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OPERATIONS MEMOS

Eleven 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 #17 distributed 1/23/25** notifying sites about the IRB annual renewal effective 1/21/25.
- **T06 #18 distributed, 2/19/25** notifying sites that changes have been made to the INJ form.
- **T06 #19 distributed 3/12/25** notifying sites that MOP v8.0 was available.
- **T07 #12 distributed, 2/14/25** notifying sites that changes have been made to the SCR form.
- **T010 #14 distributed 1/23/25** notifying sites that changes have been made to the SCRiH form.
- **T010 #15 distributed 2/11/25** notifying sites that MOP v6.0 and Pharmacy Manual v3.0 were available.
- **T010 #16 distributed 2/12/25** notifying sites that that changes have been made to the PREH form and only QxQs for EDS and NINF forms. Data Management Manual 'Table of Forms' and 'Forms List' were also updated.
- **T010 #17 distributed 2/24/25** notifying sites that MOP v7.0 was available.
- **T010 #18 distributed 2/28/25** notifying sites that changes have been made to the SCRiH form.
- **T010 #19 distributed 3/19/25** notifying sites that changes have been made to the LAB form and Q X Q only revisions for SCRPH, SCRiH and NINF.
- **T010 #20 distributed 3/20/25** notifying sites about the IRB annual renewal effective 3/18/25 and that the updated consents are 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.

SPOTLIGHT

LITES is making the CriSP-TBI and DEEP datasets available to all LITES investigators! If you would like access to the data, please contact Laurie Silfies (silfies@pitt.edu) at the Data Coordinating Center.

When working on secondary analyses, please remember ;

1. To eliminate duplicative efforts, **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. Please use this link to submit your Publication Requests:
<https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=3LANCM7TH8>
3. **Presentations must include a funding statement and disclaimer statement** – see the CriSP and DEEP sections for details.
4. **Publications in peer-reviewed journals must include a funding statement** - see the CriSP and DEEP sections for details.



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

Please be reminded that the publication request form now includes 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. We look forward to collaborating with you on your proposed secondary analyses!

CriSP-TBI

The primary manuscript for CriSP-TBI was published ahead of print in January in the *Annals of Surgery*.

Read it here: DOI - [10.1097/SLA.00000000000006640](https://doi.org/10.1097/SLA.00000000000006640).

The study found that in brain injured patients requiring platelet transfusion, early cold stored platelet transfusion is feasible, and did not result in improved 6-month Glasgow Coma Scale-Extended scores. Early cold stored platelet transfusion was associated with a lower rate of neurosurgical operative intervention without an increase in adverse events. The storage age of the cold stored platelet product was not associated with outcome differences.

LITES will be making the CriSP-TBI dataset 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;

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

"This research is supported by DoD Contract No. W81XWH-16-D-0024, Task Order W81XWH-19-F-0494. 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."

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-19-F-0494."



TASK ORDER 005 / PACT UPDATE

*As of 4/1/25, we are at **1729** enrollments which means we only need **261** enrollments to complete enrollment!*

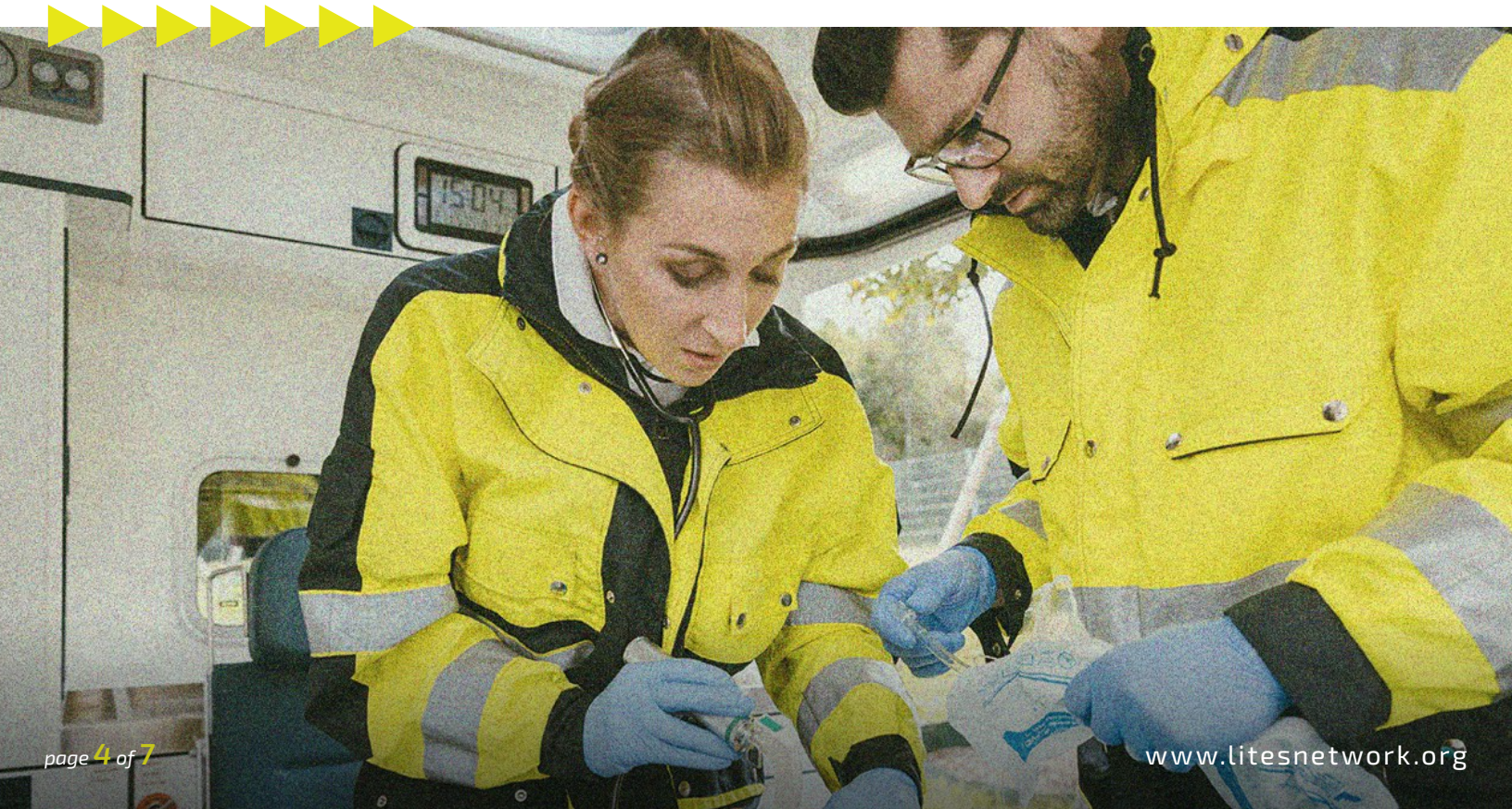
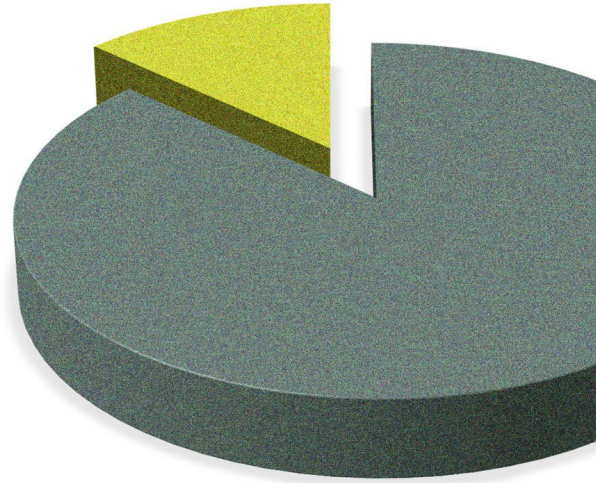
Monitoring Committee/All-Site calls continue the 2nd Friday of each month at 10am (ET). The next calls will be on April 11th, May 9th, and June 13th. This once-a-month call provides all the details of how the study is progressing and distributes the Study Monitoring Committee tables so that all sites can follow our progress.

The last services to step over to SGA-first arm have done so and now all 24 EMS services will complete the study in the SGA-first arm.

The most recent DSMB meeting was held on 4/4/2025. Once we receive the communication from that meeting, we will forward it to all sites to keep in their regulatory binders.

As a reminder, all consent uploads are due on 4/30/2025. 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.

Please continue to encourage your EMS service(s) to stay engaged. As we approach the summer months, we will start to develop a communication plan to end enrollments. More details to follow as we get closer to our 2009 needed enrollments. Stay tuned!



TASK ORDER 006 / PAIN UPDATE

As of 4/1/25, we are at 65 of our 994 enrollments needed for the PAIN (Prehospital Analgesia Intervention) study.

Nine sites 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.

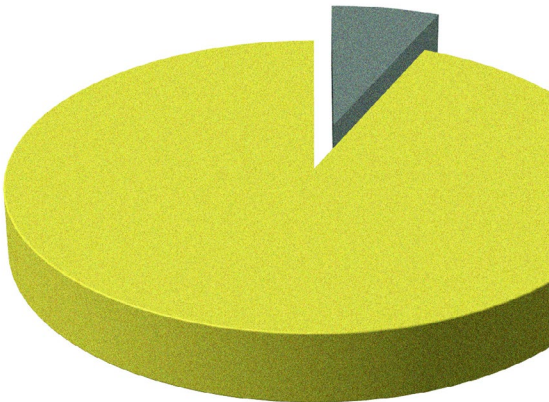
Two sites anticipate starting enrollments within quarter 2 of 2025: University of California San Francisco and the University of Vermont Medical Center. We are also looking to onboard two additional sites, one in Texas and one in Utah. LITES is currently working with those sites to begin contracts and IRB reliance.

Pine Pharmaceuticals provided Spring Study Drug to enrolling sites which will require replacement on May 14, 2025. Please remember to update the kit status in MATRIX ASAP for those kits being destroyed/wasted when a new batch of drug is delivered.

EMS training slide decks and reminder materials are available on the EMS Resource tab on the LITES network website using the passcode **ems2021**.

Quarterly consent uploads and data payout lock occurred on February 28th for all enrollments in November, December, and January. Those consent reports were distributed March 31st. Please be sure to have signed reports returned by April 15th. Also, any queries will need answered by April 30th. The next Quarterly consent uploads and data payout lock will occur on May 31st for all subjects who were are enrolled in February, March, and April.

Monthly all site calls are held on the first Wednesday of each month at 2pm (ET). The next all-site calls will be May 7th, and June 4th. Talk to you all then!



TASK ORDER 007 / TOWAR UPDATE

Since last quarter, the University of Manitoba Health Sciences Centre commenced enrollment and enrolled their first patient on February 26th! Enrollment study wide has surpassed 75% and we’re in the home stretch. Based on current projections, enrollment is estimated to be complete by late spring or early summer of this year. Sites should begin local discussions regarding their wind down plan with their EMS services and blood suppliers in preparation for study closeout. A comprehensive plan from the Coordinating Center detailing study-wide closing procedures will be forthcoming.

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 April 1st is as follows:

Pitt	UW	Vandy	UMMC	UC	UT Hou	Knox	Metro	Lou	UAB	Man	TOTAL
138	129	74	103	59	218	107	39	27	19	2	915

As a reminder, all consent uploads are due on 6/30/2025. Any subject with complete data entry and without edits on 6/30/2025 is eligible for payout at the beginning of next corresponding month.

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) 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 in Anesthesia and Analgesia in February 2025, *"A Randomized Controlled Trial of Sublingual Sufentanil in Early Management of Pain in Trauma."*

LITES will be making the DEEP dataset 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:

1. 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."
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-21-F-0448."



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.

Allegheny General Hospital enrolled the first prehospital phase CAVALIER subjects this quarter! Congratulations to AGH and collaborating EMS partners for a strong start. AGH has enrolled 6 in the prehospital phase and the Pittsburgh site has had 34 in-hospital phase enrollments as of April 1, 2025.

Enrolling sites, please note the following deadlines:

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

Kudos to the University of Arizona and Denver Health sites for receiving sIRB approval of their community consultation and public disclosure results!

CAVALIER sites and services continue to drive community consultation and public disclosure efforts across the country. We anticipate many sites wrapping up activities soon and drafting results reports for submission to sIRB. When submitting your site's results, please be sure to include local informed consent forms and OHRO Addendums for your site and service(s) (if applicable).

The monthly All-Sites call resumed on April 4 (updates for March were distributed via email). Our next regularly scheduled CAVALIER All-Sites call will be on Friday, May 2nd 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.

IMPORTANT DATES

APRIL

April 11, 2025	10:00am ET	PACT Study Monitoring Committee and conference call
April 30, 2025	--	PACT consent uploads due
April 30, 2025	--	PACT data due to be eligible for payment
April 30, 2025	--	CAVALIER consent uploads due

MAY

May 2, 2025	2:00 PM ET	CAVALIER monthly Coordinator call
May 7, 2025	12:00 pm ET	TOWAR monthly call
May 7, 2025	2:00 pm ET	PAIN monthly Coordinator call
May 9, 2025	10:00am ET	PACT Study Monitoring Committee and conference call
May 31, 2025	--	PAIN data due to be eligible for payment
May 31, 2025	--	PAIN data due to be eligible for payment

JUNE

June 4, 2025	12:00 pm ET	TOWAR monthly call
June 4, 2025	2:00 pm ET	PAIN monthly Coordinator call
June 6, 2025	2:00 PM ET	CAVALIER monthly Coordinator call
June 13, 2025	10:00am ET	PACT Study Monitoring Committee and conference call
June 30, 2025	--	PACT data due to be eligible for payment
June 30, 2025	--	TOWAR consent uploads due
June 30, 2025	--	TOWAR data due to be eligible for payment
June 30, 2025	--	CAVALIER data due to be eligible for payment

JULY

July 2, 2025	12:00 pm ET	TOWAR monthly call
July 2, 2025	2:00 pm ET	PAIN monthly Coordinator call
July 11, 2025	10:00am 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



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