BayCare Health System Institutional Review Board

Standard Consent Process

1. Principal Investigator: _____ Phone: _____

2. Protocol Title:

Sponsor: _____ Protocol No: _____

3. Describe the consent process specific to this study. Please include statements concerning safeguards to be employed for subjects to give knowledgeable, informed, voluntary consent. Also include anything unusual regarding the consent process for this particular study. This may include the accrual of subjects that are in transition from one state or country to another. By stating the intent to accrue subjects in transition during consenting for the purpose of research, you may eliminate the need for a reportable deviation that may be reported as a lost to follow-up that can be reported on the (CR) Yearly Report.

4. How many subjects will be accrued on this protocol?

5. If your proposal involves minors, what is your process for obtaining assent?

_____ _____

Signature of Principal Investigator **Date**

IRB 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

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