CAPTIVA DOCUMENTATION OF THE CONSENT PROCESS

This sponsor-provided tool reflects best practice according to GCP and StrokeNet policy specific to the CAPTIVA trial.
The use of this tool is optional and it can be modified to accommodate local practices and/or procedures.

Study & Subject Information	
Study Title	Comparison of Anti-coagulation and anti-Platelet Therapies for Intracranial Vascular Atherostenosis
Site Principal Investigator	
Current CIRB Approved Protocol Version Date	
Current CIRB Approved ICF Version Date	
Subject ID	

Initial ALL that Apply	**Initials**
Enter the details for the individual who confirmed subject eligibility per the *Inclusion and Exclusion* criteria in the CIRB-approved version of the protocol: Name: _____ Study Role on DOA: _____	
A copy of the ICF was given to potential subject for review.	
The potential subject was provided adequate time to review the ICF and to discuss study participation with others.	
Study participation was discussed with the potential subject and the ICF was explained and reviewed. If the informed consent was reviewed with the potential subject multiple times, enter the dates below: Date: _____ Date: _____ Date: _____	
The subject agreed to take part in the study and personally signed and dated the **Statement of Consent** *prior to any study interventions.*	
The subject personally signed and dated the **Statement of Authorization**.	
The subject agreed or did not agree to **sample and data banking** by personally initialing.	
The subject agreed or did not agree to **genetic data sharing** with NIH by personally initialing.	
The person obtaining consent personally signed and dated the **Statement of Consent**.	
If the consent process (not just the signing of the form) was witnessed by a third party, enter the details below: Name: _____ Relationship: _____ Name: _____ Relationship: _____ Name: _____ Relationship: _____	
A copy of the entire ICF was placed in the subject's medical record.	
The original signed copy of the entire ICF was placed in the subject's research chart.	
A copy of the entire ICF was given to the subject.	
A Medical Records Release was obtained from the subject and placed in the subject's research chart.	
The following topics were reinforced with the subject and caregiver(s):	
• How to take study medications and document intake on the *optional* Medication Diary	
• Timing, requirements, and expectations for in-person 1M, 4M, 8M and 12M visits	
• The importance of notifying a study team member of medication changes	
• The importance of notifying a study team member if hospitalized or seen in an emergency room	
• How to contact a study team member	
• The importance and frequency of INTERVENT coaching calls	

Notes/Comments:

Printed Name of Person Obtaining Consent and Completing this Form | Signature | Date

Informed Consent Reminders and Frequently Asked Questions

- Subjects must consent for themselves (the use of a LAR is not permitted).
- Consent, enrollment, & randomization should occur on the SAME day.
    - If a potential subject is interested in participating in CAPTIVA but cannot be randomized that day (e.g. is an in-patient who is about to be discharged), send them home with the consent but do not execute it until the subject returns and is ready to be randomized. Please DO NOT have them sign consent until you will right away be able to enroll them in WebDCU, randomize to drug, and provide drug.
    - If a potential subject is going to a rehabilitation or skilled nursing facility, you need to confirm the ability of that facility to provide study medications and cooperate with your study team before you consent, enroll, and randomize the subject. Some sites have been surprised to learn after consenting and randomizing subjects, that the rehab or SNF facilities will not provide study medications to subjects.
- Refer to the *Advarra Short Form Navigation Guide* in the WebDCU Toolbox if you do not have a fully translated consent in the subject's native language. Advarra has a bank of short forms in various languages readily available to use. If language needed is not available in CIRBI, contact NCC Project Manager for additional support.
    - If a *Short Form* is used, contact the NCC Project Manager to initiate the process to translate the consent to the subject's native language.
    - In WebDCU > CAPTIVA > Regulatory Document > Site Reg Doc Status, you can see all fully translated consent versions available at your site. This is also visible in CIRBI.
    - As with the English version of the consent, ensure the translated version matches the most up to date version of the consent available in CIRBI.