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Message From the NIH and STEP MPIs...

Welcome to the first edition of the **STEP** newsletter! We are very excited to take this first "step" together with you on what will hopefully be one of the most important trials to come out of the NIH StrokeNet!

Clinical Trial Agreement (CTA)

We appreciate your patience while we finalize the CTA template.

Central Institutional Review Board (cIRB)

We now have the University of Cincinnati cIRB approval for the STEP trial!



We are hopeful that CTAs and cIRB/Regulatory Documents can be sent in the near future!

Updated STEP Study Start-Up Timeline



Start-Up Timeline	
February 2024	Sites selected
May 2024	UC StrokeNet NCC to issue CTA to sites
May 2024	UC StrokeNet NCC to issue cIRB packet to sites (UC IRB)
Early Summer 2024	Sites to complete CTA and cIRB packets within 4-6 weeks of receipt
Summer 2024	Half-day Virtual Investigator Meeting (mid-July)
Late Summer	Site Readiness Calls
Fall 2024	First participant enrolled

STEP Performance Sites

STEP will allow the addition of performance sites if ALL of the following conditions are met:

1. The performance site is covered under the same IRB approval as the selected site (one IRB submission with two enrolling locations listed on the consent).
2. The performance site will be covered under the same CTA (The annual Site PI and Coordinator payment will not be increased for adding an additional performance site[s]).
3. The performance site is covered under the same GWTG agreement (i.e. has the same hospital ID).

OR

The performance site's data for STEP randomized participants will be directly entered into WebDCU™.

If you plan to add a performance site, please notify Harriet Howlett-Smith and Melissa Hoffman IMMEDIATELY!

Get With The Guidelines (GWTG) Agreements

Thank you to those sites that have already executed the GWTG amendment.

We recognize that some sites will not be able to execute the GWTG agreement until the CTA/cIRB approval for the site is in place. If you have not done so already, please let us know if that is the case at your site so we can let the AHA team know not to email you until your site's CTA/cIRB approval are in place.



Investigator Meeting



STEP will have a half-day virtual Investigator Meeting in mid-July.

Calendar invite to follow.

Stay tuned for more information!



Do you Have New Ideas for STEP ?

The OTA for new proposals for STEP can be found at:

[OTA-24-009 STEP Domain Clinical trials - Stage 1 Preliminary Application \(nih.gov\).](https://www.fda.gov/oc/ota/ota-24-009-step-domain-clinical-trials-stage-1-preliminary-application-nih.gov)



STEP Website



Find all things STEP at:

<https://nihstrokenet.org/trials/step-trial/home>.

NIH StrokeNet Education

There is now an Education tab located on the NIH StrokeNet website. You will find educational resources for Fellows, Clinical Research Professionals, and Regional Coordinating Center Managers. These educational resources can be found at: <https://www.nihstrokenet.org/strokenet-education>.

STEP Primary Study Contact List

Title and Responsibility	Name	Contact Information	When to Contact
Prime Project Manager	Harriet Howlett-Smith, RN	howletha@ucmail.uc.edu	Study related clinical or trial operations questions.
NCC Project Manager	Melissa Hoffman	hoffm2ma@ucmail.uc.edu	Study or trial operations questions, regulatory and cIRB submissions, site payments.
NDMC Data Manager	Faria Khattak, MPH	khattak@musc.edu	Study related data management questions.
NDMC Site Monitoring Manager	Caitlin Schaffner, MPH	schaffne@musc.edu	Study related data management questions.

UC StrokeNet NCC Contact List

Title and Responsibility	Name	Contact Information	When to Contact
NCC Regulatory Compliance Specialist	Jennifer Golan, MS	golanjl@ucmail.uc.edu	Questions about <i>initial</i> cIRB submission and cIRB modifications.
NCC Contract Specialist	Wren Hanson	hansonwm@ucmail.uc.edu	Questions regarding CTAs.
NCC Financial Specialist	Anne Murphy	strokenettrialpymts@ucmail.uc.edu	Per-subject payment questions.