Federalwide Assurance 00006065

IRB File # _____ Agenda Date: _____ Last CR Approval Date: _____ CIRB: _____

For the purpose of this form, a serious adverse event is any unfavorable medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/ incapacity, results in congenital anomalies/birth defects or in the opinion of the investigators represents other significant hazards or potentially serious harm to research subjects or others. A serious adverse event is considered unexpected if it is not described in the Package Insert or in the Investigator's Brochure (for FDA investigational agents), in the protocol, or in the informed consent document.

Please type and complete all questions below.
Tab and arrow through application to appropriate blank. The fields will expand if needed.

An adverse event must be reported to the IRB Office within 5 working days of the actual event. All deaths should be reported immediately upon the notification to the Principal Investigator.

A. General Information

Principal Investigator: **Phone:** **Fax:**

Mailing Address:

Sub-Investigators:

Study Coordinator: **Phone:** **E-mail:**

Regulatory Associate:

B. Protocol General Information

Title:

Sponsor: **Protocol No:**

C. Brief Description of Subject:

Sex: ☐ **M** ☐ **F** **Age:**

Research ID: **Initials:** **Date of Randomization/Enrollment:**

SAE Diagnosis: **Date of Notification:**

D. Brief description of the adverse event (*No abbreviations*):

E. Category (outcome) of the serious adverse event:

Research: Check as many as apply

☐ **Death**

☐ **Disability /Incapacity**

☐ **Life-threatening to subjects and others**

☐ **Congenital anomaly**

☐ **Hospitalization- initial or prolonged**

☐ **Required intervention to prevent permanent impairment**

☐ **Any serious adverse event caused by or associated with the test article not previously anticipated**

☐ **Other:**

Relationship of serious adverse event:

☐ **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)**

Severity:

☐ **Grade 1 = Mild**
☐ **Grade 2 = Moderate**
☐ **Grade 3 = Severe**
☐ **Grade 4 = Potentially Life Threatening**
☐ **Grade 5 = Death**

F. Have similar adverse events occurred on this protocol?

☐ **Yes** ☐ **No** **If yes how many?**
Please describe:

What steps do you plan to take as a result of the adverse event reported above? Provide documentation to the IRB 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:**

Required documents for IRB Review:

- ☐ 1 copy of this form.
- ☐ 1 copy of current informed consent, 1 copy of all supporting documentation regarding this adverse event. If Applicable 1 copy of the revised informed consent(s), with changes highlighted.
- ☐ Originally signed form must be mailed to the IRB Office.
- ☐ **All information and documents must be uploaded into IRBANA.**

Submit originally signed applications to the IRB Office:

Location: BayCare Health System IRB Office

Baycare Health System Offices
2995 Drew. St.
East Building 3rd Floor
Clearwater, FL.

Questions: Call the IRB Office at:
(727) 467-4577

INCOMPLETE PROPOSALS WILL BE RETURNED TO THE INVESTIGATOR

Principal Investigator's Statement of Assurance

I understand that I cannot initiate any changes in my approved protocol before I have received IRB approval and/or complied with all the contingencies made in connection with that approval. When the outcome is not yet known or if further information is received on this event, I will submit a follow-up report.

_____ _____

Signature of Principal Investigator **Date**