NIH StrokeNet

PREVENTION | TREATMENT | RECOVERY

Manual of Operations and Procedures (MOP) for Remote Evaluation

CAPTIVA

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

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LIST OF ABBREVIATIONS

BP	Blood Pressure
CCC	Clinical Coordinating Center
CRF	Case Report Form
HIPAA	Health Insurance Portability and Accountability Act
MOP	Manual of Operations and Procedures
mRS	Modified Rankin Scale
NCC	National Coordinating Center
PSC	Primary Study Coordinator
RFMC	Risk Factor Management Center
SBP	Systolic Blood Pressure

1.0 INTRODUCTION

The role of the CAPTIVA Remote Evaluation MOP is to provide operational details to facilitate consistency in remote evaluations, blood pressure measurement, and data collection across multiple subjects and study sites.

2.0 OVERVIEW

In-person evaluations of CAPTIVA subjects are preferred and ideal. *At minimum*, subjects should be willing and able to return for **in-person visits** at the **1 month** and **12 month** follow-up if they consent to participate. When it is impractical for the subject to return to the clinic or be visited at home or at an inpatient rehabilitation facility, evaluations may be completed remotely using institutionally-approved HIPAA-compliant telehealth platforms. Sites should follow local guidelines to ensure study conduct and data collection is secure and HIPAA-compliant.

Sites must complete all study required assessments, evaluations, data collection and entry in the same manner and of the same quality as in-person visits. Site remediation may be required if study procedures are not being conducted in an equivalent manner.

3.0 STUDY-PROVIDED BLOOD PRESSURE DEVICES

Whenever feasible, blood pressure measurements will be obtained with a study-provided device that is provided to the enrolled subject in advance of the video evaluation. Sites may request additional blood pressure devices to be used for these video evaluations by reaching out to the Risk Factor Management team (see Appendix 3). Site discretion should be used in choosing subjects appropriate to receive and utilize these devices. Sites should set the expectation that devices are meant to be returned at the completion of each subject's participation. The devices can be sanitized for subsequent use by CAPTIVA subjects at the site. If a device is lost by the site or subjects, please contact the RFMC team to request a replacement.

4.0 SUBJECT REQUIREMENTS

To avoid incomplete study evaluations, subjects should *at minimum* be willing and able to return to the site for **in-person evaluations** at the **1** and **12 month** follow-up timepoints. Additionally, for any remote evaluations to occur, subjects must have a secure internet connection and a computer, tablet, or phone with video capabilities. Subjects must also be willing and able to obtain blood pressure measurements at home during a video evaluation. Site staff will perform a training session with the subject at one of their in-person evaluations to verify the subject's willingness, ability, and available resources to participate in remote evaluations. For some individuals, this will require the assistance of a family member or friend to correctly apply the device, so it is recommended to engage and train this support person as well. Once the ability to proceed is verified, the site will supply the subject with the study-approved blood pressure device and the CIRB-approved "How to Measure Your Blood Pressure At Home" document. This document will be a useful tool to guide subjects on proper set-up of their device and to record accurate readings.

5.0 TRAINING

5.1 SITE TRAINING

Site personnel conducting remote evaluations may request additional training for educating subjects to take their blood pressure at home.

Contact information is provided in **Appendix 3** to schedule individual or group training sessions with the Risk Factor Management Team.

5.2 SUBJECT TRAINING

Site personnel should provide the CIRB-approved "How to Measure Your Blood Pressure At Home" document (refer to **Appendix 1**) to the subject, indicate the "selected arm" (right or left) on the document, and review its content in detail with the subject and any available support persons. The subject should be provided with a study-provided blood pressure device and demonstrate measuring their blood pressure using the correct technique (refer to **Section 8.0** below) to site personnel. If a subject cannot reliably measure their blood pressure, they can still undergo video evaluations but will not be able to report blood pressure measurements on the F117 Vital Signs CRF. Sites are encouraged to troubleshoot solutions with subjects for maximal and reliable data collection. If a subject has a home device (which was not study-provided), the measurements can be recorded on the form, but the device type must be indicated as "Other."

6.0 CONDUCTING REMOTE EVALUATION PROCEDURES

CRFs are available in WebDCU via the [Project Setup] tile then [CRF Collection Schedule] table and can serve as source documentation if needed. Refer to the Data Collection Guidelines via the [Toolbox] tile then [Project Documents] table in WebDCU for additional information.
Complete and document the following study-required evaluations and assessments in the same manner as an in-person evaluation:

Conduct Neurological Examination
Assess Adverse Events
Obtain & Review Risk Factor Data
Document Modified Rankin
Administer PACE Questionnaires
Review Medications
Perform Pill Counts & Assess Study Medication Compliance
Prescribe Risk Factor Medications
Order & Provide New Study Antithrombotic Medications

Complete and document the following study-required evaluations and assessments in the same manner as an in-person evaluation, *with the following additions*:

Vital Signs: Form 117 (protocol specified visits) & Form 117a (Risk Factor Re-Assessment)

- Select "Video" as the Contact type on Form 308: Visit Summary or Form 117a.
- If required, record the subject-reported weight on the date of assessment. If not feasible, record the most recent subject-reported weight. Add a note in the General Comments section if the subject-reported weight was obtained on a different date.
- Ensure blood pressure is obtained in accordance with **Section 8.0** below.
- Question 23 asks for the type of blood pressure measuring device:
  - If your site provided a study-approved Omron device to the subject to use at home, the device type will be "Study provided/approved device."
  - If a subject has a home device (which was not study-provided), the device type will be "Other." Indicate the reason the study provided device was not used in Question 39, and reach out to the RFMC if your site needs Omron devices for remote evaluation use.

Neurological Exam (not documented in WebDCU)

- Site PI or approved SubIs will evaluate and document as much of the neurological exam as feasible.
- Report any neurological changes from baseline or prior visit as an adverse event on Form 104.

Count All Study Antithrombotic Medications: Form 512 (use the previous visit's F512)

- Ensure the F308 Visit Summary was filled out on the date of the remote evaluation above, and "Video" was selected as the Contact type.
- Visualize the current study drug bottles while conducting the video evaluation, and record pill counts for each bottle (AM, PM, and aspirin) on the **prior** F512 Study Drug form, Section D.
- Obtain a new study drug kit assignment by completing the current visit's F512 Study Drug form.
- Obtain the subject's mailing address to which you will send the resupply of study antithrombotic medications, if applicable. This should only apply at Month 4 and Month 8 evaluations.
- Mail the resupply study drug using a trackable shipping service. (If the subject will not be returning to the site for a future in-person visit, it is advisable to collect the old study drug bottles by including a self-addressed mailer for return of those old bottles.) *Ensure you are following your local procedures for shipping medications.* See Section 7 for information on drug shipment. Contact the subject as soon as delivery confirmation is received.
- Record information on Form 512, Section B, question 17 "Dispense date" to reflect the **date the subject started taking** study antithrombotic medication from the **NEW** bottle.
- Instruct the subject to start using the new bottles of study antithrombotic medications and not to combine any remaining pills from old bottles into the new bottles. This will lead to inaccurate pill counts if bottles are combined. Subjects may return the old bottles and any unused capsules in a site-supplied mailer or they may bring them to their next in-person study evaluation for confirmation of recorded pill counts and drug destruction by the site.
- Remote evaluations of subjects should not impede the distribution of the new study drug bottles nor the pill counts of old study drug bottles. *Follow-up by the site to ensure*

1) the continuity of study medications and 2) the ability to assess compliance with pill counts is of paramount importance and will be monitored by the Sponsor.

7.0 STUDY DRUG SHIPMENT

Costs and supplies associated with the shipment and return of study medications are not invoiceable to the sponsor. Please follow local guidelines for arranging method of shipment and shipping supplies. Facility costs will be minimized when sites conduct video evaluations, however the per subject payment will remain the same. This allows for flexibility in funding the associated costs of drug shipment.

Sites should check with their local pharmacy for assistance with drug shipment and should explore the cost of such service. Research personnel are also able to obtain the study drugs and ship via traceable method using a bubble-mailer and planning accordingly for any inclement weather (extreme heat, cold, or approaching storms). Unless shipping in extreme weather conditions, it is not required to ship the drug temperature-controlled nor monitored.

8.0 MEASURING BLOOD PRESSURE

Since management of blood pressure is a key component of the intensive risk factor management protocol in CAPTIVA, it is paramount that blood pressure is measured in a standardized manner. Confirm that the following points with the subject prior to and on the day of the remote evaluation.

PRIOR to the scheduled remote evaluation:

- Ensure the subject has a study-provided blood pressure device.
- Ensure the subject has reviewed the CIRB-approved "How to Measure Your Blood Pressure at Home" document (refer to **Appendix 1**) and note which arm to use on the document.
- Ensure the subject has performed a practice blood pressure measurement at home to confirm the device is working properly and the subject is familiar with it and the measurement technique.
- If none of the above were able to be done prior to the evaluation, you may allow subjects to perform blood pressure measurements with a home device, however you will need to indicate the device type as "Other" on the CRF.

On the day of the scheduled remote evaluation:

Begin the visit by explaining the remote evaluation process and that the coordinator will be observing the blood pressure measurement by video. Also, briefly review the following:

a. If provided to the subject in advance, a study-provided device will be used, and it must be plugged into the wall.
b. No consumption of caffeine or alcohol, smoking, eating, or exercising within the prior 60 minutes.

c. Sit comfortably with the selected arm supported at the heart level and stay in that position with the cuff in place, relaxing quietly for 5 minutes with feet flat on the floor and the back straight and supported, prior to the first measurement.
d. No one should be talking while the monitor is measuring the blood pressure and if a person/pet is present, they must avoid any physical contact with the subject.
e. Three consecutive blood pressure readings separated by at least 2 minutes, will be obtained.
f. No standing blood pressure will be measured for safety purposes.

Immediately after the scheduled remote evaluation:

- If the systolic blood pressure (SBP) is ≥ 140 mm Hg, or if any other risk factor issues require their attention, notify the study medical provider to adjust medication(s) accordingly and indicate any medication changes on the medication form.
- If the SBP is out of target, schedule a blood pressure reassessment in 30 days.
- Inform the subject about the study medical provider's recommendation of blood pressure medication adjustments, the date of the next appointment and, if labs are required, prepare the orders instructing the subject where and when to obtain the labs.
- Enter data in WebDCU as soon as the remote evaluation is completed.

9.0 MOP MAINTENANCE

This MOP will be updated throughout the conduct of the study to reflect all study-specific changes. At a minimum, this MOP will be reviewed annually while subjects are actively participating in CAPTIVA. Refer to **Appendix 4** for a summary of changes.

APPENDIX 1: HOW TO MEASURE YOUR BLOOD PRESSURE AT HOME

The arm used for CAPTIVA blood pressure measurements is your _____ arm.

1. Select a place in your home where you can follow these instructions and can be alone and relaxed while taking your blood pressure. The dining room provides a good place since you will need a chair and a table.
2. Make sure you haven't had anything to drink that contains caffeine or alcohol or smoked for the last 60 minutes.
3. Make sure you have not exercised or eaten anything for the last 60 minutes.
4. Make sure your OMRON Blood Pressure monitor is ready and connected to the electrical outlet and on top of the dining table (or table at a chosen room).
5. Sit with your back straight and supported by the chair. Both feet should be flat on the floor and your arm supported by the table at your heart level. Place the blood pressure cuff on your upper arm as shown in the picture printed on the cuff. Use the arm that is listed above. It should be tight enough that it does not slide off.
6. Relax holding that position for a few minutes. Avoid contact and don't talk to anyone around you while relaxing or measuring your blood pressure.
7. Press the ON button on your blood pressure monitor and stay still. Repeat this step to obtain a total of 3 measurements, waiting at least two (2) minutes in between measurements. Write the results down after each reading.

APPENDIX 2: REMOTE EVALUATION PROCESS CONTACTS

Clinical Coordinating Center (CCC) at the University of Florida

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APPENDIX 3: SUMMARY OF MOP CHANGES

Changes in Version 1.0 dated 24 May 2023
Not Applicable; New Document

Significant Changes in Version 2.0 dated 24 September 2025		
Sections Affected	**Changes in the MOP**	**Justification of Change**
Title Page, Header, and Footer	Added new version number and version date	To maintain version control
Table of Contents	Added new and deleted sections	Narrative sections of MOP
3.0 Approval Process	Removed section	Approval process no longer required
5.1 Site Training	Removed language about required training. Added information about as needed training	Training no longer required
Appendix 2	Updated Title and personnel	To align with updates and current study personnel