Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ Participant Letters: __ __ __

This form is completed to record the details of any <u>serious adverse events</u> that occur during this study. This form should be completed with as much information as is known and faxed to the TrialNet Coordinating Center at (301) 468-1676 within 24 hours of clinic notification of event. Attach additional pages, if needed.

A. MEDWATCH Report Information

1. Report Date: __ __/__ __ __/__ __ __ __ (DAY MONTH YEAR) 2. Report by: _____ 3. Phone #: _____

4. Reason for Report *(check all that apply):*
- ☐ 1 Death
- ☐ 1 Life-threatening
- ☐ 1 Hospitalization*
- ☐ 1 Overdose
- ☐ 1 Congenital anomaly/birth defect
- ☐ 1 Treatment to prevent a serious event or outcome
- ☐ 1 Disability/Incapacity
- ☐ 1 Other: a. _____

** Initial or prolonged*

5. Adverse Event ID #: __ __ __ __

B. Patient Information

1. Age: __ __ years 2. Gender: ☐ 1 Male ☐ 2 Female 3.Weight: __ __ __.__ kg OR __ __ __.__ lb

4. Serious Adverse Event Being Reported: _____

5. Onset Date: __ __/__ __ __/__ __ __ __ (DAY MONTH YEAR) 6. Current Status: ☐ 1 AE Ongoing ☐ 2 AE cleared on: a. __ __/__ __ __/__ __ __ __ (DAY MONTH YEAR)

7. Describe the Adverse Event, including treatment of the event (e.g., comment on the patient's condition just prior to the adverse event, the onset and development of the event, and –**If known at time of this report**—the duration and outcome of the adverse event.):

8. Pertinent Medical History (*including pre-existing medical conditions*):

9. Concomitant Medications Taken at the Time of Onset of the Adverse Event:

10. Pertinent Laboratory Test Results (*both normal and abnormal*):

C. Study Medication Information

1. Randomization Date: __ __/__ __ __/__ __ __ __ (DAY MONTH YEAR) 2. Last Dose of Drug Given: __ __ __ __. __ mg

3. Date of Last Dose Given *(if applicable)*: __ __/__ __ __/__ __ __ __ (DAY MONTH YEAR) 4. Dose Following Event:
- ☐ 1 Unchanged
- ☐ 3 Discontinued
- ☐ 2 Interrupted
- ☐ 9 NA

5. If Dose Interrupted or Discontinued, Did Patient Improve? ☐ 1 Yes ☐ 2 No *(not yet)* ☐ 9 NA

6. If Dose Interrupted or Discontinued, Do You Plan to Re-start Patient? ☐ 1 Yes *(or already have)* ☐ 2 No ☐ 3 Undecided

7. If Patient Re-started on Study Medication, Did Adverse Event Reappear? ☐ 1 Yes ☐ 2 No ☐ 9 NA