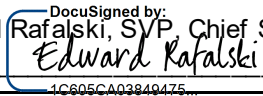




POLICY & PROCEDURE

Title: <p style="text-align: center;">BAYCARE IRB INITIAL APPROVAL OF RESEARCH</p>	Policy Number: BC-IRB-401 Page: 1 of 3
SPONSORED BY: Sponsored Programs and Research Committee	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
Original Issue Date: <u>1/2022</u> Review Dates: Revision Date:	
Approved by: Ed Rafalski, SVP, Chief Strategy & Marketing Officer Signature: 	

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).

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.