BayCare

POLICY & PROCEDURE

Title: **IRB PROCESS FOR CONTINUING REVIEW**	**Policy Number:** BC-IRB-404 **Page:** 1 of 4
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 **IRB PROCESS FOR CONTINUING REVIEW** 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:

BayCare's Office for Human Research Protection - Institutional Review Board (IRB) - requires that human subject research activities be reviewed in accordance with federal regulations and at intervals appropriate to the degree of risk.

PROCEDURE:

A. Conduct of Continuing Review

1. The approval criteria for continuing review are the same as the criteria for approval at initial review and are described in the Institutional Review Board (IRB) policy: *IRB Initial Approval of Research (BC-IRB-401*)
2. The IRB determines the interval for continuing review of research as described in IRB document: *IRB Initial Approval of Research (BC-IRB-401)*.
3. Research activities initially approved by the convened IRB are reviewed by a convened IRB at continuation unless:
   a. The IRB determines and documents at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified, OR
   b. One of the following criteria are met at the location(s) approved under the investigator's application:
      i. The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
      ii. No subjects have ever been enrolled at the location(s) approved under the application and no additional risks have been identified from any institution engaged in the research or from any other relevant source; or
      iii. The remaining research activities are limited to data analysis. Research activities originally approved using expedited review may receive continuing review using expedited review procedures unless the research activities no longer meet the criteria for expedited review.

B. Investigator Responsibilities

1. The following continuing review documents are provided to all IRB members, including alternate members, if attending, and consultants for review by or on behalf of the Principal Investigator:
   a. IRB Continuing Review Application (Status report) containing the following information:
      i. The number of participants accrued

ii. Adverse events and outcomes experienced by participants
iii. Unanticipated problems involving risks to participants and others
iv. Participant withdrawals and reasons for withdrawal
v. Complaints about the research
vi. Amendments or modifications
vii. Any relevant recent literature
viii. Any interim findings
ix. Any relevant multi-center trial reports, if applicable

b. The researcher's current risk-potential benefit assessment based on study results
c. Research protocol
d. Informed consent/ assent form
e. Data and Safety Monitoring Plan (if applicable)

C. IRB Presentation and Discussion of Protocols at the Convened Meeting

1. Protocols undergoing continuing review are presented individually to the IRB by the assigned Primary and Secondary Reviewers. IRB staff verify that Primary and Secondary Reviewers stay the same throughout the lifecycle of the project.

2. If one or both Reviewers are no longer available, the project is re-assigned to the Board Chair for the remainder of the project's lifecycle. Presentation, discussion, and deliberation require a quorum of the members. Members not present (excused) for a substantial part of the discussion and deliberations abstain from voting.

3. The IRB:
   a. Reviews and determines whether the research continues to meet the criteria for approval of research (45 CFR.46.111 and 21 CFR 56.111). The IRB determines that:
      i. Risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits.
      ii. Selection of subjects continues to be equitable.
      iii. Informed consent (as applicable) continues to be obtained and documented.
      iv. Adequate provisions for monitoring the data collected to maintain the safety of the subjects when appropriate.
      v. Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate.
      vi. Safeguards for vulnerable populations are provided.
   b. Determines 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).
   c. Determines the appropriate interval for continuing review.
   d. Reviews (as applicable) the IRB-approved consent/ assent document(s) attached to the continuing review report. Any significant new information that may relate to the subject's willingness to continue participation is provided to the subject using updated document(s) or other mechanisms the IRB determines to be appropriate.

4. When conducting continuing review of a research project, the IRB, at its discretion, may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available to the IRB. The input of such expert consultants may be provided through:
   a. submission of written reports to the IRB prior to the IRB meeting at which a research project for which consultation was sought is to be reviewed and/or
   b. the attendance and participation (either in person or by telephone or videoconference) of the expert consultants in the deliberations at the IRB meeting.

5. These individuals may not vote with the IRB (45 CFR 46.107(f)), and their attendance at an IRB meeting must be documented in the minutes of the IRB meeting if they attend the meeting (45 CFR 46.115(a)(2)). The minutes of the meeting will document the role any expert consultant played in the IRB's review.

6. *Oral* presentations conducted by the primary reviewer with the assistance of the secondary reviewer should include:
   a. The primary reviewer provides a brief synopsis of the research:
      i. The number of participants accrued.
      ii. Adverse events and outcomes experienced by participants
      iii. Unanticipated problems involving risks to participants and others
      iv. Participant withdrawals and reasons for withdrawal.
      v. Complaints about the research.
      vi. Amendments or modifications.
      vii. Any relevant recent literature.

viii. Any interim findings.
ix. Any relevant multi-center trial reports, if applicable.

b. and a statement that:
i. No concerning issues have arisen since the prior IRB review and approval.
ii. Changes to the project are being proposed by the investigator.
iii. Adverse events in subjects have been of the type and frequency expected.
iv. The research appears to continue to satisfy criteria for approval under the regulations at 45 CFR 46.111 (and subparts B, C, and D, when applicable); and
v. The reviewer recommends approval as presented/ approval pending modifications/ tabling/ disapproving the project.

c. The IRB chairperson makes a request for discussion by the IRB members.
d. Following any discussion, the IRB chairperson calls for a motion on the project.
e. The primary reviewer makes a motion and another member seconds the motion.
f. The IRB chairperson calls for a vote on the motion to approve as presented/ approve pending modifications /table/ disapprove the project.

7. If the continuing review of a study for which the investigator reports the following:
a. The rate of serious adverse events occurring in subjects is significantly higher than expected.
b. A recently completed research project reported in the literature identified previously unrecognized risks for the same experimental intervention being tested in the clinical investigator undergoing continuing review.
c. The investigator is proposing several substantive revisions to the protocol in response to the new risk information, including the addition of new exclusion criteria and new safety monitoring procedures for subjects; and
d. The investigator is proposing substantive changes to the informed consent document to add a description of the new information regarding reasonably foreseeable risks

8. The IRB Board spends significantly more time at the convened meeting on its continuing review of the research as it carefully reassesses whether the risks to subjects still are minimized and reasonable in relation to the anticipated benefits, if any, to the subjects and the knowledge that is expected to result, given the new information presented by the investigator. The IRB Board will assess whether the changes to the protocol and informed consent document proposed by the investigator are appropriate and adequate to approve as presented, or whether additional changes are required.

D. Possible IRB Determinations

1. After presentation by the primary and secondary reviewers and complete discussion by the IRB, each protocol is voted upon for one of four possible dispositions:
a. **Approved**: It is approved as written with no explicit conditions.
b. **Approved Pending Modifications**: Approval pending modifications is not a final approval. The protocol was approved with minor changes or simple concurrence of the PI. These will be identified to the PI, and completion and documentation are required prior to beginning the research. For these conditions, the IRB Chair or a designated reviewer, upon reviewing the PI's response(s) to the conditions, may approve the research on behalf of the IRB. PI responses to conditions deemed to be significant or that are directly relevant to regulatory criteria require review at a convened meeting.
c. **Tabled**: The information in the submitted documents has deficiencies preventing accurate determination of risks and benefits or requires significant clarifications, modifications, or conditions that, when met or addressed, require full IRB review and approval of the PI's responses and revisions. The deficiencies are specified to the PI, who is required to address every IRB concern in a written response. The PI may be asked to attend the full board meeting to clarify the points in question. PIs may respond to a "tabled" decision with a written request. The IRB will review the appeal and invite the PI to the IRB meeting if the IRB has additional questions. The IRB reconsiders its original decision based upon new information presented by the PI. The second decision is final.
d. **Disapproved**: The submitted materials describe events or situations that indicate that research risks outweigh potential benefits. PIs may appeal a determination for disapproval in writing or by attending an IRB meeting and presenting reasons for reconsideration. Upon appeal, the IRB will reconsider its original decision based upon new information presented by the PI. The second decision is final.

E. Length of Approval Period

1. The IRB determines the interval for the continuing review of the research, appropriate to the degree of risks that will be experienced by subjects.

2. The interval for continuing review is at least once per year (not to exceed 365 days; 366 days during a leap year) but may be shorter.

3. When the IRB grants approval for one year at the time of continuing review and performs the continuing review and re-approval (with or without pending modifications) of the research within 30 days prior to the IRB approval period expiration, the IRB retains the anniversary of the expiration date of the initial IRB approval as the expiration date of the subsequent one-year approval period.
4. Protocols that have not undergone continuing review expire at midnight on the expiration date. Research activities may not continue after midnight of the expiration date.
5. The IRB may require certain protocols be reviewed more than once a year. Reasons for the IRB to require more than annual review include but are not limited to the following:
   a. Increase in risks over what was originally anticipated.
   b. Noncompliance history.
   c. As necessitated by protocol Quality Assurance recommendation.

F. Third Party Observation

1. The IRB has the authority to observe or appoint a third-party to observe research conduct, including consent procedures. It may consider whether a study requires independent verification from sources other than the PI to verify that no material changes have occurred since the last IRB approval. The IRB requires verification of the information provided for continuing review when:
2. Continuing review materials appear inconsistent or inaccurate compared to prior applications or records and discrepancies cannot be resolved via communication with the PI; or
3. The IRB determines that such actions are useful as part of a corrective action plan for any unanticipated problem or event.
4. If the findings of such investigations during the continuing review process warrant corrective actions, the IRB may suspend or terminate a research project to ensure the quality of research and protection of research subjects.