BayCare Health System
Institutional Review Board **Continuing Review/Final Report Form**
Federalwide Assurance 00006065

IRB File #:_____ Agenda Date: _____ Original Approval Date: _____ Last IRB Review Date: _____

_____ **Continuing Review** _____ **Final Report**

Full Board _____ Expedite_____

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

1. General Information

Principle Investigator: **Phone:**

Mailing Address:

Sub-Investigators:

Study Coordinator(s): **Phone:** **Fax:** **Email:**

Regulatory Associate:

2. Protocol General Information

Title:

Sponsor: **Protocol No:**

3. What is the Current Protocol Information Study Status? (Highlight Response Please)

Common Rule Changes to ICF	**Yes: Date: No**
Active	**Closed to Accrual Date:**
Closed to Treatment (Date):	**Temporary Closed to accrual (Date):**
Temp Closed to Accrual &Treatment	**Study Completed: (Reason & Date)**

For Final Reports go to page 4.

4. Please Provide the Following Study Information (This site only)

Total number of subjects approved to be enrolled in the study: _____

How many subjects signed an informed consent form as of this report: _____

How many subjects signed the informed consent, but did not meet criteria: _____

How many subjects were randomized on the study: _____

How many subjects are still current participants: _____

How many subjects completed study as of this report: _____

How many subjects withdrew/terminated study due to a Serious Adverse Event: _____

How many subjects continued on study with a reported Serious Adverse Event: _____

Other:

Describe the reason for any withdrawal and/or termination during the study:
_____

Please Provide the Following HUD Information:

How many subjects utilized the device: _____

How many devices were unsuccessfully deployed: _____
A summary description of subject experiences (benefits, adverse reactions)

Were there any Serious Adverse Events to report/reported: _____

Any new information since the IRB's last review. _____Yes _____ No.

Other:

5.0 How is the study progressing with respect to accrual, withdrawals, and follow-up? Is the study having any difficulties, beyond those anticipated in the protocol, meeting its intended outcomes? If "yes", please explain below:

5.1. *Have any findings from this study been presented or published, including Progress Reports to the FDA and/or a Data Safety Monitoring Board or Committee? If "yes", please explain and attach the relevant document.

If YES; date of last review. MM/DD/YYYY _____

5.2. Has any relevant information relating to the participants' risk and benefits on this study become available since the last IRB review? This would include any new information about the drug(s), device(s) or procedure(s) used in this study, as well as any new information on alternative therapies for the condition being studied.

Yes: _____ No: _____ If yes, explain and attach relevant documents. (Literature Search)

5.3. Have there been any material changes in the research activity or revisions, amendments, addendum to the protocol, consent form(s), or questionnaires?

Yes: _____ No: _____ If yes, please list all amendments submitted in the past year including month and year approved by the IRB:

5.4. Has the IRB received any reports from the Principal Investigator about any serious adverse events or expected toxicities (as defined in the protocol), injuries, or problems involving risk to participants or others or protocol deviation/violations?

Yes:_____ No:_____

5.5. Has the Informed Consent Form(s) been revised to reflect any revisions/amendments during the past year? Yes: _____ No: _____ Not Applicable: _____ If yes, attached a copy of the highlighted changes to the last approved Informed Consent Form(s).

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*For example, as noted above, sponsors of investigational drug studies are required by 21 CFR 312.33 to submit annual reports to FDA on the progress of their studies. Sponsors of investigational device studies are already required to provide progress reports to all reviewing IRBs at least annually (21 CFR 812.150(b)(5)).

Continuing Review Application Submission

Must be submitted:

- ☐ **All information and documents must be uploaded into IRBANA.**
- ☐ **1 Signed Application (The signed application must be uploaded to IRBANA with the submission)**
- ☐ **1 copy of the CLEAN/UNSTAMPED informed consent form (s) for IRB renewal. (1 copy of the current informed consent form(s), a highlighted copy of the consent changes if revised during the past approval year, a copy of the study summary and a copy of the last approved protocol and/or IDB and any other relevant documents as stated in the application. *(eLibrary Access granted from the last submitted and approved version in IRBANA) You have the ability to attach the documents to this submission.***
- ☐ **1 Yearly Signed Conflict of Interest Form per investigators**
- ☐ **Check or Money Order in the amount of $1000.00 (Full Board Submission)**
- ☐ **For HUD Submissions, please include 1 copies of the Humanitarian Use Device Accountability Form**

PRINCIPAL INVESTIGATOR'S STATEMENT OF ASSURANCE

Continuing Review Report:

I understand that additions to, or changes in procedures involving human subjects as well as problems connected with the use of human subjects once the project has been approved for continuation it must be brought to the attention of the IRB. I agree to insure the rights and welfare of the human subjects are properly protected. I understand that I cannot initiate any changes before I have received approval and/or complied with all contingencies made in connection with that approval. I confirm the information stated above is accurate.

_____ _____

Signature of Principal Investigator **Date**

6. Please Provide the Following Study Information for Final Report (This site only)

Total number of subjects approved to be enrolled in the study: _____

How many subjects signed an informed consent form as of this report: _____

How many subjects signed the informed consent, but did not meet criteria: _____

How many subjects were randomized on the study: _____

How many subjects completed study as of this report: _____

How many subjects withdrew/terminated study due to a Serious Adverse Event: _____

How many subjects continued on study with a reported Serious Adverse Event: _____

Other:

Describe the reason for any withdrawal and/or termination during the study:

Final Report Application Submission

- ☐ **1 copy of the current informed consent form(s), a copy of the consent changes if revised during the past approval year, a copy of the study summary and a copy of the last approved protocol and/or IDB and any other relevant documents as stated in the application.**
- ☐ **Letter/email from the sponsor about the closing of the study**
- ☐ **1 Signed Application**
- ☐ **All information and documents must be uploaded into IRBANA.**

PRINCIPAL INVESTIGATOR'S STATEMENT OF ASSURANCE

Final Report:

I confirm the information stated above is accurate and am terminating this study because:

_____ _____

Signature of Principal Investigator **Date**

Submit originally signed application to an IRB Office:

Location: **BayCare Health System IRB Office**

2995 Drew St.
BSO East MS#: 1059
Clearwater, Florida 33759

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

INCOMPLETE PROPOSALS WILL BE RETURNED TO THE INVESTIGATOR.