# Serious Adverse Event (SAE) Report Form

**STUDY NAME**

For the purposes of this form, a serious adverse event is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/incapacity, or in the opinion of the investigators represents other significant hazards or potentially serious harm to a study subject. A serious adverse event is considered unexpected if it is not described in the clinical study protocol, or in the informed consent document.

**eProtocol Number:** \_\_\_\_\_\_\_\_\_\_\_\_\_ **Date was reported:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Pt ID:**

1. SAE onset date:
2. SAE stop date:
3. Was this an unexpected adverse event?  Yes  No
4. Brief description of the nature of the SAE (attach description if more space is needed):

1. Category of the SAE:

[ ] death

[ ] disability/incapacity

[ ] life-threatening

[ ] hospitalization-initial or prolonged

[ ] required intervention to prevent permanent impairment

[ ] other

1. Relationship of event to study/intervention:

[ ] 1 = unrelated (clearly not related to the research)

[ ] 2 = unlikely (doubtfully related to the research)

[ ] 3 = possible (may be related to the research)

[ ] 4 = probable (likely related to the research)

[ ] 5 = definite (clearly related to the research)

8. Have similar adverse events occurred on this protocol?  Yes  No

9. What medications or other steps were taken to treat the SAE?

10. What steps do you plan to take as a result of the adverse event reported above? Provide documentation to the CRC for review and approval of any of the steps checked below.

[ ] no action required

[ ] amend consent document

[ ] amend protocol

[ ] inform current subjects

[ ] terminate or suspend protocol

[ ] other, describe:

Signature of principal investigator: Date: