BayCare

POLICY & PROCEDURE

Title: **CLINICAL RESEARCH TEAM ROLES AND RESPONSIBILITIES**	**Policy Number:** BC-IRB-402 **Page:** 1 of 2
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
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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 **CLINICAL RESEARCH TEAM ROLES AND RESPONSIBILITIES** 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

PURPOSE:

To describe the responsibilities of IRB members, Clinical Trial Office (CTO), and Clinical Research Staff, and guidelines for conducting submission and a thorough review of items, including new applications, modifications, continuing reviews, and reportable events.

PROCEDURE:

A. Principal Investigators (PI) Responsibilities include but are not limited to:
   1. Verification that all personnel listed on the research protocol have completed the human subjects research training.
   2. Verification that covered individuals listed as research personnel on non-exempt protocols have submitted a Financial Interest Disclosure.
   3. Submit protocols for IRB review and approval of proposed research activities prior to commencing the research activities.
   4. Employ sound study design in accordance with standards of the PI's discipline.
   5. Determine that adequate time and resources are available before conducting a research study. Maintain oversight of each research study, research staff, and delegated research responsibilities and functions.
   6. Verify that the research is conducted according to the protocol, any signed agreements, in compliance with all applicable laws and regulations and organizational policies and procedures with the highest of ethical standards.
   7. Submit for review and approval proposed protocol and consent form changes prior to implementing the changes in the protocol except where necessary to eliminate immediate hazards to human subjects.
   8. Obtain informed consent from subjects prior to commencement of research activities unless the requirement is waived by the IRB.
   9. Uphold and protect the rights, safety, and welfare of the research subjects.
   10. Follow reporting requirements for problems that require prompt reporting.
   11. Submit requested data at specified times for continuing review of ongoing research activities.
   12. Upon completion of a study, honor all commitments that were agreed to as part of the approved research, e.g., providing information about the study results to research subjects or honoring commitments for reimbursements to subjects.
   13. Upon completion of a study, submit a Closure Report to the IRB.
   14. Disclose conflicts of interest.

15. Retain records as required by the regulations, the sponsoring entity and local policy for the designated time period.
16. When PI is the lead researcher for a multi-site study, applications include information about the management of information that is relevant to the protection of research participants: interim results; protocol modifications; management of unanticipated problems involving risks to participants or other unanticipated problems ; communication of unanticipated problems to all sites ;management of protocol modifications adherence to formal agreements delineating each site's roles and responsibilities.
17. If you hold an IND/IDE, adhere to sponsor responsibilities in addition to investigator responsibilities.
18. Verify that applicable clinical trials and National Institutes of Health (NIH) sponsored clinical trials are registered on the governmental database at ClinicalTrials.gov.
19. Address research participant's concerns, complaints, or requests for information.

Members of the International Committee of Medical Journal Editors (ICMJE) consider the results of clinical research for publication only if the trial has been registered prior to enrollment of the first subject. ICMJE defines a clinical trial as: "Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and health outcome." …This definition includes drugs, surgical procedures, devices, behavioral treatments, process-of-care changes and the like." ICMJE further defines "medical intervention" as "any intervention used to modify a health outcome."

B. Faculty Sponsors (if applicable to BayCare) Responsibilities include but are not limited to:
   1. The responsibilities for a Faculty Sponsor (FS) are equivalent to those for a principal investigator.
   2. Actively involved in the research, from protocol design to data analysis and report preparation. In many cases, it may be the student's first experience with formal research. The success of the student's experience will be measured not only in the outcome of their projects, but also in what they learn from the faculty sponsor. These experiences will help form their perception of scientific research, and in some cases, determine whether a career in academic research is right for them. Advise the student on the selection of a topic, the content and preparation of their research proposal. Understand the research hypothesis, goals, and methodology.
   3. Guide and interact with the student throughout the research project.
   4. Assist the student with application preparation. Complete and sign forms as required.
   5. Verify that the student obtains all necessary approvals (i.e., IRB) before initiating the project, implementing any changes in the research activities.
   6. Serve as the IRB of record for the student when the research meets the criteria for exemption from the regulations or for any ongoing research when the student leaves the institution prior to completing the research protocol.
   7. Provides the student with information on BayCare policies relating to administration of their protocol.
   8. Determine that the student understands the underlying ethical principles for conducting research with human subjects and the applicable research regulations and local policies and procedures.
   9. Maintain on-going status of the protocol and compliance with federal regulations and institutional policies and procedures relating to human subject's research and IRB required reporting.
   10. Advise and assist students with the preparation of poster presentations and papers, as applicable.
   11. Verify that all study documents and data are archived at the end of the study in accordance with federal, state and local policy and regulations.
   12. Be available to the student during the active research period.

C. Clinical Trial Office (CTO)
   1. Serves as the centralized business office for sponsored research conducted at BayCare Health System.
   2. Provides efficient, compliant, professional end-to-end clinical trial lifecycle support to key stakeholders from within and partnered with BayCare Health System.
   3. Serves as the liaison between those participating in sponsored research and the BayCare IRB.
   4. Supports contract negotiations, contract administration and regulatory compliance in one business office to maintain complete and accurate information on sponsored research activity.
   5. Develops, communicates, and enforces the BayCare IRB standard policies and procedures.