Study Organization

Regulatory Reminders and Tips

Study Organization

Central

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

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

Column 1:
- ⌄ STUDY NAME HERE
  - ⌄ Correspondence
    - DSMB
    - Local Study Team
    - NCC
    - Newletters
  - ⌄ Financial
    - ⌄ CTA
      - Amendments
      - Initial
    - Invoices
    - WebDCU Payments
  - Imaging
  - ⌄ Investigator Brochure
    - IB Receipt of Acknowledgement

Column 2:
- 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

Column 3:
- ⌄ 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

Column 4:
- 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 Organization

Regulatory Reminders/Tips

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

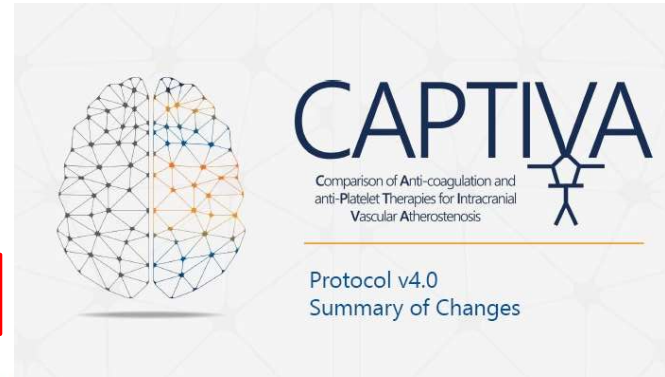Site Principal Investigator Signature   Date   6/6/2023

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

CAPTIVA

Comparison of Anti-coagulation and anti-Platelet Therapies for Intracranial Vascular Atherostenosis

Protocol v4.0
Summary of Changes

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

NIH StrokeNet

TRAINING LOG

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

NAME	DATE REVIEWED	SIGNATURE
	6/15/2023	
	6/15/2023	
	6/15/2023	
	6/15/2023	

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

Study Organization

Regulatory Reminders/Tips

Training and Communication

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

Reminders of specific regulatory items that could be OVERLOOKED

CIRB Reporting

Study Organization

Regulatory Reminders/Tips

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

Study
Organization

Regulatory
Reminders/Tips

Financial Disclosure
Local

- **<u>At the time of award</u>** 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 <u>all</u> 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.