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BayCare

POLICY & PROCEDURE

Title: **BAYCARE IRB COMPOSITION, ROLES AND RESPONSIBILITIES**	**Policy Number:** BC-IRB-400 **Page:** 1 of 5
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 COMPOSTION, 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 composition and responsibilities of BayCare Institutional Review Board (IRB) members and the procedure for reviewing items, including new applications, modifications, continuing reviews, and reportable events when the BayCare IRB is the IRB of Record.

PROCEDURE:

A. BayCare IRB Composition:
   1. has at least five members with varying backgrounds to promote complete and adequate review of research commonly conducted by the organization
   2. is comprised of both male and female members
   3. is comprised of members representing multiple professions
   4. has at least one member specializing in scientific areas
   5. has at least one member specializing in nonscientific area
   6. has at least one member who is not otherwise affiliated with the organization and not part of the immediate family of a person who is affiliated with the organization
   7. has at least one member representing the perspective of research participants

B. **Responsibilities of BayCare IRB Members**
   1. IRB members' primary responsibility is the protection of the rights and welfare of the individual human beings who are serving as the subjects of research.
   2. Members are versed in regulations governing human subject protection, biomedical and behavioral research ethics, and BayCare policies and procedures.

C. **Selection and Appointment of Members and Alternate Members:**
   1. **Board Members**
      a. The Chair, Director for Sponsored Programs and Research, and the IRB/HRPP Manager select members. The process is conducted in consultation with the Institutional Official, Department Chairs, and other IRB members.

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b. The Institutional Official appoints the IRB members. IRB members receive an appointment letter after their appointment is confirmed. The letter states the term of service. IRB members serve 3-year renewable terms. There are no term limits.
c. Members may resign at any time by submitting a letter of resignation to the IRB Chair and the IRB Manager.
d. The IRB Chair may remove members from the committee who are no longer able to complete his/her term.

D. **IRB Chair and Vice-Chair**

1. The Institutional Official, the Director for Sponsored Programs and Research, and the IRB Manager select an IRB Chair, Vice Chair, and other IRB members.
2. The Institutional Official appoints the IRB Chair and Vice-Chair who receive an appointment letter after appointment confirmation. There are no term limits for serving as Chair or Vice-Chair.
3. The IRB Chair or Vice-Chair may resign at any time by submitting a letter of resignation to the Institutional Official. The Institutional Official removes the IRB Chair or Vice-Chair if he/she is unable to complete his/her responsibilities.

E. **Institutional Official (IO)**

1. The IO is designated by the BayCare Chief Medical Officer to have responsibility for the Human Research Protection Program (HRPP) with the authority to delegate activities necessary to fulfill the following:
    a. Compliance with institutional policies and applicable regulations for the protection of human research subjects.
    b. Authorized to represent the institution in matters regarding human subject's research and is the signatory authority for the Federal-Wide Assurance to the Office for Human Research Protections.
    c. Review and evaluation of reports on HRPP performance and quality improvement activities.
    d. Reviews copies of all BayCare IRB meeting minutes, containing reports of IRB board member deliberations on human subject's protocols, the results of QI audits, and noncompliance findings.
    e. Signs correspondence and reports sent to federal regulatory agencies.
    f. Ensures protocol assignment to the appropriate IRB to act as IRB of Record following the requirements set forth under the Common Rule and by BayCare policy, including assuring the BayCare IRB adheres to the responsibilities and requirements in its role as either a reviewing or as a relying IRB.
    g. Neither the IO nor any other BayCare official can approve research that was disapproved by the IRB of Record to which the study was submitted.

F. **BayCare IRB Responsibilities:**

1. Include but are not limited to:
    a. Review of initial protocol submissions, continuing reviews and revisions to protocols of human subject's research.
    b. Approve, require modifications to secure approval, defer (table), or disapprove research activities, regardless of location of the research activities.
    c. Systematically analyze protocols for benefits to subjects, the knowledge expected to be gained, and potential benefits in relation to the potential risks involved in the research.
    d. Report in writing the findings and actions of the IRB to the PIs, IO, and, when applicable, to federal regulatory agencies or departments,
    e. Determine the interval ongoing studies need to be reviewed by the IRB, at a minimum of annually.
    f. Determine which studies need verification from sources other than the researchers that no material changes have occurred since the previous IRB review.
    g. Observe, or have a third party observe, consent processes and/or the conduct of research.
    h. Verify prompt reporting of changes in research activities to the IRB by researchers.
    i. Verify prompt reporting, by PIs, to the IRB and/or federal agencies or departments (where applicable) of:
        1. Unanticipated problems involving risks to subjects or others.
        2. Serious or continuing noncompliance with regulations.
        3. Suspension or termination of IRB approval.
2. Determine if studies involving drugs need an investigational new drug (IND) number designated by the FDA.
3. Determine if studies involving investigational devices pose significant or non-significant risk and whether an IDE is required.
4. Suspend or terminate approval of research not being conducted in accordance with IRB requirements or that is associated with unexpected serious harm to subjects.
5. If applicable, act as the Privacy Board for research involving use of PHI.

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G. **BayCare IRB Chair and Co-Chair(s) Responsibilities:**
1. Include but not limited to:
    a. Serve as public spokesperson for the BayCare IRB.
    b. Chair convened meetings of the BayCare IRB.
    c. Maintain expertise for review and determinations.
    d. Verify quorum for meetings.
    e. Review protocols, continuing review reports, unanticipated problem and deviation reports, and other documentation submitted to the BayCare IRB.
    f. Obtain an individual vote on all BayCare IRB actions (In Favor, Against, Abstain, Excused, Recused).
    g. Delegate review responsibilities as indicated.
    h. Maintain current knowledge of human subject regulations and pertinent events.
    i. Consult with investigators as necessary.
    j. Suspend the conduct of research when individuals are placed at an unacceptable level of risk.
    k. Collaborate with the IRB administrative team members to provide continuing education for IRB members.
    l. Collaborate with the IRB Manager to resolve issues with faculty or subjects.
    m. Recognize and support partnership with IRB administrative team members to maintain IRB efficiency and effectiveness.

H. **BayCare IRB Members Responsibilities**
1. Include but not limited to:
    a. Knowledgeable regarding IRB policies and procedures and federal, state, and local regulations policies and guidelines relating to human subject's research.
    b. Review submitted proposals as assigned by the IRB administrative team members and IRB Manager
    c. Review meeting documents in advance of meetings and be prepared to discuss submitted protocols.
    d. Act as a primary or secondary reviewer of protocols when assigned.
    e. Maintain confidentiality of BayCare IRB proceedings.
    f. Disclose conflicts of interest, if applicable.
    g. Attend a minimum of 75% of scheduled meetings.
    h. Maintain current human subjects training.
    i. Actively engage in continuing education related to human subject research.

I. **Assigned Reviewers Responsibilities:**
1. For each research protocol submission to be considered by a convened IRB, assigned reviewers are selected from the regular or alternate members. Assigned reviewers may be designated as primary reviewers and/or secondary reviewers.
2. The primary reviewer:
    a. Conducts a comprehensive review of all submitted materials
    b. Presents findings resulting from that review, provides an assessment of the criteria for approval, and recommends specific actions to the IRB.
    c. Leads the discussion of the assigned item.
3. A secondary reviewer is assigned to new applications and to selected continuing reviews and modifications. Secondary reviewers also conduct comprehensive reviews to supplement those provided by the primary reviewer, focusing on areas or issues not otherwise addressed. The secondary reviewer may serve as the discussion leader in the unexpected absence of the primary reviewer.
4. Assigned reviewers are authorized and expected to contact the IRB administrative staff to resolve questions or concerns whenever possible prior to the IRB meeting. Assigned reviewers use the IRB Reviewer Checklists and/or Reviewer Worksheets to assist in organizing and documenting reviews for presentation to committee members. Assigned reviewers document reviews in the IRB electronic system at least 48 hours prior to the IRB meeting, to provide members time to read the reviewer findings and recommendations, to be familiar with any issues, to contribute to the discussion, and to prepare to vote.

J. **Pre-Meeting Distribution and Review of Documents in Advance of the Convened Meeting**
1. Meeting agendas, including reviewer assignments and access to review materials, are distributed electronically to members at least 1 week prior to the scheduled meeting date. The IRB electronic system provides all BayCare IRB members and alternates access to the complete IRB record for each item under review, including the initial application, modifications, continuing reviews, reportable events, related reviewer notes, supporting materials, and the IRB minute history.

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K. **New Applications**

1. Initial review materials available to the primary and additional assigned reviewers via the IRB electronic system include, when applicable, but are not limited to:
    a. IRB electronic application form
    b. Complete study protocol
    c. Proposed consent, assent, or HIPAA documents
    d. Proposed consent or assent scripts for remote consent process
    e. Recruitment materials including any advertisements intended to be seen/heard by potential subjects
    f. Participants contact materials
    g. Relevant grant application(s) and/or budget information
    h. Investigator's brochure, other study product information, or certificate of analysis
    i. Disclosures of Financial Interest and related letters of determination from the Conflict of Interest (COI) Review Board
    j. Certificate of Confidentiality if applicable
    k. Reviews by relevant Department/Division or Institutional committees
2. Assigned reviewers perform a comprehensive review of each assigned item and make recommendations for consideration by the IRB. The reviewers assess whether:
    a. The proposed activity is research involving human subjects (45 CFR 46.102).
    b. The ethical principles of research with human subjects are upheld
    c. All criteria at 45 CFR 46.111 (Criteria for Approval of Research) and 21 CFR 56.111 (as applicable) have been met
    d. The research includes enrollment of vulnerable subjects and if safeguards are in place
    e. The research involves use of an FDA-regulated product(s) and the regulatory status of the product(s)
    f. The consent process, as described by the investigator, is appropriate
    g. The consent document is understandable and contains basic and additional elements as appropriate
    h. The study requires data and safety monitoring to maintain subject safety The interval for continuing review of the research is appropriate.
    i. The research fulfills the criteria for referral for continuing review by expedited review procedures
    j. The research design and scientific merit are appropriate (often informed by departmental research scientific review recommendations)
    k. Conflict(s) of interest exist for any study team member(s) and, if present, provisions exist to protect human subjects from any additional significant risk and to maintain the integrity of the research
    l. Ad hoc expertise (i.e., use of a consultant) is needed to assist in the review of issues requiring expertise beyond or in addition to that available on the IRB
3. Members attending the convened IRB have access to the same new application materials via the IRB electronic system. When a member is not an assigned reviewer, the member is to review, at a minimum, the following materials to prepare for active participation in the discussions and the vote:
    a. The full protocol, application, or a summary of research activities to make the determination required under federal regulations.
    b. Proposed consent, assent, or HIPAA documents
    c. Proposed consent or assent scripts
    d. Any recruitment materials, including advertisements intended to be seen or heard by potential subjects

L. **Modifications to Previously Approved Research**

1. For convened IRB review of modifications to previously approved research:
    a. All members including alternates in attendance have access to and review the revised materials through the IRB electronic system.
    b. Assigned reviewers are selected from the regular or alternate members scheduled to attend the specific convened IRB meeting.
    c. Each assigned reviewer conducts a review of the request for modifications in accordance with the criteria for approval and assesses whether the proposed modifications are consistent with continued protection of subjects.
2. In addition, assigned reviewers consider whether:
    a. Any new significant findings have arisen that may impact the subject's willingness to continue participation.
    b. Any new information resulting from the modification or from other sources necessitates an adjustment to the IRB's prior determination(s), such as inclusion of protected or vulnerable populations and findings regarding FDA-regulated products.

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c. The proposed modifications to the research require revision of the consent document(s), and if so, whether the revised consent documents are accurate and understandable to the subject population.
d. The modifications warrant re-consenting of currently enrolled subjects or notification of subjects who have completed research interventions.
e. More frequent Continuing reviews are required than previously determined.

3. Assigned reviewers present findings and recommendations during the convened IRB meeting. See Modifications to Previously Approved or Exempt Research for additional information.

M. **Continuing Review**

1. For continuing review of research by a convened IRB:
    a. All members including alternates in attendance have access to and review the:
        1. Full protocol, application, or a protocol summary containing the relevant information to determine whether the proposed research continues to fulfill the criteria for approval
        2. Current consent document(s) (as applicable), and
        3. A status report of the progress of the research (i.e., the investigator's continuing review application).
    b. Assigned reviewers are selected from the regular or alternate members scheduled to attend the specific convened IRB meeting. Each assigned reviewer conducts a comprehensive review of the ongoing research and status report, including the:
        1. Full protocol
        2. Current consent document(s) (as applicable)
        3. Modifications previously approved by the IRB and any occurring since the last IRB review, and
        4. Progress and findings to date as reported in the investigator's continuing review application.
    c. At a minimum, assigned reviewers assess:
        1. Whether the research continues to meet the criteria for approval,
        2. If any new information resulting from the specific research under review or from other sources necessitates an adjustment to the IRB's earlier determination(s), and
        3. The appropriate interval for continuing review.
    d. Assigned reviewers present findings and recommendations during the convened IRB meeting.
    e. See Continuing Review of Research Projects for additional information.
    f. NOTE: Revisions to research study protocol, consent form(s), or any other study materials proposed by the investigator at the time of continuing review, is submitted as a separate request for modification via the IRB electronic system. The IRB coordinates the review of the request for modification with the investigator's continuing review application, such that the items are considered by the same convened IRB during a single meeting.

N. **Guidelines for Reviewer Presentations of Initial Submission, Continuing Review, Modifications to Currently Approved Project, and Serious Adverse Events at Convened IRB Meetings.**

1. Oral presentations conducted by the primary reviewer include:
    a. A succinct summary of the research study
    b. An overview of the population of subjects being studied, including protocol specific findings pertaining to adequacy of protections for any vulnerable subjects
    c. As applicable, a description of the FDA-regulated product(s) under study and the regulatory status of the product(s), including recommendations for significant/non-significant risk device determinations
    d. A recommendation regarding whether or not the criteria for approval of research are met
    e. Background to justify the performance of the research information for the members to make an informed decision on the approvability of the research
    f. A critique that includes deficiencies or criticisms of the application
    g. Comments regarding the consent process and the content of the consent document
    h. Detailed information regarding needed changes by the investigator enabling other members and support staff to understand what is needed in meeting minutes and notifications to the investigator
    i. Additional reviewers focus on areas of disagreement with the previous reviewer(s) or on additional findings not previously covered.
    j. A motion for a determination on the item.