Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

This form is completed to record the details of any **serious adverse events** 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 that an event had occurred. **Attach additional pages, if needed.**

A. MEDWATCH Report Information

1. Report Date: __ __/__ __/__ __ __ __ (MM DD YYYY) 2. Report By: _____ 3. Phone #: _ _ _ - _ _ _ - _ _ _ _

4. Reason for Report *(check all that apply):*

☐ 1 Death ☐ 4 Life-threatening ☐ 6 Hospitalization*
☐ 2 Overdose ☐ 5 Congenital anomaly/birth defect
☐ 3 Treatment to prevent a serious event or outcome ☐ 7 Disabilty/Incapactiy
☐ 9 Other: a. _____

* Initial or prolonged

5. Adverse Event ID #: __ __ __ __

B. Patient Information

1. Age: __ __ 2. Gender: M F 3.Weight: __ __ __.__ kg OR __ __ __.__ Lb

4. Serious Adverse Event Being Reported: _____

5. Onset Date: __ __/__ __/__ __ __ __ (MM DD YYYY) 6. Current Status: ☐ 1 AE Ongoing ☐ 2 AE cleared on: a. __ __/__ __/__ __ __ __ (MM DD YYYY)

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: __ __/__ __/__ __ __ __ (MM DD YYYY) 2. Daily Dosage at Time of Adverse Event: __ __ __ __ mg

3. Frequency of Dosing at Time of Event: ☐ 1 BID ☐ 2 TID ☐ 9 Other 4. Date This Dose Started: __ __/__ __/__ __ __ __ (MM DD YYYY)

5. Dose Following Event: ☐ 1 Unchanged ☐ 2 Reduced ☐ 3 Interrupted ☐ 4 Discontinued ☐ 9 NA

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

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

8. If Patient Re-started on Study Medication, or Returned to Higher Dose, Did Adverse Event Reappear? ☐ 1 Yes ☐ 2 No ☐ 9 NA

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __