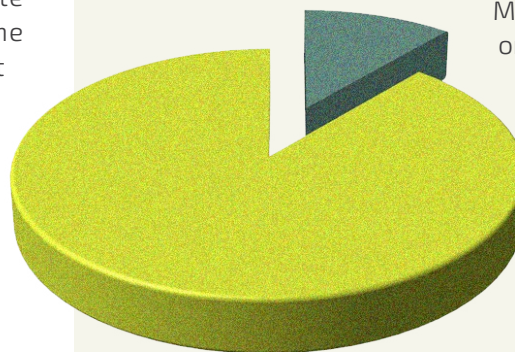
Two sites anticipate starting enrollments Summer 2025: University of California San Francisco and the University of Vermont Medical Center. We are also looking to onboard two additional sites, one in Texas and one in Utah. LITES is currently working with those sites to begin contracts and IRB reliance.

Pine Pharmaceuticals is hoping to have replacement drug for August 1, 2025; however, we are ready to implement a back up plan if necessary. Please monitor your email for any updates related to drug availability.

Updated EMS training slide decks (Full training, Refresher training, and Enrollment Reminder training) are available on the EMS Resource tab on the LITES network website using the passcode **ems2021**. Also, more durable hangtags have been purchased and will be sent to services in the near future.

Quarterly consent uploads were due to May 31st for all enrollments in February, March, and April. Those consent reports were generated June 30th. Please complete any queries from the consent reports by the end of July.

The next Quarterly consent uploads and data payout lock will occur on August 31st for all subjects who are enrolled in May, June, and July.



Monthly all site calls are held on the first Wednesday of each month at 2pm (ET). The next all-site calls will be August 6th, and September 3rd. Talk to you all then!

TASK ORDER 007 / TOWAR UPDATE

TOWAR reached accrual and closed to enrollment on 06/28/2025! Huge congratulations to all of our participating sites for their outstanding dedication and contribution to the study. Special congrats to the UT Houston site for being the top enrollers at a whopping 251 subjects - great job! Data cleaning and preliminary analyses are currently underway, with a plan to submit the primary manuscript to a high-impact journal in late summer/early Autumn. Final data entry and upload deadline is August 15, 2025.

Quarterly consent uploads and data entry were due on 06/30/2025. The final upload and data entry deadline is TBD and will be communicated to sites once it has been confirmed.

Final enrollment totals are as below:

Pitt	UW	Vandy	UMMC	UC	UT Hou	Knox	Metro	Lou	UAB	Man	TOTAL
150	140	82	116	63	251	114	39	34	24	7	1020

The DCC and CCC want to extend our thanks and gratitude to the TOWAR site teams, EMS agencies, and everyone else involved in the execution of this trial. We look forward to sharing the results with everyone soon!



TASK ORDER 008 / DEEP UPDATE

DSUVIA Early Evaluation of Pain (DEEP) was 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. The primary manuscript was published online in Anesthesia and Analgesia in February 2025, "A Randomized Controlled Trial of Sublingual Sufentanil in Early Management of Pain in Trauma." The article is expected to appear in a print issue of the journal this summer.

The DEEP dataset was made available to all LITES investigators in April 2025. If you would like access to the data, please contact Laurie Silfies (silfies@pitt.edu) at the LITES Data Coordinating Center. Additionally:

- Presentations that use DEEP data must include the following:
"This research is supported by DoD Contract No. W81XWH-16-D-0024, Task Order W81XWH-21-F-0448. Any opinions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the Department of Defense."
- Publications in peer-reviewed journals must include the following:
"This research is supported by DoD Contract No. W81XWH-16-D-0024, Task Order W81XWH-21-F-0448."



STUDY SPOTLIGHT

TASK ORDER 010 / CAVALIER UPDATE

CaIcium 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.

1,050 subjects will be enrolled in the prehospital phase, in-hospital phase, or both phases by seventeen LITES trauma centers and participating prehospital agencies (**new in Q2**).

- ▶ University of Arizona
- ▶ Allegheny General Hospital
- ▶ Denver Health
- ▶ University of Arkansas for Medical Sciences
- ▶ Hennepin County Medical Center
- ▶ University of Miami
- ▶ University of Mississippi
- ▶ **Chandler Regional Medical Center**
- ▶ University of Missouri Healthcare
- ▶ University of New Mexico
- ▶ Ohio State University
- ▶ University of Pittsburgh
- ▶ University of Washington, Seattle
- ▶ Texas Tech University Health Sciences Center
- ▶ University of California, San Francisco
- ▶ **University of Maryland, Baltimore**
- ▶ **University of Colorado Anschutz Medical Campus**

Bravo to the team at Denver Health Medical Center who activated the in-hospital phase on June 20th, 2025!

Warm welcome to the teams at our newest CAVALIER sites: University of Maryland, Baltimore (Baltimore, MD), University of Colorado Anschutz Medical Campus (Aurora, CO) and Chandler Regional Medical Center (Chandler, AZ).

Kudos to the University of Miami, University of California, San Francisco, Hennepin County Medical Center, University of Washington, Seattle, Texas Tech University Health Sciences Center and University of New Mexico for receiving sIRB approval of their community consultation and public disclosure results!

In-hospital CAVALIER enrollment is 42 as of June 30, 2025. Prehospital CAVALIER enrollment is 14 as of as of June 30, 2025. No dual phase enrollments have occurred to date.

All-Site updates for July will be distributed via email. We will resume our regularly scheduled CAVALIER All-Site calls on Friday, August 1 at 2pm (EST). At least one representative from each site and service should attend each call in this monthly series. Please make every effort to attend.

Enrolling sites, please note the following deadlines:

Consent forms uploaded to Florence eTMF	July 31, 2025	October 31, 2025
Data entry complete in MATRIX to qualify for quarterly payment.	June 30, 2025	September 30, 2025

LITES 2: TASK ORDER 002 / PREEVEnT

The Plasma Resuscitation Early to Evaluate Volume and Endotheliopathy of Thermal Injury (PREEVEnT) Trial is the first clinical trial task order under the new LITES-2 contract. PREEVnT will be the first burn study conducted by LITES, as well as the first burn study to operate under Exception from Informed Consent in the US. PREEVEnT is an open-label, Phase III, randomized clinical trial. It will have a 4-year enrollment period utilizing 15 busy burn centers from within the LITES-2 Network and will enroll 750 patients.

PREEVEnT will compare patients that receive early plasma resuscitation versus standard care and have a composite primary endpoint of 28-day all-cause mortality and/or 28-day Persistent Organ Dysfunction. The target cohort is adult patients with a $\geq 20\%$ Total Body Surface Area (TBSA) thermal burn that are expected to require ICU-level care. Enrollment is expected to begin in Spring 2026. The University of Pittsburgh will be the Clinical Coordinating Center and the Data Coordinating Center for this study. The CCC has obtained IND approval, selected participating sites, and submitted the initial application for review to the sIRB. We are excited to be progressing well with startup of this landmark trial!



IMPORTANT DATES

▶ July 11, 2025	10:00 am ET	PACT Study Monitoring Committee and conference call
▶ July 31, 2025		PACT consent uploads due
▶ July 31, 2025		PACT data due to be eligible for payment
▶ July 31, 2025		CAVALIER consent uploads due
▶ August 1, 2025	2:00 pm ET	CAVALIER monthly Coordinator call
▶ August 6, 2025	12:00 pm ET	TOWAR monthly call
▶ August 6, 2025	2:00 pm ET	PAIN monthly Coordinator call
▶ August 8, 2025	10:00 am ET	PACT Study Monitoring Committee and conference call
▶ August 15, 2025		TOWAR final data entry and upload deadline
▶ August 31, 2025		PACT data due to be eligible for payment
▶ August 31, 2025		PAIN consent uploads due
▶ September 3, 2025	12:00 pm ET	TOWAR monthly call
▶ September 3, 2025	2:00 pm ET	PAIN monthly Coordinator call
▶ September 5, 2025	2:00 pm ET	CAVALIER monthly Coordinator call
▶ September 12, 2025	10:00 am ET	PACT Study Monitoring Committee and conference call
▶ September 30, 2025		PACT data due to be eligible for payment
▶ October 1, 2025	12:00 pm ET	TOWAR monthly call
▶ October 1, 2025	2:00 pm ET	PAIN monthly Coordinator call
▶ October 3, 2025	2:00 pm ET	CAVALIER monthly Coordinator call
▶ October 10, 2025	10:00 am ET	PACT Study Monitoring Committee and conference call
▶ October 31, 2025		PACT data due to be eligible for payment
▶ October 31, 2025		CAVALIER consent uploads due

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*Any opinions, findings and conclusions or recommendations expressed in this material
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