

From: Beckmann, Rose (beckmar)
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 Subject: NIH StrokeNet Biweekly Update 3-July 2020
 Date: Thursday, July 2, 2020 10:43:51 AM
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Biweekly Update 3-July 2020

StrokeNet Enrollment Update

ARCADIA	447/1100	CREST 2	1680/2480
Sleep SMART	258/3062	CREST H	145/500
TRANSPORT2	12/129	MOST	44/1200
I-ACQUIRE	22/240	ARCADIA-CSI	53/500
ASPIRE	1/700	SATURN	3/1480

StrokeNet Trial Updates



- On May 12, 2020, the cIRB approved out plan to **re-open the trial to enrollment** and procedures for remote consent, randomization, and participant follow-up.
 - Suspended sites have been contacted to enquire if they are able to resume enrollment.
 - Before being re-released to enroll, the site PI must attest that resumption can take place safely, in conformity with local restrictions, and without contributing to shortage of resources needed for care of COVID-19 patients.
 - All sites must complete a Remote and Electronic Informed Consent Implementation form to be submitted to the cIRB via the ASPIRE NCC Project Manager.
 - The cIRB approved **ASPIRE Remote Study Procedures** and **Remote and Electronic Informed Consent Implementation form** are posted in WebDCU > ASPIRE Toolbox
- Screening activities are continuing as permitted by local institutional policies.
- Please remember to update the **COVID-19 Impact Assessment v2** in WebDCU to alert us to any changes in local restrictions on screening or enrollment.
- For sites still pending activation, please:
 - Upload/waive pending regulatory documents.
 - Enter addresses for study drug and lab kit shipments.
 - If CTA and cIRB approval in place, schedule readiness call.
- ASPIRE next Webinar is July 22, 2020 3:00p-4:00p EDT <https://nihstrokenet.adobeconnect.com/trials/>
To take part in the conversation dial 1 (877) 621-0220 Pass Code: 745694



Amendment V2 has been approved by the cIRB. The approved protocol and protocol signature page can be found in WebDCU in the toolbox. Complete the protocol signature page and upload into WebDCU.

The following sites have been approved for Protocol Amendment V2 and are re-released to enroll:

University of Texas Health Science Center San Antonio
University of Cincinnati
University of Mississippi
MUSC
University of Alabama
University of Utah
OSU Wexner
Yale New Haven

All sites must complete the Covid 19 Impact Assessment Form in WebDCU prior to re-opening.

Sites still pending activation:

- Update **all** regulatory documents in WebDCU
- If you need to schedule your site readiness call – do so by contacting study team members below

Sites who were open prior to the Covid-19 pause:

- Update all regulatory documents
- Upload the approved continuing review documents

Please contact Tashia Harris, herndotl@ucmail.uc.edu or Stephanie Kemp, skemp@stanford.edu with any questions.



Re-Opening: On Wednesday, June 16 the Central IRB (CIRB) at the U of Cincinnati approved our re-opening plan. On clinicaltrials.gov, we have removed the “trial suspension” designation and restored the open and “recruiting” designation.

Last week, Max Mays from the National Coordinating Center (NCC) at the U of Cincinnati sent to each site the specific details for how your local site can “open up” by reviewing the guidelines and then entering your “plan” agreement on the WebDCU. Remember that if your site will not comply with or is adding extra elements to your plan, you must submit this to [Laura Bateman](#) for our leadership team to review and approve.

A copy of the letter of acceptance and a copy of the plan for the overall trial for safe and healthy guidelines for re-opening was e-mailed to each site. Please reach out if you have any questions.

Save the date: Our next PI/Co-I/Coordinator Webinar will be Thursday 09 July (12-1pm ET).



Our next PI and Coordinator call will be on **Monday, 7/6/2020 at 11am ET**. If anyone has topics they would like to discuss during the call, please send them to Kristina Balderson (Kristina.balderson@duke.edu) or Julia Gonzalez, (Julia.jackson@duke.edu).


As sites are planning to reopen to enrollment, please take inventory of your supplies and contact either Julia Gonzalez or Kristina Balderson for restock. When reaching out, please indicate the number of supplies needed, contact, and shipping location with confirmation that someone will be able to receive these shipments. Home addresses are approved for receiving shipments during this time of remote working or limited time at the site. For other questions or concerns, please contact Julia or Kristina.

Please make sure you have completed your BlueCloud recertification training by logging into the website: <http://duke-transport2.trainingcampus.net>. Individuals who have expired or about to expire training have been sent reminder emails. **Note this is for the scoring of the Fugl Meyer, not the video training.** Annual renewal is now being tracked in WebDCU, which will notify coordinators directly when any of their staff have outdated training.

Congratulations to Medstar and UAB for successfully reopening to enrollment amidst the new COVID-19 restrictions. We are hopeful that by the end of July, the following sites will be reopened to enrollment: Baystate, Emory, University of Cincinnati, and University of Kentucky. Cleveland VA has a fully executed CTA and CIRB approval, and currently working through their local IRB submission. Duke has received IRB approval, is working through their training certifications. UPMC has received CIRB approval and is working on signing the CTA. There are 12 subjects randomized in the trial. Five have completed the study, and six have completed the intervention phase and are in the follow-up period.

Thank you for your continued effort and flexibility during this time!

From the CREST-2 Clinical Coordinating Center:

	CREST-2		CREST-2 StrokeNet
	CEA	884	382 (44% of total)
	CAS	799	134 (17% of total)
	Total	1683	516 (31% of total)

We surpassed our June goal! As you know, the CREST-2 recruitment goal until October 2020 is **15** patients a month. With your help, we finished strong in June with **23** randomizations! Congratulations to the following StrokeNet sites that randomized this month: **VA Ann Arbor, Mayo Clinic Rochester, Mayo Clinic Florida, UPMC Hamot, UPMC Altoona, Novant, OHSU, Ochsner, University of Iowa, Northwestern University, and UAB.** Currently, **30 of 57** StrokeNet sites have communicated to their respective site managers that they have completed the steps to re-initiate CREST-2 enrollment at their institution. We encourage you to reach out to the Clinical Coordinating Center to let us know the status of your institution opening up research operations and specifically CREST-2.



Site Startup and Enrollment Updates: sites: **54**; enrollments: **145/350**

WE ARE BACK IN BUSINESS! We have 32 of our 54 sites that have been “unpaused” although 6 of them are still waiting for research imaging to resume. We have had 6 enrollments since reopening, bringing our total to 145, **41%** of our target. We are looking forward to reopening of the remaining 22 sites. We have **6** additional sites in the onboarding pipeline.

There have been questions from several sites about **remote consenting and e-consent** for CREST-H. For now, e-consenting is not available. What is acceptable is to discuss the CREST-H study over the phone or video once the patient has consented to CREST-2. An electronic version of the CREST-H consent form can even be emailed or mailed to the patient to facilitate the discussion. In order to save the patient an extra trip to your medical center, you can have the patient simply sign the CREST-H consent when they arrive at the scanner. Please don't hesitate to contact Jaya, Kevin, or one of the CREST-H PIs with any questions about this.

Also, due to **restrictions on research imaging** at some medical centers are still on hold at the moment, so **1-year CREST-H perfusion scans** may be delayed. We have gotten approval to delay the 1-year scans until after your site reopens its scanners to research. You will have up to 3 months from that point to complete the scan.

We are still recruiting additional sites. Contact Randy Marshall rsm2@columbia.edu, Ron Lazar rlazar@uabmc.edu, Jaya Vijayan vijayan.jaya@mayo.edu, or Kevin Slane KJS4@columbia.edu with any questions.



- **Kaiser Permanente Los Angeles Medical Center, Sarasota Memorial Hospital, Memorial Hermann Texas Medical Center and University of Cincinnati Medical Center** enrolled one subject each in the past week! Well done Dr. Sangha, Dr. Concha, Dr. Barreto, Dr. Demel and teams!
- Congratulations to **University of Kansas Hospital** and **University of Utah Healthcare** who have been released to enroll!
- There are now **61** sites that have been released to enroll, **31** of which are actively recruiting!

MOST Enrollment Update:

- Total randomizations: **44**
- Sites released to enroll with at least one patient consented: **19**

MOST Update:

- The StrokeNet Central IRB has approved the use of remote consent for MOST, including the centrally managed eConsent through REDCap. We are excited to be the first StrokeNet Trial to test this consenting method.

MOST Appreciated:

- For sites that are released to enroll please continue to complete screening logs in WebDCU™.
- For sites that have not been reactivated, please continue to update the COVID Impact Assessment in WebDCU™ with information on anticipated timelines for resuming research activities.

Thank you all for your efforts!

The PI hotline is available 24/7 for any questions: 1-833-229-MOST



Thank you for your participation in Sleep SMART. We hope you are doing well, especially during this difficult time.

AMENDMENT: Amendment v5.0 changes to your site-specific ICD were in most cases already made by the NCC, and submitted to the CIRB on your behalf. Most have already been approved. Once you receive your site CIRB approval letter with the approved ICD, please upload those to WebDCU as soon as possible and submit to your local IRB for acknowledgement, if required.

RE-OPENING: On May 15, 2020, the CIRB approved our request to end the study-wide hold on in-person interactions, including enrollment, in Sleep SMART. Please report this to your local IRB, if appropriate. In WebDCU, please update the COVID Impact Assessment survey to reflect the current status of research at your institution and, if you are ready to re-start enrollments, to indicate confirmation (in 'general comments') of the statements in the memo dated May 15, 2020. Email Joelle to let her know when your local IRB has acknowledged the recent amendment. Pending NDMC queries may delay our ability to release you, so please catch up on these. You will not be released to enroll until you receive official permission through a WebDCU email. Since our re-opening, 15 sites have been re-released to enroll and have in-person interactions. We have also had 2 subjects randomized since the COVID-19 hold.

Sites not previously released to enroll:

If your site was not previously released to enroll, please work toward site activation:

- CIRB submission
- Finalize the Clinical Trial Agreement and FusionHealth DUA and Consignment agreement
- Upload site and people documents to WebDCU
- Complete online trainings (<https://webdcu.musc.edu/campus/>)
- Complete readiness call
- Please review the site to-do checklist found in the WebDCU toolbox

Sites that have already enrolled:

Don't forget these important reminders:

1. Who is considered a proxy in Sleep SMART (for the outcome assessments)? Someone who spends enough time with subject in the opinion of the study team member and proxy to estimate how the subject would have answered the question. Proxies should leave blank any question to which they don't feel capable of providing an informed response.
2. Please perform the 3- and 6-month follow-up visits by telephone within the assessment window(!), by a blinded study team member: 90 days (-14 days, +30 days), 180 days (-14 days, +60 days).
 - If a blinded study team member is not available, but the assessment can still be done within window by an unblinded study team member, please take advantage of that opportunity and report performance by the unblinded investigator.
3. If the window for the 3-month visit ends and you have not been able to reach a subject, please continue to reach out to him/her until the 6-month window begins. Please pursue 6-month assessments out to 3 months past the 6 month assessment time point before considering the subject lost to follow-up.
4. If you can't get in touch with the subject by phone to schedule the outcome assessment, please check the consent form to see if you have permission to contact him/her by text or email. Alternative contacts may also be found in the back of the consent. Sleep SMART also has a letter template available on our

website (<https://www.nihstroke.net.org/sleep-smart-trial/research-team> "unable to reach letter template") and for those on the verge of being lost to follow-up, a lost to follow-up letter.

5. As a reminder, please ask subjects to answer PROMIS questions as they are written (do not provide specific instructions to attempt to eliminate the influence of COVID).
6. Please check "Alerts" in WebDCU to find unresolved queries.
7. Visit our website: www.nihstroke.net.org/sleep-smart-trial/research-team to review helpful materials.
8. If you missed one of our webinars, they are all available here: <https://www.nihstroke.net.org/sleep-smart-trial/webinars>
9. Recall that the informed consent checklist is mandatory to use for all enrollments.
10. Please complete the alternative contact information section of the informed consent document, and provide this information in KOEO.
11. Before hospital discharge, help initiate contact between intervention subjects and Care Team (program number in cell phone, help make first call, remind about \$10 for call completed within 1 week of discharge).
12. Remember to charge the Nox T3 internal clock quarterly.
13. All responses to Data Clarification Requests (DCRs) must be submitted within 5 days of query generation, except those associated with Serious Adverse Events, which must be answered within 24 hours of query generation. Site payments are contingent upon the subject's data being entered, submitted, and all DCRs addressed.
14. For stroke outcome events, please be sure to upload documentation in the outcome packets that provides information about new stroke symptoms, including focal neurological symptoms and signs on exam, and associated dates.



SATURN has enrolled 3 patients!!! Congratulations to Beth Israel Deaconess Medical Center, Harborview and UF Health Shands on enrolling a subject!

We recently amended the study protocol to allow for obtaining remote consent from potential subjects or their surrogates to minimize in-person exposure. Protocol and ICF v4 were distributed to all sites.

Procedures for reopening SATURN enrollment were distributed to all sites.

In order to restart enrollments for sites that were previously released to enroll:

- Site must be approved on Protocol v4, Informed Consent Form v4.
- Indicate on the COVID Impact Assessment in WebDCU that your institution allows subject enrollment.
- Notification will be sent when site enrollment suspension is lifted in WebDCU

Sites that have not yet been released to enroll should follow the steps outlined above once they have been activated. This requires reconciling all regulatory documents in WebDCU. The COVID Impact Assessment will only be accessible to the sites that have been activated.

Please continue to update the COVID Impact Assessment with information on anticipated timelines for resuming research activities.

MGH has resumed shipping lab kits out to sites who have completed a readiness call. Please remember to confirm receipt of the lab kits in WebDCU once you are able to do so.

If you have any questions regarding SATURN and reopening enrollment at your site please contact:

Kimberlee Bernstein NCC Project Manager gammk@ucmail.uc.edu

Sarah Marchina Prime Project Manager (BIDMC) smarchin@bidmc.harvard.edu



Happy and Healthy 4th of July!



We wish everyone a happy and restful holiday! We need it! We are also delighted to announce that full recruitment is now available as we have reopened several sites, the Echo lab, and the Core Lab!

We have re-opened 58 sites and a brand new site --welcome to the team DHR Health in Texas! Stanford, Maimonides, University of Minnesota, Yale and Swedish Cherry Hill have been able to finalize 6 pending randomizations and OU Medical Center has just randomized the first new subject since re-start, bringing us to 447 randomized subjects. Ten sites have enrolled 13 subjects since re-starting, resulting in 1722 consented subjects. Thank you ALL for moving ARCADIA forward!

We hope to continue to re-start sites as per the ARCADIA re-start plan and as possible at all the sites. Ninety-two of the ARCADIA sites have noted on the COVID-19 Impact Assessment form that you can enroll, even if in a limited fashion, yet many of you have not completed the requirements for re-release.

Please take the time to read these instructions and complete the online forms once your site is allowing the re-start of enrollment in ARCADIA (if you haven't already done so):

- COVID-19 Impact Assessment with the General Comment PI attestation. The specified phrase confirms local institutional ability to re-open and that you will follow the ARCADIA re-start plan.
- Upload the cIRB site-wide approval letter dated 4/29/2020 (Protocol v5 - 16APR2020).
- Upload Protocol Signature Page (Protocol v5 - 16APR2020) – this can be digitally signed by the PI.
- **cIRB Approved Administrative Amendments – the cIRB site-specific consent approval letter for your new consent forms – this upload is missing for many sites.**
- CIRB Approved Informed Consent Form (v7) – the PDF document; don't worry about translations for re-start, but please request them if you haven't already done so.
- Also, let Rebeca know if you need to submit to your local IRB before using the new consent forms.
- Email Rebeca (ra2356@cumc.columbia.edu) when your site has completed the requirements and is ready to be considered for re-release to enroll even if only doing remote screening, enrollments and follow ups.

In the meantime, please continue screening/keeping lists of potential participants that we can contact after the consent/randomization pause is lifted and stay in touch with patients to be sure they are weathering the crisis, and that their study-related medications continue.

As personnel changes and new staff come onboard often, we ask that you communicate with all of your team members regarding ARCADIA emails sent to the site's PI & PSC.

We thank you for your continued support and effort during these challenging times, but together we can move forward in ARCADIA.

In solidarity with all, we hope you will all keep safe!

Webinar: Our next PI and coordinator webinar will be July 28th at 2 PM Eastern--save the date! We're asking that at least 1 person from each site attend the monthly webinar and pass the information along to their team. Also, please send suggestions for topics you'd like discussed.

If you miss out on a webinar, you will soon be able to find the slides on the StrokeNet website (<https://nihstrokenet.org/intranet/minutes/trial-webinars>).

NIH COVID-19 Research Opportunities

Dear StrokeNet Colleagues,

As part of NIH's multi-faceted response to the COVID-19 pandemic, we have launched an unprecedented four-pronged initiative, entitled Rapid Acceleration of Diagnostics, or RADx, to catalyze the scientific community to improve testing technologies, capacity, and accessibility for the country. As one of the four RADx components, RADx-Underserved Populations (RADx-UP) will establish a network of community-engaged projects to improve access to and acceptance of testing in underserved and vulnerable populations. As part of the RADx-UP initiative, NIH has released four funding opportunities to solicit community-engaged research on COVID-19 testing among underserved and/or vulnerable populations to both understand and close the disparity gap:

<https://www.nih.gov/research-training/medical-research-initiatives/radx/funding>

NINDS has signed on to the first three in **BLUE**. NINDS has specifically identified StrokeNet's eligibility in the first opportunity.

These funding opportunities include:

1. Emergency competitive revision applications to existing awards for large consortia, multi-site trials, centers and other current networks that have adequate capacity, infrastructure, and established community-engaged relationships to support large-scale testing interventions or have the capacity to ramp up quickly to reach underserved or vulnerable populations.
 - a. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-121.html>
2. Second, complementary emergency competitive revision opportunity which shifts eligibility to collaborative and individual research awards, generally focused on smaller underserved or vulnerable populations.
 - a. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-120.html>
3. Emergency competitive revisions to solicit research to understand the social, ethical, and behavioral implications (SEBI) of COVID-19 testing in these populations.
 - a. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-119.html>
4. A new Coordination and Data Collection Center (CDCC) award (U24), a key component of the consortium. The CDCC will serve as a national resource, working with NIH scientific staff and consortium members to provide overarching support and guidance in the following four domains: (1) Administrative Operations and Logistics, (2) COVID-19 Testing Technology, (3) Community and Health System Engagement and (4) Data Collection, Integration and Sharing.
 - a. <https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-20-013.html>

Applications for this first phase will be accepted through August 2020 for FY20 funding. A second phase will be staggered to provide flexibility and to allow for adaption to the ever-changing needs that may be present as this pandemic evolves. Please visit Rapid Acceleration of Diagnostics (RADx) (<https://www.nih.gov/RADx>) to learn more.

We encourage you to share this information widely. If you have any questions, contact Scott Janis and Richard Benson at NINDS directly.

Best,

NINDS StrokeNet Team

Coordinator Webinar

Coordinator Webinars are a requirement for the NIH StrokeNet RCC Coordinators/Managers however, all are welcome to attend

Information for the next Coordinator webinar will be available soon.

Steering Committee Call

*Steering Committee Calls are a requirement for all NIH StrokeNet RCCs
Please invite your satellite sites to attend*

The next Steering Committee call is scheduled for **Wednesday, 8-July, 2020, 12 noon ET**. Dial in: 513-621-0220; 1-877-621-0220; Passcode 434578. Agenda attached. This will be a *webinar* so please log in as well as dial in:

To join the meeting: <https://nihstrokenet.adobeconnect.com/steering/>

Grand Rounds

*Grand Rounds are a requirement for the NIH StrokeNet Trainees, however all are welcome to participate.
Information for the next Grand Rounds will be available later this summer. Stay tuned.*

Professional Development Webinar

*Professional Development Webinars are a requirement for the NIH StrokeNet Trainees
Information for the next PDW will be available later this summer. Stay tuned.*

NIH StrokeNet Employment Opportunities

*For more information about StrokeNet employment opportunities, please visit
<http://nihstrokenet.org/education/employment-opportunities>*

Please share this update with your satellites and study teams!

Contact: Jamey Frasure, PhD, RN, Administrative Director · frasurej@ucmail.uc.edu · 513-558 1742
<https://www.nihstrokenet.org>