

Study Organization

Regulatory Reminders and Tips

Study Organization Central

UCSD Medical Center - Hillcrest Hospital, San Diego, CA ▾ Expire Window (days): 60 Apply














Site Documents	
Site Status	Released to enroll
CAP/CLIA Certification	
CIRB Approval (Protocol v7 - 21Oct2022)	
CIRB Approved Administrative Amendments	
CIRB Approved Full Translated Informed Consent Forms (v29Apr2021)	
CIRB Approved Informed Consent Form (v29Apr2021)	
CIRB Site Specific EFIC Approval	
FDA Form 1572 - Statement of Investigator	
Full Translated Site Specific Stand-alone Bill of Rights	
Full Translated Site Specific Stand-alone HIPAA Authorization Form	
Institutional Drug Destruction Policy/SOP	
Institutional Pharmacy License	
Lab Reference Ranges	
Local IRB Acknowledgement	
Local IRB Full HIPAA Waiver of Authorization	
Local IRB Partial HIPAA Waiver of Authorization for Screening	
Protocol Signature Page (Protocol v7 - 21Oct2022)	
Site Specific EFIC Plan	
Site Specific Stand-alone Bill of Rights	
Site Specific Stand-alone HIPAA Authorization Form	

WebDCU maintains all regulatory documents uploaded by sites. This is considered the Trial Master File (TMF).

Person		ABC/2 and IVH Score Certification	Curriculum Vitae	GCP Training	Human Subjects Protection Training Certification	Medical/Professional License	mRS Certification	NIHSS Certification	Pharmacy Training	Protocol Training	Sponsor Financial Interest Disclosure Form
Study Personnel Entered Here											

Study Organization

Local

- ▼  STUDY NAME HERE
 - >  Correspondence
 - >  Financial
 -  Imaging
 - >  Investigator Brochure
 - >  IRB
 -  Meetings and Webinars
 - >  MOP
 - >  Pharmacy
 - >  Protocol
 - >  Regulatory
 - >  Study Documents
 - >  Subjects

Every Site **MUST** maintain a file of the documents in WebDCU and **MORE** (eg. items from Toolbox)

EXAMPLE FILE STRUCTURE

Example – Local Site Study File - expanded

- STUDY NAME HERE
 - Correspondence
 - DSMB
 - Local Study Team
 - NCC
 - Newletters
 - Financial
 - CTA
 - Amendments
 - Initial
 - Invoices
 - WebDCU Payments
 - Imaging
 - Investigator Brochure
 - IB Receipt of Acknowledgement

- IRB
 - CIRB
 - Approval Letters - Prime
 - Approved Submissions - Site
 - ICF
 - 1_Current ICF - combined
 - Bill of Rights
 - E Consent Email Script
 - Main ICF_word versions
 - Stand Alone HIPAA
 - Verification Dates
 - IRB Roster
 - Issues
 - Protocol Deviations_Exceptions_Violations
 - SAEs
 - Serious Non Compliance
 - Unanticipated Problems
 - Local IRB
 - Local Site Approval Letters
 - Local Site Submissions
 - 2022 10 XX Initial Application
 - Meetings and Webinars

- MOP
 - Imaging
 - Lab
 - Pharmacy
 - Study
- Pharmacy
 - Drug Destruction Policy
 - Orders
 - Pharmacy License
- Protocol
 - Protocol Sig Page
- Regulatory
 - 1572
 - CV
 - DOA Log
 - Financial Disclosure
 - GCP
 - Human Subjects
- Lab Documents
 - CAP_CLIA Certs
 - Lab License
 - Lab Ref Ranges

- Monitoring
 - Data Quality Reports
 - Visits
- mRS
- NIHSS
- Prof License
- Training
 - Local Trainings
- Pharmacist
- Protocol
- Study Coordinator
- Study Documents
- Templates
- Tools
- Subjects
 - 2001
 - 2002
 - 2003

Reminders of specific regulatory items that could be OVERLOOKED Training and Communication

Study
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Training and
Communication

- Receipt, review and/or training of new protocols, amendments, IBs, MOPs, and study guidance provided on webinars
 - How is this disseminated? Documented? and where is it filed?

Version 4.0 | April 24, 2023

CAPTIVA Protocol Signature Page

I have read this protocol and agree to adhere to the requirements. I will provide copies of this protocol and all pertinent information to the study personnel under my supervision. I will discuss this material with them and ensure they are fully informed regarding the investigational plan and the conduct of the study according to 21 CFR parts 50, 54, 56 and 45 CFR part 46, ICH Good Clinical Practices Guidelines and Institutional Review Board (IRB) requirements.

UCSD - 1455 - LA JOLLA
Clinical Site

[Signature]
Site Principal Investigator Signature

Date 6/6/2023

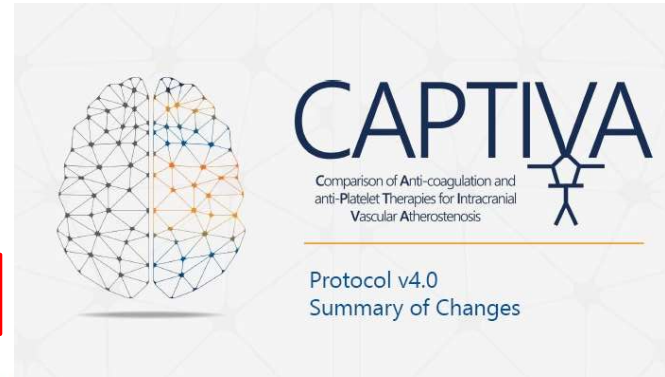
[Signature]
Site Principal Investigator Printed Name

Study Organization

Regulatory Reminders/Tips

Training and Communication

- Training
 - 2022 07 07 SAE Reporting - General Training
 - 2022 09 01 CAPTIVA Team Training Protocol V3
 - 2023 01 31 CAPTIVA New SC Training
 - 2023 06 15 CAPTIVA Team Training Protocol V4**
 - 2023 08 10 AE_SAE reporting_training
 - 2023 09 06 CAPTIVA_Covid_Paxlovid_team review
 - 2023 09 21 CAPTIVA Remote Training
 - 2023-2024 New Fellow Team Training
 - 2024 05 29 CAPTIVA Annual Meeting
 - 2024-2025 CAPTIVA New Fellow Training v4
 - CAPTIVA August 8 2023 Newsletter updates



PROTOCOL v4.0: SUMMARY OF CHANGES

CHANGES WERE MADE TO:

- Protocol-wide Verbiage
- Inclusion Criteria
- Exclusion Criteria
- Study Drug Kit – Loading Dose Simplification
- Schedule of Assessments & Evaluations – NIHSS Requirement

CAPTIVA logo and NIH StrokeNet logo are visible at the bottom of the slide.

TRAINING LOG

STUDY: CAPTIVA Protocol v4
TRAINING PROVIDED BY: Dawn Meyer 6/15/2023

NAME	DATE REVIEWED	SIGNATURE
[REDACTED]	6/15/2023	[REDACTED]
[REDACTED]	6/15/2023	[REDACTED]
[REDACTED]	6/15/2023	[REDACTED]
[REDACTED]	6/15/2023	[REDACTED]
[REDACTED]	6/15/2023	[REDACTED]

Reminders of specific regulatory items that could be OVERLOOKED

Training and Communication


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Training and
Communication


- Ongoing Communication with the Study Team
 - How is this documented and where is it filed?


Fri 6/28/2024 12:57 PM

 McQuaid, Theresa
FW: **Major changes to Sleep SMART enrollment criteria, please

To Meyer, Brett; Meyer, Dawn; Bavarsad Shahripour, Reza; Modir, Roya; Hemmen, Thomas;
 Davila, Claire; Hansra, Harjot; Bu, Julia; Wood, Carla; Hailey, Lovella; Mortin, Melissa

Cc Rapp, Karen; Price, Mariah; Jajo, Maryo

 This message was sent with High importance.

 InterimAnalysisInfo.docx
16 KB

Dear Team:

IMPORTANT—PLEASE READ THE EMAIL BELOW. An alert has also been sent as a What's App communication for you to read your email. We will discuss this further at our next staff meeting on July 11, 2024.

Have a great day,

Teri

From: Novitski, Kayla <kcrosse@med.umich.edu>
Sent: Friday, June 28, 2024 10:50 AM
Cc: Brown, Devin <devinb@med.umich.edu>; Chervin, Ronald (Ron) <chervin@med.umich.edu>; joseph.broderick@uc.edu; 'durkalsv@muscv.edu' <durkalsv@muscv.edu>; Scott Janis <janiss@ninds.nih.gov>
Subject: **Major changes to Sleep SMART enrollment criteria, please read!**
Importance: High

Dear Sleep SMART PIs/study coordinators and RCC PIs and PMs,

At the recommendation of the DSMB, and with NINDS concurrence, as of today, the enrollment criteria for Sleep SMART have changed to limit the population being enrolled.

The inclusion criteria are now:

Reminders of specific regulatory items that could be OVERLOOKED

CIRB Reporting

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Miscellaneous – CIRB
Reporting

- SAE and UAE Reporting to CIRB
 - University of Cincinnati (UC) IRB Studies –
 - You (the site) are responsible for submitting the report to WebDCU per the study reporting requirements.
 - **The NCC submits to the UC CIRB on your behalf.**
 - Advarra IRB Studies –
 - You (the site) are responsible for submitting the report to WebDCU per the study reporting requirements.
 - **After the central review of the event, if it meets the reporting requirements to Advarra, the NCC Project Manager will send you an alert to submit it to Advarra.**

Reminders of specific regulatory items that could be OVERLOOKED

Financial Disclosure

- At the time of award sub recipients must indicate they are compliant with PHS COI policy (CTA)
- At the time of Continuing Review (CR) - Assessment of Financial Disclosure must occur on all Study Personnel
 - Only the site PI is required to be uploaded in WebDCU and therefore other team members could be easily missed
 - Your site PI must attest that no study team member has any **new** reported conflict at CR. This is difficult to attest to without evidence.

The NIH StrokeNet Network Standard Operating Procedure

SOP Number: ADM 02

SOP NAME: Reporting Conflict of Interest and Financial Disclosures

Effective Date: 1-September-2019

intact. The blinded FCOI- forms will be scanned and stored on electronic storage medium for the life of the network plus five (5) years.

2. The NIH StrokeNet Clinical Performance Sites are required to collect a StrokeNet FCOI form initially for all study team members and any new investigator on a trial. Sites are to file the forms onsite (electronically or as paper files) for all study team members and made available for monitors/auditors when requested for the length of the trial. Sites are to refer to their local policy/requirement for annual renewal of the FCOI during the continuing review process. Sites will be asked to verify that there have not been changes to any study team member's FCOI on the continuing review form submitted to the cIRB annually. Key study personnel should always disclose any FCOI as soon as it is presented so that it can be collected and submitted to the cIRB. Study team members' disclosures will be stored in WebDCU™ along with the site PI FID form in the designated site section.

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