GCRC SERIOUS ADVERSE EVENT REPORT

A. Patient Information

1. Patient Identifier (in confidence):

2. Date of Birth:_____(mo/day/yr)

3. Gender: ☐ Male ☐ Female

4. Weight: _____lbs (or) _____kg

B. Adverse Event

1. Outcomes attributed to adverse event
(Check all that apply)

☐ death _____(mo/day/yr)
☐ life-threatening
☐ hospitalization - initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other _____

2. Date of event: _____(mo/day/yr)

3. Date of this report: _____(mo/day/yr)

4. Describe the event:

5. Relevant test/lab date, incl. dates:

6. Other relevant history, incl.pre-existing medical conditions (e.g., allergies, race, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, etc.):

C. Suspect Medication(s)

1. Name

#1_____

#2_____

2. Dose

#1_____

#2_____

3. Therapy dates

#1_____

#2_____

4. Diagnosis for use (indication)

#1_____

#2_____

5. Event abated after use stopped or dose reduced

#1 ☐ yes ☐ no ☐ n/a

#2 ☐ yes ☐ no ☐ n/a

6. Concomitant medical products & therapy dates (exclude treatment of event):

D. Reporter

1. Name & address:

2. Phone number:_____

3. E-mail address:_____

4. Occupation:

_____

5. Also Reported to:

☐ manufacturer
☐ user facility
☐ distributor
☐ other
☐ NIH
☐ FDA
☐ External DSMB
☐ Study sponsor/manufacturer