Change in Procedure

IRB File #: **Agenda Date:** **Reviewers:** _____

Expedite **Full Board**

Instructions: Per requirements of 45 CFR 46.103(b)(4), and 21 CFR 56.108(a)(3)(4), changes in approved research cannot be initiated without IRB review and approval unless necessary to eliminate apparent immediate hazards to the subject or provide important information relevant to the informed consent. In this circumstance, the IRB must be notified immediately. To review your Change in Procedure, the IRB must have the following information provided according to the specific instructions in each subpart. Additional pages can be used as necessary.

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

1. General Information:

Principal Investigator: **Phone:**

Mailing Address:

Sub-Investigators:

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

2. Protocol General Information

Title:

Sponsor: **Protocol No:**

3. Type of Change - Check all that apply to this change

	Addendum		**Revised Protocol and/or Summary**		**New Protocol Title**
	Amendment		**Revised Consent Form(s) #**		**Investigator's Drug Brochure**
	Modification		**Change in Investigator(s)**		**Other**

4. Change in Procedure Information

Give a brief description of the proposed changes (tab down, continue to type space will expand):

Describe any anticipated benefits to the subjects (tab down, continue to type space will expand):

Describe any additional risks the subjects may experience (tab down, continue to type space will expand):

Has the informed consent been revised? **Yes__ No ___ (If yes, highlight changes and attach)**
How many informed consent form(s) associated with this study: #

---

5. Application Submission

Must be submitted:

- ☐ **This original form.**
- ☐ **1 copy of the current informed consent form(s) (if the change is ICF related).**
- ☐ **1 clean copy of the revised informed consent form(s) (if applicable) for IRB Approval.**
- ☐ **1 copy of the revised informed consent form(s) with changes highlighted (if applicable).**
- ☐ **1 copy of all supporting documentation regarding this change (Protocol, Protocol summary, ICF(s), IDB).**
- ☐ **All information and documents must be uploaded into IRBANA.**
- ☐ **Check or Money Order in the amount of $50.00**

Submit originally signed application to an IRB Office:

Location: BayCare Health System IRB Office
2995 Drew St., Clearwater, Florida 33759
East Building MS 1059

Questions: Call (727)-467-4577

INCOMPLETE PROPOSALS WILL BE RETURNED TO THE INVESTIGATOR.

6. 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.

_____ _____

Signature of Principal Investigator **Date**