BayCare

POLICY & PROCEDURE

Title:	**LEGACY Policy Number:** BC-IRB-406
INSTITUTIONAL REVIEW BOARD PRINCIPLES, AUTHORITY AND COMMITMENT	**Page:** 1 of 5
SPONSORED BY: Sponsored Programs and Research Committee	**Issued for:** All BayCare, including without limitation: Bartow Regional Medical Center BayCare Alliant Hospital BayCare Wesley Chapel Hospital 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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Approved by: Ed Rafalski, SVP, Chief Strategy & Marketing Officer **Signature:** DocuSigned by: Edward Rafalski 1C605CA03849475...	

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 **INSTITUTIONAL REVIEW BOARD PRINCIPLES, ATUTHORITY AND COMMITMENT** 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 BayCare Health System's governing principles, commitment to protecting human research subjects, the appointment of Institutional Review Board (IRB) Committees, the authority and independence of the BayCare (IRB), and activities subject to IRB jurisdiction.

PROCEDURE:

A. Principles Governing the BayCare Institutional Review Board (IRB)

The BayCare Institutional Review Board (IRB) and Human Research Protection Program (HRPP) are guided by the ethical principles set forth in the *Belmont Report* regarding Human Subjects Research. All institutional and non-institutional Research performance sites conducting research within BayCare Health System will be obligated by BayCare Health System to conform to ethical principles which are at least equivalent to those of BayCare Health System.

B. Principles Considered by the BayCare IRB in Reviewing Research

1. To review and make decisions on protocols for all Human Subjects Research.
2. To protect Human Subjects from undue risk and from deprivation of personal rights and dignity.
3. Protection is derived by consideration of the following:
   - ✓ **Respect for Persons**: That voluntary participation by the Human Subjects is assured as indicated by free and informed consent,
   - ✓ **Beneficence**: That an appropriate balance exists between the potential benefits of the Research to the Human Subject or to society and the risks assumed by the Human Subject; and
   - ✓ **Justice**: That there are fair procedures and outcomes in the selection of Research subjects.

C. Implementation of Principles by the BayCare IRB in its Review of Research

1. **Respect for Persons**:
   a. Conduct a careful review of the recruitment and consent process and of the consent form or information sheet to be used with Human Subjects, to ensure a voluntary informed consent process is included.

b. Whether the study is designed for a Subject's own direct benefit or for the general advancement of scientific knowledge, confirm the consent language clearly outlines what is to be done and what the potential risks and benefits are.
c. Verify the process describes the ability for interested persons to give their consent freely without pressure or inappropriate inducement.
d. The informed consent is extended to those studies in which the subjects are not able to give personal consent for themselves. In these instances, ensure the consent document and process is addressed to those legally responsible for the Human Subject's wellbeing (e.g., parents of Children) to assist these persons to make an informed decision, which is in the best interest of the Human Subject.
e. Consider the nature and capacity of the study population for truly informed and voluntary participation in Research. At one extreme, there may be ample understanding and manifest freedom from coercion; at the other, there may be degrees of understanding and freedom that affect the consent of potential subjects.
f. Exercise care when considering subjects whose ability to give free and informed consent may be compromised in any way and ensure that additional safeguards are included as appropriate.

2. **Beneficence:**
   a. Examine the risk-benefit ratio of the research under review and decide whether the risk to subjects are reasonable in relation to anticipated benefits, if any, to subject and the importance of the knowledge that may reasonably be expected to result. Give consideration to the following factors:
      1) risks of injury or discomfort to the individual that can be physical; psychological and/or social; and
      2) potential benefits to the individual, a group to which the individual belongs and/or to society.
   b. In reviewing Research protocols, assess the types and degrees of both risks and benefits for a given subject population, as well as the investigator's communication of these risks and benefits in the consent process and form.
   c. While the BayCare IRB is not charged with reviewing the scientific design of Research, it may do so when assessing the risk/ benefit ratio. If a study's design does not seem adequate to attain the stated aim of the study, then no benefit can be anticipated from conducting the study, and there is no justification for placing any Human Subject at risk, however minimal.

3. **Justice:**
   a. Verify that the Research involves a fair selection of Human Subjects by:
      1) sharing of Research risks and
      2) sharing of Research benefits.
   b. Both the risks and potential benefits of Research are spread fairly among potential individual Research subjects and Research subject groups.
   c. Study design and selection of subjects are not avoid biased for or against particular social, racial, sexual, or ethnic groups.

4. *Sharing Research Risks*:
   a. Ethical selection of Research subject groups requires that any risks of the Research should fall upon the groups who might benefit from the Research. If the results of a risky protocol might benefit the general population, it would be unethical to focus subject recruitment on vulnerable or disadvantaged groups (e.g., institutionalized people or Prisoners; or patients at free clinics primarily patronized by people unable to afford other medical care) simply because they are easily accessible or can be persuaded to participate.
   b. Prevent an undue share of Research risks to groups already burdened by other factors and by including a fair sampling of the populations who might benefit from the study.
   c. When Research involves persons whose autonomy is compromised, check and confirm that the Research bears some direct relationship to the conditions or circumstances of the Research subject population.
   d. Verify all groups are fully able to consider Research risks and informed consent and those whose autonomy is not compromised are asked to face Research risks before more Vulnerable Populations. For example, Investigational Drugs are usually tested in Adults before they are tested in Children. Certain Investigational Drugs and procedures may be tested in healthy volunteers before being tested in patients.

5. *Sharing Research Benefits*:
   a. Consider the desires of various groups to be included in Research including:
      1) Members of other social, racial, sexual and ethnic groups.
      2) Women (especially those of child-bearing age) are asked to make their own choices regarding participation after being fully informed of the risks of the Research.
      3) A study design convering a broad a range of Research subjects where feasible, and
      4) The data analysis plan will uncover responses that differ between groups, where feasible.

Ethical principles from other sources may also be applied to research covered by the HRPP, for example:

- To an individual protocol because its particular circumstances raise a type of ethical issue that most other protocols do not
- When they are recognized by the federal or other funding source or the state or country where the research will occur
- When they have been developed for specific areas or types of subjects (e.g., embryos and fetal tissue, illiterate subjects)

When Sponsor terms and conditions require the application of another set of ethical principles, the BayCare office reviewing the contract attempts to remove the requirement, and if the terms and conditions remain, that office will alert the IRB.

D. Institutional Authority

The Chief Executive Officer (CEO) has designated the Chief Medical Officer (CMO) of BayCare Health System the power and authority to appoint the individual within the Health System to serve as the Institutional Official (IO) responsible for carrying out BayCare's Human Research Protections Program (HRPP). The person designated as Institutional Official must meet the qualifications set forth below.

E. Appointment of the Institutional Official (IO)

The CMO of BayCare Health System shall appoint the IO in writing. As of the effective date of these P&Ps, the CMO of BayCare Health System has appointed the person named in Appendix 1 to serve as the IO. Appendix 1 is updated as necessary to reflect any changes in this appointment.

The IO holds ultimate responsibility for:

1. Oversight of the BayCare Institutional Review Board (IRB)
2. All BayCare Health System investigators
3. Assuring the BayCare IRB members are appropriately knowledgeable in accordance with ethical standards and applicable regulations
4. Determining the investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations
5. Development and implementation of an educational plan for BayCare IRB members, team members, and investigators.

Qualifications of the IO: In order to be eligible for appointment as the IO, an individual must be an employee of BayCare Health System who holds a position within the System per which they have the legal authority to act and speak for BayCare Health System as a whole, and per which they can ensure that BayCare IRB will effectively fulfill its Research oversight functions.

Term of Appointment of the IO: The IO shall serve in this position until the earlier of the date on which:

- The IO leaves BayCare Health System;
- The IO no longer has the ability or capacity to fulfill the role of IO;
- At the CMO's discretion, requests the IO's resignation and appoints a new IO; or
- Until IO tenders a resignation from the position and the CMO appoints a new IO.

The IO's resignation is required at any time the CMO determines the IO does not meet the qualifications for this position.

F. Designation and Authority of Institutional Review Boards (IRBs) Designation of BayCare IRB:

The CMO of BayCare Health System has designated the BayCare IRB as the body within BayCare Health System that has jurisdiction over all Human Subjects Research conducted under the auspices of BayCare Health System, as described below entitled Human Subjects Research Subject to IRB Authority. The BayCare IRB discharges its duty to external IRBs where BayCare Health System has chosen to rely under

an executed reliance agreement, by complying with the requirements of the Common Rule, state regulations, the Federal-wide Assurance FWA, and BayCare policies.

Human Subjects Research Subject to IRB Authority: The Human Subjects Research under the auspices of BayCare Health System that is subject to the authority of the IRB includes:

- Human Subjects Research conducted at the system;
- Human Subjects Research conducted by or under the direction of any employee or agent of the system in connection with their institutional responsibility;
- Human Subjects Research conducted by students at the system in connection with their institutional responsibilities;
- Human Subjects Research conducted by or under the direction of any employee or agent of BayCare Health System using any property or facility of system or involving system non-public information to identify or contact Human Subjects.

Collaborative Research Projects: In the conduct of collaborative research projects, BayCare Health System acknowledges that each institution is responsible for safeguarding the rights and welfare of research participants and for complying with pertinent federal regulations and institutional policies. BayCare Health System may enter into a joint review arrangement or rely on the review of another IRB, ethics committee, or any institution with a Federalwide Assurance (FWA).

If BayCare Health System participates in a multi-site study involving non-exempt human subjects research funded by the National Institutes of Health (NIH) via a grant or contract submitted to the NIH on or after January 25, 2018, then following suit with the NIH single IRB (sIRB) policy, BayCare Health System requires the use of a single IRB to accomplish IRB review and approval for all domestic sites.

The BayCare IRB, and any IRB designated by BayCare Health System under an executed IRB Reliance Agreement to review research, have the authority to:

a. Approve, require modification to secure approval, or disapprove all human subjects research activities overseen and conducted by BayCare Health System.
b. Make determinations as outlined in BayCare policy and under procedures set forth by the BayCare IRB/ HRPP Office regarding whether proposed research projects meet criteria for exemption.
c. Suspend or terminate the approval of research which is found to be noncompliant with the IRB's requirements or research associated with unexpected and/or serious harm to participants.
d. Observe the consent process and/or the conduct of the research.
e. Require and conduct continuing review of the research.

BayCare Health System team members, including the IO, may not approve the conduct of human subject research if it has been disapproved by an IRB authorized under this policy, including external IRBs where BayCare has entered into a reliance agreement with such an IRB.

G. Federal-wide Assurance (FWA)

BayCare Health System holds a Federal-wide Assurance (FWA) #6065, approved by the Office for Human Research Protections (OHRP). The terms of the FWA apply whenever BayCare becomes engaged in Human Subjects Research that is conducted or supported by any U.S. department or agency that has adopted the requirements set forth by federal statue known as the "Common Rule") unless the Research is otherwise exempt from the Common Rule requirements or the federal department or agency conducting or supporting the Research determines that the Research be conducted under a separate assurance. All activities of the BayCare IRB regarding any Human Subjects Research that is covered by the Common Rule, as set forth above, are governed by and subject to the terms and conditions of the FWA. With regard to Human Subjects Research that is not conducted or supported by any U.S. department or agency that has adopted the Common Rule, BayCare applies the standards and requirements of its internal Human Research Protections Program.

BayCare's Execution of the FWA: The BayCare FWA, and any modifications or amendments thereto, shall be executed by the IO or designee.

BayCare's Agreement to Terms of FWA: BayCare, including the BayCare IRB, is subject to and agrees to:

1. Abide by the Terms of Assurance required by the OHRP.
2. To provide oversight to Human Subjects Research conducted or supported by a U.S. department or agency that has adopted the Common Rule that is carried out under its jurisdiction
3. Provide this oversight in accordance with the terms and conditions of the BayCare FWA.

BayCare-Related Components Covered by the BayCare FWA: The IO must grant approval to any additions or withdrawals of the components covered by the BayCare FWA. The IRB manager is responsible for filing any necessary documentation with the Office of Human Research Protections (OHRP) for the addition/ withdrawal of a component from the BayCare FWA.

Other Institutions that Rely on the BayCare FWA: Per agreement with BayCare Health System, all institutions that rely on the BayCare FWA are subject to the terms thereof and to these Policies and Procedures.

BayCare FWA Renewal:

1. Every thirty-six months, even if no changes have occurred, in order to maintain an active OHRP-approved FWA.
2. Ensuring that the BayCare FWA is renewed in a timely fashion and is not permitted to expire.
3. Keep a copy of the complete current BayCare FWA in the BayCare IRB offices.