Title:	Policy Number: BC-IRB-416
INSTITUTIONAL REVIEW BOARD (IRB) PROCESS FOR LAPSED CONTINUING REVIEW	**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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Approved by: Keri Eisenbeis, Chief of Staff **Signature:** _____	

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 (IRB) PROCESS FOR LAPSED 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

PURPOSE
To describe the responsibilities of the Principal Investigator (PI) and the Institutional Review Board (IRB) requirements upon expiration of IRB approval for Human Subjects Research when IRB Continuing Review (CR) is required.

DEFINITIONS
Expired Study: When continuing review of the research does not occur prior to the end of the approval period specified by the IRB on the approval letter and the informed consent document.

IRB Electronic Notifications: The IRB electronic system issues an Expiration Notice to the PI automatically at 90, 60, and 30 days prior to the study expiration that is set at 365 -1 day from the study last review and approval.

There are no provisions for any grace period extending the conduct of research beyond the expiration date of IRB approval. When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically.

A lapse in IRB approval of research occurs whenever an investigator has failed to provide continuing review information to the IRB, or the IRB has not conducted continuing review and re-approved the research by the expiration date of IRB approval. In such circumstances, all research activities involving human subjects must stop. Enrollment of new subjects cannot occur after the expiration of IRB approval.

PROCEDURE:

A. PI Responsibilities
1. All research activities must cease upon expiration and must not resume until and unless the IRB grants approval.

2. If cessation of all the research activities **will <u>not</u> jeopardize the health or safety** of any currently enrolled subject, the PI:
    a. Ceases all research activities, including enrollment of new subjects, study interventions, data collection, and data analysis.
    b. Submits a CR report including research activity that occurred after the expiration date to the IRB within 5 calendar days.
3. If cessation of all or some of the research **activities would jeopardize the health or safety** of a currently enrolled subject, the PI:
    a. Consults with the IRB Chair or Vice-Chair. If the Chair or Vice-Chair agrees that it is in the best interests of individual subjects to continue participating in all or some of the research interventions or interactions, the PI may be allowed to continue those interventions or interactions with currently enrolled subjects.
    b. Ceases all other research activities, including data collection, data analysis and enrollment of new subjects.
    c. Submits a CR report via the electronic Institutional review Board application (eIRB) within 5 calendar days.

B. Chair and Vice-Chair Responsibilities

1. The Chair or Vice-Chair determines whether cessation would jeopardize the health or safety of currently enrolled subjects.
2. If cessation of all research activities **will not jeopardize** the health or safety of a currently enrolled subject, the Chair or Vice-Chair will instruct the PI to cease all research activities, including enrollment of new subjects, study interventions, data collection, and data analysis.
3. If cessation of all research activities **will jeopardize** the health or safety of a currently enrolled subject, the Chair or Vice-Chair will:
    a. Advise the PI to continue protocol events for currently enrolled subjects but stop enrollment of new subjects.
    b. IRB Chair/Vice-Chair may limit the study to specific protocol events as appropriate.
4. Chair or Vice-Chair will instruct the PI to submit a CR report to the IRB within 5 calendar days. IRB approval of the PI continuing review submission will be required before resuming any human subjects research activity.

C. IRB Staff Responsibilities

1. Upon receiving notification from the Chair or Vice-Chair that a PI cannot continue, or may continue study interventions on currently enrolled subjects, IRB Staff will record the notice using the Correspondence section within the eIRB Study Site workspace.
2. CR report must be submitted within 5 calendar days.
3. If the CR has not been submitted in 5 calendar days, the IRB staff will escalate the matter to the Chair or Vice-Chair for a determination on whether to revoke approval of the research.

D. IRB Responsibilities

The IRB reviews CR reports in accordance with the approved IRB procedure, Continuing Review of Research Policy