Initial Study Review Form for Human Subjects Research

BayCare Health System (BCHS) Institutional Review Board

Location(s): BayCare Health System IRB Office
2995 Drew St., BSO East MS #: 1059, Clearwater, FL. 33759
Office: (727) 467-4577 Fax: (727) 333-6319 Email: IRB-BCHS@baycare.org

1. STUDY TITLE

2. SPONSOR

3. PRINCIPAL INVESTIGATOR(S)

Name (Last, First, MI):
Department:
Phone: Email: Fax:

SUB-INVESTIGATOR(S)

Name: Specialty:
Name: Specialty:
Name: Specialty:

4. KEY PERSONNEL

Key personnel are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent (coordinators), or who collect study data including regulatory individuals.

Name (Last, First, MI):	***Phone:***	***Email:***
Name (Last, First, MI):	***Phone:***	***Email:***
Name (Last, First, MI):	***Phone:***	***Email:***

5. HUMAN SUBJECTS PROTECTION TRAINING

Have all study and key personnel completed and or updated the required web-based course (CITI) in the protection of human research subjects? **(Please submit in IRBANA)** ☐ Yes ☐ No

Educational requirements (initial and continuing) must be completed with a ≥80% satisfaction score prior to submitting the application for IRB review.

6. FINANCIAL CONFLICT OF INTEREST

All investigators and key personnel (sub-I, ARNP, PA) on study must have a current COI Financial Disclosure Form (updated as necessary for the proposed research) before IRB review. Examples of financial interests that must be disclosed include (but are not limited to) consulting fees or honoraria; stocks, stock options or other ownership interests; and patents, copyrights and royalties from such rights.

a. **Have all investigators and key personnel completed the required Financial Disclosure Form?** ☐ Yes ☐ No

7. OTHER INSTITUTIONAL APPROVAL

Check all that apply and provide applicable documentation. IRB review cannot be conducted until required institutional approvals or exemptions are obtained.

☐ **None**

☐ **Clinical Review:** For Clinical Research Projects Only. (collection and analysis of blood, tissues, or other samples) Excludes health services or public health research

☐ **Administrative Review-** Approval require for research sponsored by industry or research that utilizes any BayCare facility in order to conduct research and should be submitted to the IRB.

☐ **Scientific Advisory Committee-** Approval required for research of any drug or device that requires a SAC determination. Final IRB approval will be held pending receipt of this approval.

☐ **Other:**

LOCATION OF THE RESEARCH

Location Name and Address (or description)

8. OTHER RESEARCH REQUIREMENTS

Study requires a 1572 completed ☐ Yes ☐ No **If Yes → Please Submit**

Is there a Data Safety Monitoring Committee for this study? ☐ Yes ☐ No

If Yes → How frequently will the committee meet?

Is there Marketing recruitment involve in this study? ☐ Yes ☐ No

If Yes → Recruitment materials require Marketing Department approval before submission to BCHS IRB.

9. RESEARCH METHODS & ACTIVITIES

Identify and describe all interventions and interactions that are to be performed solely for the research study. Distinguish research (i.e., study related only) activities from non-research activities (i.e., standard of care (SOC)).

10. DURATION

What is the starting and ending time period for the study, including individual interactions and long-term follow-up, if any.

11. NUMBER OF PARTICIPANTS

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

a. Provide the total number of participants (or number of participant records, specimens, etc.) for whom you

are seeking BCHS IRB approval: **Required # _____**

b. Is this a multi-site study?

☐ No

☐ Yes → Indicate the total number of participants to be enrolled across all sites:

12. STUDY POPULATION

a. Specify the age(s) of the individuals who may participate in the research:

Age(s):

b. Specify the participant population(s). Check all that apply:

☐ Adults

☐ Children (< 18 years)

☐ Adults with decisional impairment

☐ Non-English speaking

☐ Pregnant women/fetuses

☐ Neonates (uncertain viability/nonviable)

☐ Neonates (uncertain viability/nonviable)

☐ Other:
Specify _____

13. PARTICIPANT IDENTIFICATION, RECRUITMENT & SELECTION

a. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

b. List the names of investigator(s) and/or key personnel who will recruit participants.

c. Describe the process that will be used to determine participant eligibility.

d. Describe the recruitment process; including the setting in which recruitment will take place. ***Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, and oral/written scripts).***

14. INCENTIVES TO PARTICIPATE

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, travel reimbursement, lodging) to participate in the research study? ***Compensation plans should be pro-rated (not contingent upon study completion) and should consider participant withdrawals, as applicable.***

☐ Yes

☐ No

If Yes → Describe the incentive, including the amount and timing of all payments.

15. INFORMED CONSENT PROCESS

a. List the names of investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives.

b. Who will provide consent or permission (i.e. participant, legally authorized representative, parent and/or guardian)?

c. Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation.

d. Explain how the possibility of coercion or undue influence will be minimized in the consent process.

16. SERIOUS ADVERSE EVENTS REQUIREMENTS

a. Is this a Drug/Device study: ☐ Yes ☐ No Is this a Bio-specimen/Data Collection study: ☐ Yes ☐ No

b. List the Reportable SAE for this study as indicated in the protocol:

17. PRIVACY OF PARTICIPANTS

Describe the provisions to protect the privacy interests of the participants. ***Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants' expectations of privacy.***

a. Does the research require access to personally identifiable private information? ☐ Yes ☐ No

If Yes → Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., bio-specimens, surveys, medical records, etc.).

18. CONFIDENTIALITY OF DATA

Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records. ***Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with BayCare policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure BayCare location, or if electronically transmitted.***

a. Indicate what will happen to identifiable data at the end of the study. ***Primary research data should be retained for a minimum of five years after final project closeout. Other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)***

☐ Identifiable data was not collected

☐ Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)

☐ Identifiable or coded/linked data will be retained and stored securely (as appropriate)

☐ Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

19. HIPAA RESEARCH AUTHORIZATION

Will individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rules requirements be accessed, used, or disclosed in the research study? ☐ Yes ☐ No

20. PARTICIPANTS COSTS & REIMBURSEMENTS

a. List any potential costs participants (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

b. List any costs to participants that will be covered by the research study.

21. ASSURANCE: PRINCIPAL INVESTIGATOR(s)

I agree to follow all applicable federal regulations, guidance, state and local laws, and BayCare policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators, including, but not limited to, the responsibilities described in Guidance for IRB's, Clinical Investigators, and Sponsors.

I verify that the information provided in this Initial Review of Human Subjects Research application is accurate and complete. I will initiate this research only after having received notification of final BCHS IRB approval.

Name of Principal Investigator **Date**

Signature of Principal Investigator

22. Service Line Director (or Signatory Official) (If Applicable)

If Applicable: As Department Chair (or Signatory Official) for the Principal Investigator, I acknowledge that this research is in keeping with the standards set by our department and that it has met all Departmental requirements for review.

If the PI or any co-investigator is also the Department Chair, the signature of the Signatory Official, such as the Chief Medical Officer for your facility, must be obtained.

Printed Name of Department Chair (SO)

Signature of Department Chair (SO) **Date**