Checklist for Necessary Screening and Randomization Steps

Screening and Baseline visits can be completed on the same day or separate days.

CREST-2

Screening Visit (to establish eligibility)

☐ Ultrasound (F17) and/or other qualifying imaging modalities (*i.e.*, MRA, CTA, etc., within 180 days prior to randomization)

☐ Inclusion Criteria (F01)

☐ Exclusion Criteria (F02)

☐ Specific CEA exclusion (F03A) or specific CAS exclusion (F03B)

Please note:

- These CRFs can be entered any time after obtaining consent and prior to completing the randomization form (F04).
- If patient is randomized to procedure, the procedure should be scheduled within 14 days after the date of randomization.

Baseline Visit

☐ F01, F02 and F03 (A or B) must be entered and locked before continuing with the forms below.

If you inadvertently choose the wrong form in eDES, please submit a delete request that form. Once the "wrong form" is cleared, you will have access to the correct form. If the wrong form is entered and it is after-hours during the process of randomization, please enter new patient so that you do not delay randomization. (Please contact the SDCC to walk you through the process to delete the other forms during the next business day).

☐ Randomization (F04)

☐ Patient Contact Form (F34)

Please note: When this form has been entered and locked, INTERVENT will be notified to contact the patient.

☐ Cognitive Assessment (conducted by Survey Research Unit (SRU) at UAB

Please note:

- **We strongly encourage the baseline cognitive assessment to be completed at the clinic visit. Once the patients is randomized, the baseline cognitive assessment should be completed within14 days or PRIOR to procedure if randomized to procedure).**
- **You must make a reservation in eDES prior to your calling the UAB Cognitive Assessment Phone Line. To make a reservation, click Cognitive Reservation System in eDES to reserve a date and time.**
- **Baseline cognitive assessment can be initiated only after the Patient Contact Form (F34) has been entered and locked. Please allow 5 minutes after locking F34 before calling the UAB Cognitive Assessment Phone Line.**
- **To perform the cognitive assessment, please call the UAB Cognitive Assessment Phone Line at 205-934-2462. This number should be used only to perform the cognitive assessment and only after locking the F34. Do not use this number unless your patient is ready for the assessment, and use only for conduct of assessment.**
- **If there are problems connecting, or if you have questions about how to perform the assessment, call Jason Avery at (205) 934-1780 or Robert Caldwell at (205) 934-3395.**

☐ Demographics and Social Status (F05)

Please note: This form must be entered and locked immediately following randomization in order to provide required demographic information to NINDS in real time.

☐ On the day of enrollment (day of consent), blood pressure MUST be collected and the medical management protocol MUST be started (*i.e.,* enter and lock the following forms: F06, F07, F08 and F18).

The patient should be on ASA 325mg at the time of randomization .For those patients intolerant to aspirin 325 mg p.o. q.d., acceptable alternatives include :aspirin 81 mg p.o. q.d., clopidogrel 75 mg p.o. q.d., ticagrelor 90 mg p.o. bi.d., or prasugrel 10 mg p.o. q.d. (if patient <60 kg or 132 pounds, consider 5 mg p.o. q.d).

☐ Baseline Medical History (F06)

☐ Baseline Vital Signs (F07) Blood pressure must be measured using the Omron Digital BP machine provided by the study.

☐ Medications (F08)

Please note:

- **Record prescription medications and aspirin patient was on PRIOR to randomization on a <u>scheduled</u> Medications Form (F08).**
- **Record any changes made to prescription medications AFTER randomization on an <u>unscheduled</u> F08.**
- **If patient is randomized to a procedure, record procedural medications on the applicable procedure form (CAS [F14] or CEA [F15]) and <u>not</u> on F08.**

☐ Laboratory Results (F18) Creatinine, sodium, potassium, lipids, AST/ALT, HgA1C, creatinine phosphokinase (CK) are acceptable if done within 90 days prior to randomization date and can be from outside labs.

☐ Modified Rankin (mRS) Scale (F09) Please note: Must be conducted by approved person on the green-light letter

☐ NIH Stroke Scale (NIHSS) (F10) Please note: Must be conducted by approved person on the green-light letter

☐ Questionnaire for Verifying Stroke-Free Status (QVSS) (F11)

☐ Site Duplex Ultrasound (F17) (if not previously completed at time of screening)

☐ If patient agrees to the baseline carotid plaque MRI, the window would be as follows after randomization:

- If patient is randomized to CEA or CAS procedure – the MRI would need to be done **<u>PRIOR to the procedure</u>**
- If patient is randomized to intensive medical management only – the MRI would need to be done **<u>prior to the 44-day visit</u>**