

Please welcome our new NCC regulatory specialist, Jen Golan, MS! Please copy Jen (golanjl@ucmail.uc.edu) on all MOST regulatory correspondence.

Start-up Timeline

Goal First-Patient-In is May, 2019!

Currently, study drug is undergoing manufacturing and FDA mandated stability testing. These tests are required because study drug is being manipulated from its commercially available form and repackaged for MOST. We are planning to hold the protocol training webinar at the beginning of April 2019. As many sites as possible should be CIRB approved, trained and ready to enroll by the end of April 2019.

What can sites do now?

CIRB packets will be disseminated to sites that have a reliance agreement in place starting the week of January 14, 2019. Sites should work diligently to upload required regulatory documents to WebDCU™ and turn around CIRB application packets expediently (within 30 days of receipt). Please email the RCC regulatory team (Emily Stinson and Jen Golan) your completed Local Site Context Form and Informed Consent Form for pre-review prior to submission to your local IRB.

International Stroke Conference Reception

Please join us at the StokeNet, ARCADIA and MOST joined mixer at the ISC in Hawaii!

Wednesday, Feb 6, 2019 at 6:30-8:30 pm

Hilton Hawaiian Village, Rainbow Suite I-II

Appetizers and cash bar

Please RSVP to Rose Beckmann (beckmare@ucmail.uc.edu) and let her know you are from the MOST team. Please limit to MOST study staff only.

Investigator Meeting

Mark your calendars for the MOST Investigator Meeting which will be held in Philadelphia, PA in conjunction with the AAN Conference on Monday, May 6, 2019. Details to follow. Please do not begin making arrangements until formal instructions are disseminated.

Ancillary Studies Solicitation

Reminder to contact Dr. Adeoye (adeoyeo@uc.edu) and Iris Deeds (deedsss@uc.edu) with MOST ancillary study proposals by *January 15, 2019*.

FAQS

Which Lab Reference Ranges should be provided?

Please provide reference ranges for the local labs being required/requested by the Protocol. Those labs include: Glucose, Creatinine, Blood Urea Nitrogen (BUN), Hemoglobin (HGB), Hematocrit (HCT), White Blood Cell Count (WBC), Platelet Count (PLT), INR, Prothrombin Time (PT), and Partial thromboplastin Time (PTT).

Please add the name of the local lab on the 1572 in box 4 and make sure the reference range document references that lab name and address. CAP and CLIA need to also match the lab listed in box 4 on the 1572.

Who should be listed on the 1572 and the DoA?

Please do not list the pharmacist on the 1572 but do list them on the DoA. Essential, or primary study team members should be listed on both the 1572 and DoA using the exact same

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name. Primary study team members are individuals that will be performing study related procedures. Other non-essential, or administrative team members do not need to be listed on the DoA or 1572, but can be added to the study team list in WebDCU™ in order to receive WebDCU™ access, if needed.

Please do not remove the CIRB name and address listed in box 5 of the 1572. The CIRB is the IRB of record and needs to be listed in box 5 of the 1572 NOT the sites local IRB. The sites local IRB does not need to be listed on the 1572.

Who should complete the fCOI and the FDA form 3455?

All investigators listed on the DoA and 1572 will need to fill out and sign both the fCOI and the FDA 3455. For the 3455, all boxes can be left unchecked if there is NO conflict of interest. By signing the form with all boxes unchecked confirms that the investigator is agreeing they do not have a conflict of interest. Boxes on this form only need to be checked if the investigator does have a conflict of interest.

Congratulations to the new sites to complete their fully executed Clinical Trials Agreement!

As of 12/7/2018 through 1/11/2019:

- University of New Mexico Hospital, Albuquerque, NM: PI – Tobias Kulik, MD
- University of Michigan University Hospital, Ann Arbor, MI: PI – Cemal Sozener, MD
- UPMC Presbyterian Hospital and UPMC Mercy Hospital, Pittsburgh, PA: PI – Ashutosh Jadhav, MD
- Swedish Medical Center, Englewood, CO: PI – Jeff Wagner, MD
- Abington Memorial Hospital, Abington, PA: PI – Hana Choe, MD
- Mercy Health Saint Mary's, Grand Rapids, MI: PI – Muhammad Farooq, MD
- Yale New Haven Hospital, New Haven, CT: PI – Caitlin Loomis, MD
- Greenville Memorial Hospital, Greenville, SC: PI – Sanjeev Sivakumar, MD