BayCare

POLICY & PROCEDURE

Title: **BAYCARE IRB INITIAL APPROVAL OF RESEARCH**	**Policy Number:** BC-IRB-401 **Page:** 1 of 3
SPONSORED BY: Sponsored Programs and Research Committee **Original Issue Date:** 1/2022 **Review Dates:** **Revision Date:**	**Issued for:** All BayCare, including without limitation: Bartow Regional Medical Center BayCare Alliant Hospital BayCare Hospital Wesley Chapel Mease Countryside Hospital Mease Dunedin Hospital Morton Plant Hospital Morton Plant North Bay Hospital South Florida Baptist Hospital St. Anthony's Hospital St. Joseph's Hospital Winter Haven Hospital
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This policy is developed as a guideline to address general circumstances. There may be certain instances in which the exercise of professional judgment and/or discretion by the health care provider warrants taking other actions.

This **BAYCARE IRB INITIAL APPROVAL OF RESEARCH** Policy applies to BayCare Health System, Inc. and any of its affiliated entities, including those entities listed above (collectively, "**BayCare**").

SCOPE:

BayCare Human Research Protection Program Research for which BayCare Health System's Institutional Review Board (IRB) is the IRB of Record.

PURPOSE:

Federal regulations establish criteria to allow approval of research using human subjects. Further, the IRB determines the level of review, and when applicable, the frequency of review required.

PROCEDURE:

Generally, protocols that require a review at a convened meeting are considered to be more than minimal risk studies. The IRB evaluates each project on an individual basis to assess whether the Principal Investigator (PI) is providing adequate protection for the subjects. The assessment based on the initial IRB application, which includes the applicable documents listed in Section 4.1.1 below.

Meeting documents are made accessible to all members including alternates who will be attending in place of primary members. Members may bring laptop computers to access meeting documents. In the event that a member cannot attend in person, teleconference capability is present, and members may participate through teleconference.

A. **Submission and Review Schedule**

1. If the proposal meets requirements for full board review, the following is required to be electronically submitted and included in the submission packet:
   a. A completed original IRB application with wet ink/electronic signatures of the PI.
   b. A research proposal describing:
      1. the rationale for the study
      2. research questions to be answered
      3. information that allows the IRB to determine whether selection of participants will be equitable,
      4. methods
      5. procedures
      6. data analysis plan
      7. other required information that will allow the IRB reviewer(s) to conduct an analysis of the risks and potential benefits
   c. An informed consent document(s).
   d. Training Verification. (See BC-IRB-403 Clinical Research Team Training Requirements).
   e. Recruitment materials
   f. Data and Safety Monitoring Plan (DSMP) (See Section D4.1.2 below).

g. Copies of all data collecting tools if the study involves the use of questionnaires, surveys, or similar instruments.

2. If applicable:
   a. Copy of the grant application
   b. Multicenter research protocol
   c. Sponsor protocol (and the Investigator's Brochure if available)
   d. Consent form

B. **Data and Safety Monitoring Plans**

1. Refer to Data Safety and Monitoring in Research

C. **Assignment of Primary and Secondary Reviewers**

1. BayCare IRB Office team members assign each protocol to IRB members who, as primary and secondary reviewers, review the protocol in detail and act as a liaison between the IRB and the PI.
2. Primary and secondary reviewers are assigned, as closely as possible, according to their expertise with the research being proposed and/or the subject population(s) being enrolled and their appropriate scientific or scholarly expertise to review the protocol.
3. The primary and secondary reviewers may contact the investigator, co-investigators, other IRB members, or outside sources as necessary to ensure a thorough evaluation of risks and benefits of the proposed research.
4. Members who have a conflict of interest with a protocol will recuse themselves from a review assignment.
5. If the BayCare IRB does not have the appropriate expertise to review the study for scientific or scholarly validity the IRB Chair, the Institutional Official, and the IRB Manager determine who in the BayCare System or community has the appropriate scientific expertise to serve as an expert consultant to perform an in-depth review of the study. Consultants disclose any Conflict of Interest (COI) prior to performing the review and those with a COI will not be used for protocol review

D. **Distribution of Submitted Materials to BayCare IRB Members**

1. Meeting documents are accessible to the BayCare IRB members 1 week prior to the scheduled meeting. The primary and secondary reviewers review all materials for their assigned protocol(s) Members who are not assigned as primary or secondary reviewers are expected to review at least the application, protocol and consent forms for research studies being considered at the meeting and may review all submitted materials, such as:
   a. Application form
   b. Full protocol
   c. Informed consent document
   d. Request to include vulnerable populations as subjects (pregnant women, fetuses, children, prisoners, cognitively impaired adults)
   e. Recruitment material(s)
   f. Copies of questionnaires, surveys, or similar instruments
   g. Data Safety Monitoring Board documentation
   h. Grant application
   i. Consent document or other template consent
   j. Sponsor protocol
   k. Investigator's brochure

E. **BayCare IRB Meeting Schedule**

1. The BayCare IRB is generally scheduled to meet on the third Tuesday of each month. Schedules may be adjusted as necessary to accommodate member schedules, semester breaks, and other factors that affect member availability.

F. **Presentation and Discussion of Protocols**

1. Protocols undergoing initial and continuing review at the convened meeting are presented individually to the BayCare IRB by the Primary and Secondary Reviewers.
2. BayCare IRB team members will assure members with appropriate scientific expertise, local knowledge, and other expertise specific to the protocols are present at the BayCare IRB meeting, along with at least one member who is knowledgeable about or experienced in working with vulnerable subjects, when research involving subjects who are vulnerable to coercion are reviewed.
3. If a member with the appropriate expertise, knowledge, or experience in cannot be present, a BayCare IRB team member notifies the IRB Chair to defer the review to another meeting or obtain a consultant, if needed, to provide a written report of their evaluation of the protocol.

4. To be properly presented and discussed, a quorum of the members, which includes a non-scientist, an unaffiliated member, and a prisoner representative (if research including prisoners is discussed) are required for the entire presentation, discussion, and deliberation. The BayCare IRB Office team member determines if a quorum of members is present and informs the Chair when quorum is met. Members not present for a substantial part of the discussion and deliberations abstain from voting. The presence of a quorum of members is documented in the meeting minutes. For those protocols undergoing initial review, the following are discussed in detail (list is not all-inclusive):
    a. The regulatory criteria for approval at 45 CFR 46.111 or 21 CFR 56.111 are met.
    b. The setting in which the research occurs, i.e., investigators have adequate time, staff and facilities to safely conduct and complete the research.
    c. The scientific and ethical justification for including vulnerable populations (children, prisoners, pregnant women, fetuses, cognitively impaired adults), if applicable.
    d. Analysis of the procedures to minimize risk that includes PI access to a population that allows recruitment of the necessary number of participants and the availability of medical or psychosocial resources that participants might need as a consequence of the research.
    e. The procedures to be used to ensure protection of subject privacy and data confidentiality.
    f. The scientific qualifications and experience of the investigators and their research staff.
    g. The human subject's protection training of the investigators and their research staff.
    h. Potential or disclosed investigator conflict of interest.

    If applicable:
    a. The scientific and ethical justification for excluding classes of persons from the research.
    b. Written consultant reports. (If the protocol was reviewed by a consultant, the consultant will not be present for deliberation and the voting on the protocol.

G. **Criteria for IRB Approval of Research**
1. To approve research, the BayCare IRB provides ethical and scientific review of all human subjects research to determine that all of the requirements of 45 CFR 46.111 Criteria for IRB approval of research are satisfied.
2. To verify that all regulatory requirements for review have been met, reviewer checklists are utilized. Additionally, an IRB Guide containing a list of the requirements and reminders for other required determinations is distributed to each member at the IRB meetings.

H. **Length of Approval Period**
1. The BayCare IRB determines the interval for the continuing review of the research, based upon the degree of risks that will be experienced by subjects. The interval for continuing review is at least once per year (not to exceed 365 days; 366 days during a leap year) for studies requiring a continuing review but may be shorter.
2. An IRB approval of the study protocols that have not undergone continuing review expire at midnight on the expiration date. Research activities cease after midnight of the expiration date.
3. The following but not limited to conditions may require review more often than annually:
    a. A high degree of risk to subjects
    b. Many of the proposed research procedure risks were unknown when the initial IRB approval was issued
    c. Confirmed instances of serious or continuing noncompliance
    d. An IRB member believes more frequent review is required

I. **Scientific/Scholarly Review**
1. As stated in BC-IRB-402 Clinical Research Team Roles and Responsibilities, the BayCare IRB relies upon the Clinical Trials Office (CTO) for sponsored research to assure that submissions contain appropriate information to facilitate an IRB review. The IRB to which it is submitted is ultimately responsible for the scientific/scholarly and ethical review of the research.