NIH StrokeNet

PREVENTION | TREATMENT | RECOVERY

Performance Site PI Responsibilities

MUSC Medical University of South Carolina

NIH Funded by a grant from the National Institutes of Health

UNIVERSITY OF Cincinnati

Site Selections and Feasibility

- StrokeNet Trials distribute a site level feasibility assessment to select their performance sites by:
  - Assessing the PI's readiness, site study population, and familiarity with the study tools/technology
  - Assessing the PI's experience in terms of participating in clinical research
  - Assessing the type of clinical practice, prior clinical trial experience, and availability of study coordinators, pharmacists, nurses, and other staff
  - Assessing recruitment potential, presence of competing studies, and prior experience in conducting similar studies
  - Reviewing timeliness of obtaining IRB approval and Clinical Trial Agreement execution
- RCCs are responsible for distributing the site selection survey to their performance sites and entering the information into WebDCU™.
- The Site PI is responsible for participating in and responding in a timely manner to site feasibility assessments.

Site Start-up

Once selected as a Performance Site, the site PI is responsible for ensuring the Clinical Trial Agreement and Central IRB Approval is completed in a timely manner.

Site Start-up Timeline Expectations

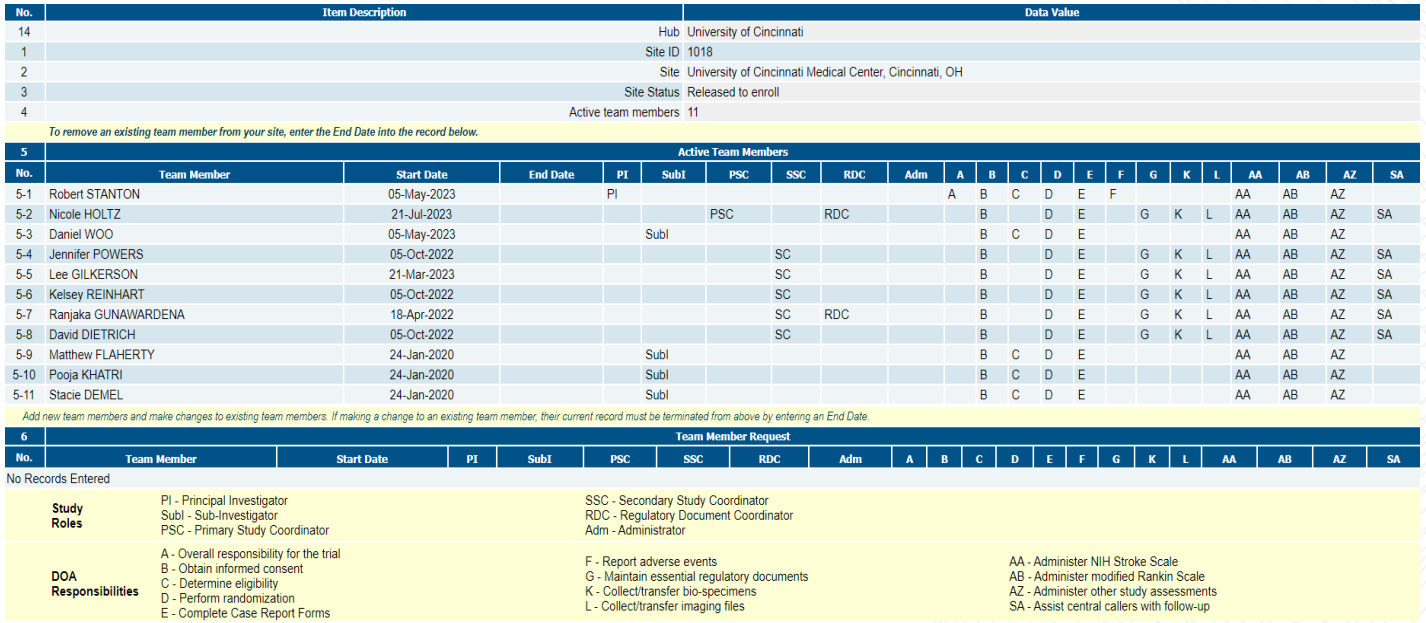
Site Selection	Clinical Trial Agreement	Regulatory Packet
1 RCC sends site selection survey.	1 NCC Contracting sends CTA. Email will include CIRB approval letter and notice for single IRB. CTA includes the payment schedule and statement of work.	1 NCC Regulatory or NCC PM sends regulatory packet. Email will include ICD template, local context or investigator form and FDA forms, if applicable.
Deadline: 3 weeks	**Deadline: 6-8 weeks**	**Deadline: 6-8 weeks**
2 NCC sends commitment letter if site selected to participate. Email will include trial synopsis, trial budget and timeline for CTA and regulatory packet.	2 If CTA not completed within twelve weeks, or otherwise communicated timeline, the trial PI may decide to drop site.	2 If regulatory packet not completed within twelve weeks, or otherwise communicated timeline, the trial PI may decide to drop site.
	Sites may complete CTA or regulatory packet first, or in parallel.	

Essential Documents

- These are the documents which individually and collectively permit evaluation of the conduct of a trial and the quality of data produced (ex: CVs, 1572, licenses, approvals)
- Though the study coordinator may be tasked with collecting and filing essential documents, it is the PI's ultimate responsibility to ensure that all essential documents for each study are appropriately filed in WebDCU™ and according to local requirements. **(NIH StrokeNet SOP ADM 21 Regulatory Document Maintenance and Storage)**
- Of particular importance in essential documentation is Form FDA 1572.
  - It is not required for all studies but is required by the FDA for IND studies.
  - This form documents that the PI agrees to conduct the study according to the obligations stated in the form.
  - This document should be completed before the start of the study and updated when there is a change in PI or specified research staff within 30 days.
    - A copy should be kept at the site and an electronic version uploaded to its placeholder in WebDCU™.

Documented Delegation

- The site PI must confirm that any person to which a study task is delegated is qualified through education, training, and experience to perform the task.
- The PI is responsible for ensuring their local study staff has been trained and added to the delegation log with applicable roles and responsibilities ***prior*** to performing any study related procedures involving the participant.



No.	Item Description	Data Value
14	Hub	University of Cincinnati
1	Site ID	1018
2	Site	University of Cincinnati Medical Center, Cincinnati, OH
3	Site Status	Released to enroll
4	Active team members	11

To remove an existing team member from your site, enter the End Date into the record below.

5 — Active Team Members

No.	Team Member	Start Date	End Date	PI	SubI	PSC	SSC	RDC	Adm	A	B	C	D	E	F	G	K	L	AA	AB	AZ	SA
5-1	Robert STANTON	05-May-2023		PI						A	B	C	D	E	F				AA	AB	AZ	
5-2	Nicole HOLTZ	21-Jul-2023				PSC		RDC			B		D	E		G	K	L	AA	AB	AZ	SA
5-3	Daniel WOO	05-May-2023			SubI						B	C	D	E					AA	AB	AZ	
5-4	Jennifer POWERS	05-Oct-2022					SC				B		D	E		G	K	L	AA	AB	AZ	SA
5-5	Lee GILKERSON	21-Mar-2023					SC				B		D	E		G	K	L	AA	AB	AZ	SA
5-6	Kelsey REINHART	05-Oct-2022					SC				B		D	E		G	K	L	AA	AB	AZ	SA
5-7	Ranjaka GUNAWARDENA	18-Apr-2022					SC	RDC			B		D	E		G	K	L	AA	AB	AZ	SA
5-8	David DIETRICH	05-Oct-2022					SC				B		D	E		G	K	L	AA	AB	AZ	SA
5-9	Matthew FLAHERTY	24-Jan-2020			SubI						B	C	D	E					AA	AB	AZ	
5-10	Pooja KHATRI	24-Jan-2020			SubI						B	C	D	E					AA	AB	AZ	
5-11	Stacie DEMEL	24-Jan-2020			SubI						B	C	D	E					AA	AB	AZ	

Add new team members and make changes to existing team members. If making a change to an existing team member, their current record must be terminated from above by entering an End Date.

6 — Team Member Request

No.	Team Member	Start Date	PI	SubI	PSC	SSC	RDC	Adm	A	B	C	D	E	F	G	K	L	AA	AB	AZ	SA
No Records Entered																					

Study Roles

PI - Principal Investigator
SubI - Sub-Investigator
PSC - Primary Study Coordinator
SSC - Secondary Study Coordinator
RDC - Regulatory Document Coordinator
Adm - Administrator

DOA Responsibilities

A - Overall responsibility for the trial
B - Obtain informed consent
C - Determine eligibility
D - Perform randomization
E - Complete Case Report Forms
F - Report adverse events
G - Maintain essential regulatory documents
K - Collect/transfer bio-specimens
L - Collect/transfer imaging files
AA - Administer NIH Stroke Scale
AB - Administer modified Rankin Scale
AZ - Administer other study assessments
SA - Assist central callers with follow-up

- **The electronic delegation log should be printed, signed and dated by the PI upon adding new personnel to document oversight. The electronic delegation log maintained in WebDCU™ will be used to set user permissions. (StrokeNet SOP GCP 12 – Regulatory and Clinical Data Maintenance Storage)**

Investigational Product Storage and Inventory

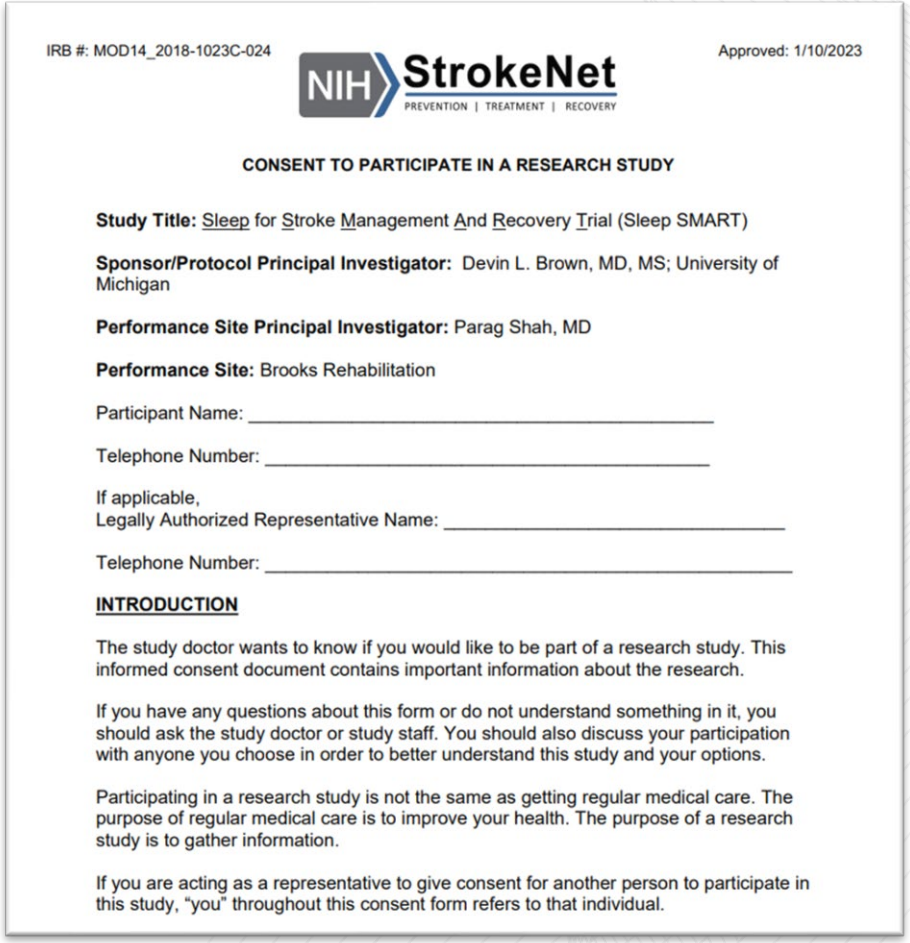
Left hand image: Apixaban 5mg active or placebo AND Aspirin 81mg active or placebo.

Right hand image: Apixaban 2.5mg active or placebo AND Aspirin 81mg active or placebo

- The PI must ensure that the investigational product is stored securely and in the proper environment. The PI may delegate responsibility to a licensed pharmacist (for example, drug dispensing) but is ultimately responsible for the product.
- The dispensing record and CRFs must agree concerning documentation of participants receiving the investigational product. This may be subject to monitoring throughout the course of the trial.
- At the end of the study, the PI will be responsible for shipping any remaining supplies to the sponsor or will destroy them at the site per sponsor specification.

Informed Consent

- The PI or designee must obtain informed consent from all study participants prior to study procedures (exception EFIC).
- The process of informed consent is an ongoing interaction between the PI or designee and the participant/LAR that continues throughout the life cycle of the study, from recruitment through study closure. If at any time the participant wishes to discontinue their participation in the trial, it is the site PI's responsibility to honor that wish.
- The informed consent document itself may be revised and participants/LARs may need to be reconsented. It is the site PI's responsibility to ensure reconsent is obtained if deemed necessary by the central IRB.



IRB #: MOD14_2018-1023C-024 Approved: 1/10/2023

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Sleep for Stroke Management And Recovery Trial (Sleep SMART)

Sponsor/Protocol Principal Investigator: Devin L. Brown, MD, MS; University of Michigan

Performance Site Principal Investigator: Parag Shah, MD

Performance Site: Brooks Rehabilitation

Participant Name: _____

Telephone Number: _____

If applicable,
Legally Authorized Representative Name: _____

Telephone Number: _____

INTRODUCTION

The study doctor wants to know if you would like to be part of a research study. This informed consent document contains important information about the research.

If you have any questions about this form or do not understand something in it, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

If you are acting as a representative to give consent for another person to participate in this study, "you" throughout this consent form refers to that individual.

Data Collection

Project Setup > CRF Collection Schedule

SATURN | Subject ID: __ __ __ __ | Visit: | WebDCU™

F126 End of Study V3 (11-Mar-2024)

Q01		Subject randomized	○ No ○ Yes R
Q02		Primary reason for study termination	○ Study completed ○ Death ○ Lost to follow-up ○ Consent withdrawn ○ Other R

Definition for Q03 Date of early termination:

- For death, enter date of death.
- For lost to follow-up, enter date subject was last known to be alive.
- For consent withdrawn, enter date consent withdrawn.
- For other, enter date of last day in study.

Q03	*If Q02 is not 'Study completed'*	Date of early termination	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy R
Q04	*If Q02 is not 'Study completed' or 'Death'*	Detailed explanation of the early termination	R 2000 char.
Q05	*If Q02 is 'Consent withdrawn' or 'Other'*	Termination due to an adverse event	○ No ○ Yes R
Q06	*If Q05 is 'Yes'*	CRF ID of the adverse event	R
Q07	*If Q01 is 'No'*	Subject was eligible for randomization	○ No, ineligibility identified ○ Yes ○ NA, eligibility assessment not completed R
Q08	*If Q01 is 'No'*	Consent withdrawn prior to randomization	○ No ○ Yes R
Q09	*If Q08 is 'Yes'*	Reason consent withdrawn prior to randomization	R 250 char.

The site PI must review and affirm the accuracy of the information reflected in all of the case report forms for this study participant. Please complete the section below after this review and affirmation is complete.

Qd	Reviewing site PI	R
Q12	Date of site PI review and affirmation	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy R

General comments

Signature and date of site PI review and affirmation Print name Signature Date

Missing data checking: R Rejection

- WebDCU provides CRFs for each trial to ensure standardized data collection. The site PI must ensure that all data collected on the CRF are accurate and match any supporting **source data**. This confirmation is documented via **wet signature** on a printout of F126 End of Study.
- **Source data** are clinical findings or observations in a study. Source data can be originals or certified copies. The purpose of source documents is to collect relevant data and support the data on a CRF.
- The PI is responsible for ensuring that data are verifiable and follow an audit trail. CRF documentation should not contradict source data. The data should be **attributable, legible, contemporaneous, original, accurate, and complete (ALCOA-C)**.
- The PI must ensure that study records are stored securely yet are accessible for monitoring and/or auditing purposes.

Adverse Event (AE) Assessment and Reporting

- Though a study coordinator may be tasked with entering the AE data in the WebDCU eCRF, only the PI or other ***delegated medically trained persons*** on the site research staff should ***assess*** if an identified AE is:
  1. Serious / Not serious
  2. Expected / Not expected
  3. Related / Not related to the research study

- The site PI is responsible for ensuring all Serious AEs are **submitted without errors into WebDCU within 24 hours** of knowledge of the event.

- Full instructions for completing and submitting the AE eCRF can be found in each trial's **'Data Collection Guidelines'** document that is located in the associated trial's **Toolbox > Project Documents**.

Unanticipated Problems and Events (UAP/UAE)

- An unanticipated problem or event (UAP/UAE) is any unexpected adverse experience, which is an event that is both unexpected and has a reasonable possibility of relatedness to the study drug, intervention(s), procedures, and study conduct. UAP/UAEs are also any other events that may place study subjects or others unexpectedly at risk during or after the research is completed. Risk of harm in this context is not limited to physical or medical risk.

- The Site PI is responsible for reporting UAP/UAEs via WebDCU **within 24 hours** of first knowledge of the event.

- For full instructions on reporting UAP/UAEs see StrokeNet ADM 12 CIRB Reporting.

Monitoring Visits

- Throughout the study, the NDMC will schedule periodic monitoring visits. The focus will be to evaluate the study conduct and perform source document verification.

- The PI and coordinator should do the following in preparation for the visit:
  - Ensure that all CRFs are completed
  - Confirm that all SAE forms have been submitted and are available for review
  - Organize study file documents for review

- PI Responsibilities after the monitoring visit:
  - Respond to action items
  - Confirm receipt of monitor report

- For full details on NIH StrokeNet Data Monitoring see: StrokeNet ADM 19 Data Monitoring and StrokeNet GCP 09 Site Performance Monitoring, Audits and Inspections

Communication

Language from StrokeNet Clinical Trial Agreement Statement of Work:

"Responsiveness of site PI to trial teams, or in his/her absence, another designated investigative team member, to email correspondence within 2-5 business days."