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StrokeNet Thrombectomy Endovascular Platform
Coordinator Webinar
July 15, 2024

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Topics to be discussed:

- DOA
- Parameters Document
- Annual PI/CRC Effort
- Payment Schedules
- Enrollment Expectations
- Local IRB review
- CIRB Submission
- WebDCU™
- Contacts

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DOA

- The person listed on your Investigator Information Form as the Regulatory PI should be the only one assigned to the **PI** role.
- The other PI (endovascular/non-endovascular) listed on your Investigator Information Form should be listed as the **MPI**.
- Any other MD/NP/PA should be listed as a **Sub-Investigator**
- Only the **PI** can be assigned to Overall Responsibility of the Trial (Responsibility "**A**")
- Only a **PI/MPI/Sub-I** will be allowed to Determine Eligibility (Responsibility "**C**") due to the complexity of the Domain A inclusion criteria.
- Only a **PI/MPI/Sub-I** will be allowed to assess for Adverse Events (Responsibility "**F**")
- Only one person can be assigned to the **PSC** role

Parameters Document

Please review the Parameters Document **PRIOR** to submitting your regulatory documents

Basics

-Only upload **PDF**

-E-Signature is allowable per Docusign, Florence eBinders, Adobe signature, or Apple Document sign

-Available in the STEP toolbox in WebDCU

Parameters Document Continued

CV- Must be signed/dated. Must list person's current affiliation with site. E-signature is acceptable. If CV has end date listed for site affiliation, use the end date and not the 5-year expiration date

HSP training- Follow local institutional policies for completion and ongoing maintenance of these certifications. If no expiration date listed and local institutional policy is greater than 5 years, documentation of institutional policy must be uploaded with certification. The expiration date in this case would be 5 years from date of upload.

License- Current license must be valid for state where the site is located.

NIHSS Certification- Certification is required for Investigators and study coordinators who will be completing the NIHSS assessment with subjects. Certification must be obtained through an authorized provider (AHA, BlueCloud, APEX Innovations, etc).

Parameters Document Continued

Protocol Training- Must be completed for **BOTH** the Master and Domain A protocols.

Heidelberg Bleeding Classification Training- Only for those assigned to responsibility **"F"** Assess Adverse Events, **PI/MPI/Sub-I**

Investigator Agreement- Must only be signed by the **PI** (Regulatory PI)

FCOI- Expiration date only required in WebDCU for **PI and MPI**. Expiration date must be the date of the CIRB Prime Expiration date. Only FCOI for people in roles A, B, C, and F are required to be uploaded to WebDCU. All other FCOIs need to be filed in your local regulatory file.

Protocol Signature Page Master and Domain A- Must only be signed by the **PI** (Regulatory PI)

Annual PI/CRC Effort

- Quarterly payments of $20,489.93, totaling **$81,959.74** annually (inclusive of F&A)
- Sites will be eligible for the first quarterly payment once the site is released to enroll.
- The first payment will be prorated to the number of months operational within the quarter.
- Participant enrollment at sites receiving this support will be closely monitored and **could be reduced or withdrawn** if the site is not meeting standards defined in the statement of work.

Annual PI/CRC Effort/Payment Schedule

- **No**, this money is NOT guaranteed for the whole 5 years.
- **Yes**, this is in addition to the per patient payment and start-up
- **No**, we aren't telling you how you can spend this money

- **Yes**, you get paid from BOTH the Master Payment Schedule and Domain A Payment Schedule each time you enroll a participant
- Participant travel expenses come from your per patient payment

Enrollment Expectations

No one gets enrolled in the Master-it just spells out the overall platform design

Domain A

25 participants in the Low NIHSS score strata (4 years)

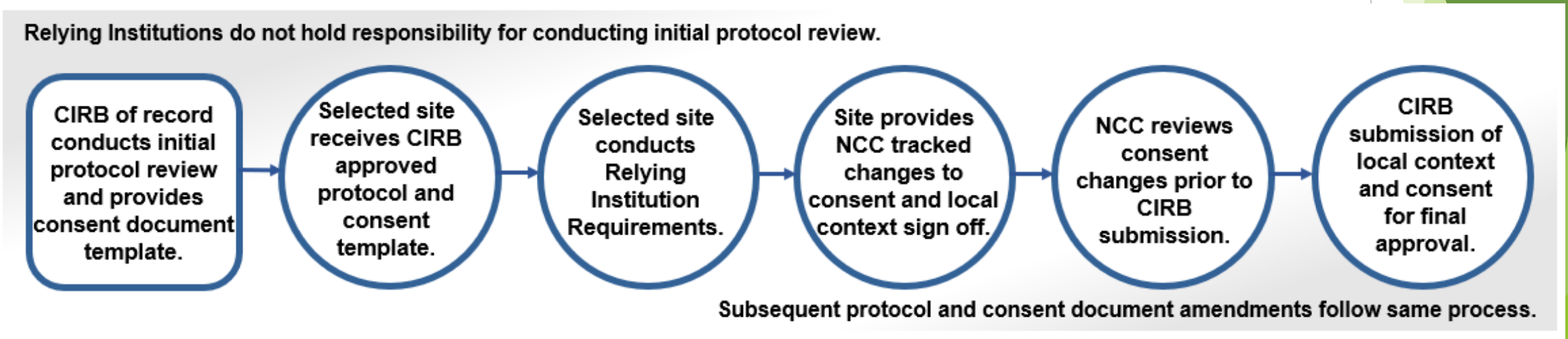
AND

25 participants in the Medium Vessel Occlusion strata (2.5 years)

Yes, this means the expectation is that each site will enroll 50 participants in Domain A

Local IRB Submission

- Remember that it is StrokeNet policy for your local IRB review to occur **PRIOR** to the CIRB review. The memo is attached in the regulatory documents email (**StrokeNet Memorandum for Local Site Context Review at Relying Institutions**).



CIRB Submission

- Jen Golan sent an email to all sites at the end of May that contained an attachment with all the documents you will need for your local and CIRB submission

- Does this look familiar????

CIRB Submission

Attachments	Information	Actions Needed
For Your Reference		
NOT-OD-18-004 Guidance on Implementation of NIH Policy for Single IRB	StrokeNet/NIH policy for relying institutions.	Please include this document with your local IRB review to help facilitate expedited review/signature at your site.
SOP ADM26-translation-policy-procedure-08-07-2023	StrokeNet process for translating study documents.	Please reference if your site will be using translations for STEP.
StrokeNet PROTOCOL Application Supplement 1FEB2023_STEP MASTER_clean	Prime cIRB application information for Master protocol.	NONE
StrokeNet PROTOCOL Application Supplement 1FEB2023_STEP EVT Expansion Domain A_Clean	Prime cIRB application information EVT Expansion Domain A protocol.	NONE
STEP Master Protocol 3.22.2024 V4.0	Current cIRB approved version of the Master protocol.	NONE
STEP EVT Indication Expansion Domain A Protocol 1.30.2024 V2.0	Current cIRB approved version of the EVT Expansion Domain A protocol.	NONE
2024-0338 STEP Platform Prime Award Protocol cIRB Approval Ltr 25APR2024	Initial Prime cIRB approval letter. All other STEP Prime Modification approval letters will be in the WebDCU™ Toolbox.	NONE
GCP 13 SOP Remote Informed Consent Process- Local Management 9.9.2020	Describes various methods of obtaining remote consent	NONE
eConsent SOP adm-24-strokenet-central-electronic-informed-consent-process-2024-02-01	Describes the StrokeNet NCC centrally managed eConsent process.	NONE
General Instructions for Consent Template - Performance Site rev	Contains general instructions for editing the informed consent	Please review prior to editing the consent form.
StrokeNet Memo for Relying Institution Local IRB Processes 2023-11-14	Provides guidance for Relying Institutions responsible for conducting local review of National Institutes of Health StrokeNet research.	Please provide this to your local IRB or HRPP office.
G200273-S001.Master	FDA IDE letter dated 01Aug2023 indicating the Master protocol may proceed.	NONE
G200273.S002.A001.Domain A Letter	FDA IDE letter dated 10Oct2023 indicating the EVT Expansion Domain A protocol may proceed.	NONE
STEP Participant Information Sheet_V1	This is a PRIME level document. No site-specific changes will be allowed to this document.	Please include as part of the Informed Consent process at your site.
STEP StrokeNet Regulatory Document Parameters	Provides instructions for regulatory document uploading in WebDCU™	NONE

CIRB Submission

Action Required on Documents Below		
StrokeNet CIRB Informed Consent_Domain A_Low NIHSS Score Strata V1_clean_16Apr2024	We are using the University of Cincinnati cIRB. No changes can be made to the consent template except as noted in the document within the bracketed blue font text.	Enter your site-specific information (bracketed blue font text). Email tracked and clean versions of consent form to Jen Golan at golanjl@ucmail.uc.edu.
StrokeNet CIRB Informed Consent_Domain A_Medium Vessel Occlusion Strata V1_clean_16Apr2024	We are using The University of Cincinnati cIRB. No changes can be made to the consent template except as noted in the document within the bracketed blue font text.	Enter your site-specific information (bracketed blue font text). Email tracked and clean versions of consent form to Jen Golan at golanjl@ucmail.uc.edu.
STEP Platform CIRB FCOI_Form 26MAR2019	Financial conflict of interest form.	Ensure each study team member completes, signs, and dates the FCOI form with one of the following CIRB acceptable signature methods: 1. Wet Ink Signature 2. Adobe Certified Digital signature 3. DocuSign signature 4. iPad Magic Pen signature Florence eBinders. Please email the Site Regulatory Principal Investigator's completed FCOI form to Jen Golan at golanjl@ucmail.uc.edu. All other study team member completed FCOI forms must be filed at your site. If a study team member has a positive disclosure, please send that study team member's completed FCOI form to Jen Golan at golanjl@ucmail.uc.edu.
StrokeNet CIRB Assurance Statement 1FEB2023	This document permits the NCC to make the submission on the site's behalf.	Site Regulatory Principal Investigator must sign. Email to Jen Golan at golanjl@ucmail.uc.edu. Note: Where the form says Principal Investigator, they are referring to the local Site Regulatory Principal Investigator.
StrokeNet Performance Site Application Supplement 2.1.2023	This form collects information about your site for the cIRB application.	Complete form. Email to Jen Golan at golanjl@ucmail.uc.edu.
StrokeNet Local Site Context Form 9MAY2024 fillable	This form notifies your local IRB that you are preparing to submit to the University of Cincinnati cIRB for the STEP trial.	Complete form. The "Site PI Name" should list the Site Regulatory Principal Investigator.

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CIRB Submission

		form with one of the following CIRB acceptable signature methods: 1. Wet Ink Signature 2. Adobe Certified Digital signature 3. DocuSign signature 4. iPad Magic Pen signature Florence eBinders, Please email the Site Regulatory Principal Investigator's completed FCOI form to Jen Golan at golanjl@ucmail.uc.edu. All other study team member completed FCOI forms must be filed at your site. If a study team member has a positive disclosure, please send that study team member's completed FCOI form to Jen Golan at golanjl@ucmail.uc.edu.
StrokeNet CIRB Assurance Statement 1FEB2023	This document permits the NCC to make the submission on the site's behalf.	Site Regulatory Principal Investigator must sign. Email to Jen Golan at golanjl@ucmail.uc.edu. Note: Where the form says Principal Investigator, they are referring to the local Site Regulatory Principal Investigator.
StrokeNet Performance Site Application Supplement 2.1.2023	This form collects information about your site for the cIRB application.	Complete form. Email to Jen Golan at golanjl@ucmail.uc.edu.
StrokeNet Local Site Context Form 9MAY2024 fillable	This form notifies your local IRB that you are preparing to submit to the University of Cincinnati cIRB for the STEP trial.	Complete form. The "Site PI Name" should list the Site Regulatory Principal Investigator.
		Email the completed form to Jen Golan at golanjl@ucmail.uc.edufor pre-review. After pre-review, send to the official in your local IRB or HRPP office for signature. Email the form to Jen Golan after the local IRB or HRPP office official's signature is obtained.
StrokeNet_HIPAA_Waiver_Of Authorization_Form rev 4_6_19 fillable	This partial waiver of HIPAA authorization form is requested to allow access to protected health information (PHI). This form is required for eligibility screening at your site.	Complete form and email to Jen Golan at golanjl@ucmail.uc.edu.
STEP Remote Informed Consent Implementation Survey	This survey response notifies the cIRB if you plan to use electronic informed consent at your site. This also will initiate the eConsent project build in REDCap.	Please complete this survey whether your site plans to use eConsent or not
PSP_STEP Master Protocol 3.22.2024 V4.0	Current Master protocol signature page.	Site Regulatory Principal Investigator must sign and date. Please ensure all

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CIRB Submission

- **YES**, it's a lot of information, but do yourselves a favor
- and review it thoroughly **prior** to starting your local or
- CIRB submission.

- Need signed/dated (within 2 years) **CV** for both the **PI** and **MPI**
- Need **FCOI** signed/dated for both the **PI** and **MPI**
- Tracked changes **and** clean ICF
- Local Site Context Form with **all** research locations listed

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WebDCU™

Any name discrepancy between the uploaded document and the name listed in WebDCU™, requires that a note-to-file (NTF) be uploaded with the document (one pdf) that explains the variation.

OR

If the name listed in WebDCU™ is incorrect, contact the NDMC team to correct it. A NTF will not address an incorrect name in WebDCU.

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Contacts

Jennifer Golan (golanjl@ucmail.uc.edu) - consent reviews, CIRB submission questions

Jessica Griffin (simonsjl@musc.edu) - IT data security questions

Melissa Hoffman (hoffm2ma@ucmail.uc.edu) - Regulatory document, CIRB submission and payment questions

Harriet Howlett-Smith (howletha@ucmail.uc.edu) - protocol questions

Caitlin Schaffner (schaffne@musc.edu) - WebDCU access, data entry questions

Email: STEP@uc.edu

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QUESTIONS

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