BayCare

POLICY & PROCEDURE

Title: **CLINICAL RESEARCH TEAM TRAINING REQUIREMENTS**	**Policy Number:** BC-IRB-403 **Page:** 1 of 2
SPONSORED BY: Sponsored Programs and Research Committee **Original Issue Date:** 1/2022 **Review Dates:** **Revision Date:**	**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
Approved by: Ed Rafalski, SVP, Chief Strategy & Marketing Officer **Signature:** DocuSigned by: Edward Rafalski 1C005CA03849475...	

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 **CLINICAL RESEARCH TEAM TRAINING REQUIREMENTS** Policy applies to BayCare Health System, Inc., and any of its affiliated entities, including those entities listed above (collectively, "**BayCare**").

SCOPE:
BayCare Health System Human Research Protection Program

PURPOSE:
To describe the training requirements for the IRB staff, IRB Board Members, Principal Investigators, and research teams directly involved in study activities.

PROCEDURE:
A. Researchers and Research Staff
1. Training IS REQUIRED for all participants whether originally listed or later added to the study through amendment, including:
    a. Researchers
    b. Students
    c. Researchers from other institutions who wish to conduct non-exempt human subjects research at any BayCare facility
    d. All key personnel:
        i. Principal Investigator (PI) and Co-PI
        ii. Student Sponsor (Faculty of Mentor)
        iii. Research Regulatory Specialist
        iv. Clinical Research Coordinators
        v. Research Specialists
        vi. Research Nurse Coordinators
        vii. Research Assistants
        viii. Ancillary staff participating in the conduct of the research
2. Researchers are required to complete mandatory training affiliated with Collaborative Institutional Training Initiative (CITI) (modules relating to ethics, regulations, risk assessment, informed consent and privacy and confidentiality).
3. Required courses:
    - Good Clinical Practice (GCP)
        - ✓ U.S. Food Drug FDA Focus
        - ✓ If global trial, International GCP Focus International Council of Harmonization (ICH)
        - ✓ If Humanitarian Use Devise (HUD) outside of single emergency use, Humanitarian Use Device Optional Module

- Human Subject Protection (HSP) biomedical research section only. If a research project involves social- behavioral component, then HSP social-behavioral section is required as well.
- Conflict of Interests (COI)

4. Training is required every three years. Protocol submissions (initial, continuing, amendments) include verification that researchers and research staff have completed training. Protocol actions are not approved until training is completed by all listed on the protocol. Webinars and local conferences are made available to the BayCare community for additional training.
5. PIs and study team members can meet the training requirement by completing the CITI GCP training course.
6. The BayCare IRB accepts other GCP training as meeting the requirement if the course is approved by TransCelerate for BayCare PIs and team members experienced with research who are transferring in from other institutions until those certifications expire. Upon expiration, CITI GCP training is required to remain active in research.

B. Clinical Trials Office (CTO): Research Regulatory Support Staff
1. Review IRB the Policies and Procedures Manual and complete mandatory CITI Training.
   - Good Clinical Practice (GCP)
   - Human Subject Protection (HSP) biomedical research section only.
   - Conflict of Interests (COI)
2. May be invited to attend IRB meetings as necessary. Webinars and conference are made available for additional training. Upon request a member of the IRB staff will meet one-on-one with a CTO team.