

ENRGISE PILOT STUDY: MEDICAL CLEARANCE

Visit Date Completed / /

Staff ID

Rev: _____

DE: _____

Date: _____

Instructions: The site MSO should complete this form while reviewing all data collected prior to randomizing participants. While all participants at this stage will technically meet inclusion and exclusion criteria, MSO's should **use their clinical judgment** to provide an overall approval (or not) for each potential participant to proceed with randomization.

Section 1: Randomization Arm Eligibility (From the Central Eligibility Check)

- Losartan/Placebo Only
- Omega3/Placebo Only
- Losartan/Placebo AND Omega3/Placebo

Section 2: Review of Participant Medical Status

1. In your medical opinion, does the participant's medical/health history raise any significant concerns about participating in the study? 1 Yes 2 No
2. In your medical opinion, do the participant's vital signs during screening raise any significant concerns about participating in the study? 1 Yes 2 No
3. In your medical opinion, do the patient's current medications (prescription or over-the-counter) raise any significant concerns about participating in the study? 1 Yes 2 No
4. In your medical opinion, do the patient's laboratory measures raise any significant concerns about participating in the study? 1 Yes 2 No

Section 3: Approval or Disapproval Signature

5. Based on your answers to the questions in Section 2, should this participant be randomized to the ENRGISE study arm(s) they are eligible for?

1 Yes →

Signature Staff ID

2 No →

6a. Reason for exclusion:
