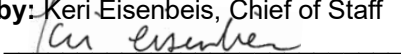


Title: IRB ACKNOWLEDGEMENT OF QUALITY IMPROVEMENT OR QUALITY ASSURANCE ACTIVITIES	Policy Number: BC-IRB-417 Page: 1 of 2
SPONSORED BY: Sponsored Programs and Research	Issued for: All BayCare, including without limitation: Bartow Regional Medical Center BayCare Alliant Hospital BayCare Hospital Wesley 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
Original Issue Date: <u>6/2024</u> Review Dates: Revision Date:	
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 **IRB ACKNOWLEDGEMENT OF QUALITY IMPROVEMENT OR QUALITY ASSURANCE ACTIVITIES** Policy applies to BayCare Health System, Inc. and any of its affiliated entities (collectively, "BayCare").

SCOPE:

BayCare Human Research Protection Program

PURPOSE

To provide consistent practice in the oversight of human subjects research.

GENERAL DESCRIPTION:

A BayCare Institutional Review Board (BCHS-IRB) acknowledgement of a Quality Improvement (QI) or Quality Assurance (QA), sometimes also referred to as Program Evaluation, is required in instances where either:

- the project is student or resident initiated,
- other health system policies require confirmation on whether an activity does or does not meet the definition of research with humans,
- or a journal or conference requires a confirmation of institutional review prior to acceptance of a manuscript for publication or presentation.

When not required, a request is welcome for an BCHS-IRB review and assessment to confirm that a project does not constitute human subjects research.

The BCHS-IRB cannot issue retroactive approval of an activity that is conducted as a QI project and is later determined to be human research.

DEFINITIONS / ACRONYMS:

Human Subjects Research - According to federal statute, a human subject is "a living individual about whom an investigator (whether professional or student) conducting research: Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Quality Improvement (QI) Project - A federal agency defines quality improvement as "...a continuous and ongoing effort to achieve measurable improvements in the efficiency, effectiveness, performance, accountability, outcomes,

and other indicators of quality in services or processes which achieve equity and improve the health of the community.”

Quality Assurance (QA) Activities – sometimes referred to as program evaluation. These activities establish a systematic process of reviewing the already evidence-based intervention or plans and methods adopted by the project or program team to verify that they meet the intended standards. A QA activity is not a testing process but part of the project or program review process.

PROCEDURE:

Team members (TMs), medical staff, or other students or residents conducting a clinical project which needs or otherwise requests a review to confirm the project does not meet the definition of human subjects research, can submit their request to the BCHS-IRB Office.

A. Initial Submission

An application through the eIRB system is not required for a QI/QA project review. If an application for IRB review and determination is made through the eIRB, and the IRB Manager determines the project does not constitute human subjects research, the IRB Office follows the process described in A.5

1. Email Requesting BCHS-IRB Acknowledgement of QI/QA

The leader of the proposed project sends an email to the BCHS IRB Office at irb.bchs@baycare.org requesting a review to confirm the project does not constitute human subjects research.

2. Attachment to include a clear description of the project which clearly explains the background, problem, current state and proposed future state, the plan to address the problem, and measurement plan.

3. IRB Manager releases an acknowledgement letter with a result of its assessment of the project as either QI/QA or human subjects research.

4. If the project is assessed and found to constitute human subjects research an initial submission is required in the eIRB following the process outlined in BC-IRB-401, BAYCARE IRB INITIAL APPROVAL OF RESEARCH, for a determination.

5. If the leader of the proposed project applied via eIRB and the IRB office assessed that the proposed activity does not constitute research involving human subjects as defined by federal regulations, the IRB Manager releases an acknowledgment letter stating that the IRB review and approval of the project is not required. The submission is administratively closed, and the project status will not be activated within the eIRB.

B. Changes to the Project

If changes are made following the review and there are questions about whether these activities constitute human subjects research, project leaders re-inquire, or submit a new application to the BCHS-IRB office for an assessment or determination, as applicable.