ENRGISE PILOT STUDY: SERIOUS ADVERSE EVENT REPORT

Date Completed ☐☐/☐☐/☐☐

Staff ID ☐☐☐☐

Rev: _____

DE: _____

Date: _____

If the investigator feels the adverse event is serious, a Serious Adverse Event (SAE) Report form must be completed and data entered within 24 hours of event notification. SAEs are ONLY Adverse Events (AEs) fitting into one of the categories in Question 1 (see MOP Chapter 14 for definitions).

Adverse Event Number ☐☐☐☐☐ *Record the AE# from the Adverse Event Report form.*

Section 1: SAE Classification

1. Indicate the type(s) of Serious Adverse Event (***Check all that apply***)

- 1☐ Death
- 1☐ Life-threatening
- 1☐ Inpatient Hospitalization
- 1☐ Prolongation of Hospitalization
- 1☐ Disability or Permanent Damage
- 1☐ Substantial Disruption in ability to conduct normal life functions
- 1☐ Other Serious (Important Medical Event)

2. Date of Onset for the Event: ☐☐/☐☐/☐☐

3. Does this SAE meet the definition of Unexpected*?

- 1☐ Yes →
- 2☐ No

Indicate reason why this is unexpected:

- 1☐ Not listed in the protocol/investigational brochure
- 1☐ Not listed at the protocol severity specified

Section 2: SAE Causality* – Indicate the relationship of the SAE to the ENRGISE medication

4. **Losartan/Placebo**

- 1☐ Not participating in this arm
- 2☐ Definitely due to study drug
- 3☐ Possibly due to study drug
- 4☐ Not due to study drug

Current Dosage ☐☐☐ mg/day

5. **Omega-3 Fish Oil/Placebo**

- 1☐ Not participating in this arm
- 2☐ Definitely due to study drug
- 3☐ Possibly due to study drug
- 4☐ Not due to study drug

Current Dosage ☐.☐ g/day

**Final determination to be made by the site MSO/MD*

Section 3: SAE History Information*

6. MedDRA Classification *(go to http://safetyprofiler-ctep.nci.nih.gov/CTC/CTC.aspx to classify)*

	Primary Diagnosis	Secondary Diagnosis	Secondary Diagnosis
Category			
AE Term			

Section 4: SAE Action Taken

7. *Please list the actions taken (check all that apply):*

1☐ No Action Taken

1☐ Decreased Losartan/placebo Pre SAE Dose ☐☐☐ mg/day Post SAE Dose ☐☐ mg/day

1☐ Decreased Omega-3 fish oil/placebo Pre SAE Dose ☐.☐ g/day Post SAE Dose ☐.☐ g/day

1☐ Discontinued Losartan/placebo Pre SAE Dose ☐☐☐ mg/day Date Discontinued ☐☐/☐☐/☐☐

1☐ Discontinued Omega-3 fish oil/placebo Pre SAE Dose ☐.☐ g/day Date Discontinued ☐☐/☐☐/☐☐

1☐ Instructed participant to discuss with PCP

1☐ Contacted participant's PCP directly to discuss

1☐ Transported participant to acute care facility (e.g. Emergency Room, Hospital)

1☐ Increased monitoring frequency for blood work

1☐ Increased monitoring frequency for blood pressure

1☐ Other: _____

**Final determination to be made by the site MSO/MD*

Section 5: SAE Relevant Tests/Laboratory Data
8. Please describe any relevant test information and laboratory values/data used during the diagnosis and treatment of this SAE, include dates:

Section 6: SAE Description/Narrative*
9. Please describe this adverse event, include all clinical information, medications used to treat/manage the adverse event, including doses. Use this area to justify the relationship, or lack of relationship, of this SAE to the study medication.

**Final determination to be made by the site MSO/MD*

Section 7: SAE Resolution

10. Participant's Current Condition (check all that apply)

1☐ Recovered 1☐ Under treatment for sequelae 1☐ Death

1☐ Resolved with decreased dose 1☐ Alive with sequelae

Section 8: Signatures

11. Sign when all information is reviewed and approved by the clinic PI/Study MD

1☐ Reviewed

_____ ☐☐☐☐

Signature *Staff ID*

Section 9: Follow-up

12. Is further follow-up required?

1☐ Yes, event is ongoing and follow-up is needed

2☐ No, this is the final → 12a. End Date: ☐☐/☐☐/☐☐

13. Sign when follow-up is complete, reviewed, and approved by the clinic PI/Study MD

1☐ Follow-up Complete

_____ ☐☐☐☐

Signature *Staff ID*

**Final determination to be made by the site MSO/MD*