Title: REQUIREMENT FOR CONTINUING REVIEW PRIOR TO AND AFTER IMPLEMENTATION OF THE COMMON RULE	Policy Number: BC-IRB-405 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
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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 **REQUIREMENT FOR CONTINUING REVIEW PRIOR TO AND AFTER IMPLEMENTATION OF THE COMMON RULE** 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 the BayCare Health System is the IRB of Record.

PURPOSE:

To outline the procedure for conducting continuing reviews of human subjects research that were approved PRIOR to, and ON or AFTER January 21, 2019 after implementation of the Common Rule.

PROCEDURE:

A. **For Research Approved PRIOR to January 21, 2019**

1. Review is required for non-exempt human subjects research on a continuing basis. The Institutional Review Board (IRB) is responsible for conducting continuing review at intervals appropriate to the degree of risk, but not less than once per year. Continuing review until the study is completed and finalized by the IRB.
2. Research initially approved by expedited procedures are reviewed by expedited procedures at the time of continuing review unless there has been a change to the research that it no longer qualifies for expedited review.
3. Research initially approved by the Full Board requires continuing review by the Full Board. There are limited circumstances where research initially approved by the Full Board can undergo expedited review at the time of continuing review:
   a. The research project involves only activities described by expedited review categories (8)* or (9)**; or
   b. Research project previously approved by the IRB at a convened meeting progresses to the stage where all of the remaining human subjects research activities involve no more than minimal risk to the subjects and fall within the scope of one or more of expedited review categories (2) through (7).
4. *Category 8
   a. Under category (8), an expedited review procedure may be used for the continuing review of research previously approved by the IRB at a convened meeting as follows:
      I. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; OR
      II. Where no subjects have been enrolled and no additional risks have been identified; OR

III. Where the remaining research activities are limited to data analysis.

5. **Category 9
   a. Under category (9), an expedited review procedure may be used for the continuing review of research previously approved by the IRB at a convened meeting that meets the following conditions:
      I. The research is not conducted under an investigational new drug application (IND) or an investigational device exemption (IDE);
      II. Expedited review categories (2) through (8) do not apply to the research;
      III. The IRB determined and documented at a convened meeting that the research involves no greater than minimal risk to the subjects[1]; AND
      IV. No additional risks of the research have been identified.
6. Regarding the third condition above, the IRB at a convened meeting must have determined that either (a) the research project as a whole involved no more than minimal risk, or (b) the remaining research activities involving human subjects present no more than minimal risk to the subjects. This determination, particularly with respect to (a), could occur as early as the convened IRB meeting at which the IRB conducted its initial review.

B. **For Research Approved ON or AFTER January 21, 2019**
1. Research that requires Continuing Review:
   a. The IRB conducts continuing review of research requiring review of the convened IRB. The IRB is responsible for conducting continuing review at intervals appropriate to the degree of risk, but not less than once per year.
2. Research that does not Require Continuing Review:
   a. Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:
      I. Exempt research
      II. Research eligible for expedited review
      III. Research reviewed by the IRB in accordance with the limited IRB review
      IV. Research that has progressed to the point that it involves only one or more of the following, which are part of the IRB-approved study:
         - Data analysis, including analysis of identifiable private information or identifiable biospecimens
         - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care
3. The IRB may determine that the continuing review is required for any research in any of the above criteria. Determination that continuing review is still required include:
   a. The research involves topics, procedures, or data that may be considered sensitive or controversial
   b. The research involves vulnerable populations
   c. The investigator has minimal experience in research or in the research topic
   d. The investigator has a history of non-compliance
4. If the IRB determines that continuing review is required for this research, it will document the rationale in the IRB record and communicate the requirement to the investigator in the IRB determination letter.
5. If a study is regulated by the Food and Drug Administration (FDA), continuing review will be conducted in compliance with the applicable FDA regulations.
6. Annual Updates for Expedited Research that Does Not Require Continuing Review
   a. The investigator is required to provide an annual update to the IRB for expedited research that does not require continuing review.

C. **Submission of Continuing Review Application if BayCare IRB is the IRB of records**
1. The Investigator submits the Continuing Review Application and all applicable documents to the BayCare eIRB for review including:
   a. Consent/ assent/ information sheet
   b. Recruitment/ screening materials
   c. Questionnaires, surveys, etc.
   d. Progress reports
   e. Data Safety and Monitoring Board (DSMB)/ Monitoring Reports
   f. Adverse Events
2. The IRB Coordinator conducts an administrative pre-review to check for document completion and for training requirements. Incomplete submissions are returned to the Principal Investigator (PI).
3. The IRB Coordinator enters the continuing review submission into the IRB tracking system.

4. The IRB Coordinator assigns the Application to the IRB members who initially reviewed the project. The same reviewers perform a review of the project for the duration of the project until its completion. In case if a primary reviewer (an MD, DO, or PharmD) is no longer available, the project is transferred to the Board Chair.

D. **Submission of Continuing Review Application if BayCare IRB is NOT the IRB of records**

1. When the BayCare IRB relies on another IRB (Reviewing IRB), the Reviewing IRB is responsible for conducting the continuing review. After the continuing review approval letter is received from the Reviewing IRB, the following documents are required by the BayCare IRB:
   a. The renewal approval letter from the reviewing IRB
   b. Changes to local study team members (that have not already been reported)
   c. A summary of all internal reportable new information submitted to the reviewing IRB since the last review, if any (and if not already reported promptly).
   d. New Reportable Information including but not limited to:
      I. Unanticipated problems that increase risk of harm to others,
      II. Noncompliance,
      III. Breaches of confidentiality,
      IV. Wrong site surgeries,
      V. Wrong drug administered,
      VI. Wrong patient,
      VII. Fabrication of data and
      VIII. Falsification of data.
   e. Provide the outcome of the reviewing IRB's review (e.g., "Noncompliance," "Serious noncompliance," "Unanticipated Problem"…). Upload a copy of the report(s) submitted to the reviewing IRB.