D. New and Transfer Investigator Pre-Review

Purpose and Policy

The purpose of the New and Transfer Investigator Pre-Review Standard Operating Procedure (SOP) is to outline the process of educating and orienting new investigators to Children's Hospital, Boston (CHB) who plan to conduct clinical research involving human subjects.

New Investigators (those conducting clinical research involving human subjects for first time) and Transfer Investigators (those who have clinical research experience involving human subjects from other institutions, but never conducted research at CHB before) must meet with the EQuIP office for a Pre-Review/Orientation prior to the release of IRB final approval.

Responsibility

Quality Improvement Specialist
Manager, EQuIP
Director, Clinical Research Compliance

Procedure

1. **Identification of New/Transfer Investigators**: CCI/IRB administrators will identify New and Transfer Investigators at the point they are being entered into the CCI Research Database when processing a new protocol application.

   New and Transfer Investigators are defined as those serving as the Principal Investigator (PI) of a clinical trial involving human subjects for the first time at CHB.

2. **Notification to New and Transfer Investigators**: the CCI/IRB office will notify identified New and Transfer Investigators during the IRB Administrative Pre-review, that they will be required to undergo a the New/Transfer Pre-Review prior to the release of IRB approval and instruct them to contact the EQuIP office.

   Once notified, the New/Transfer Investigator will be responsible for contacting the EQuIP office to set-up the required Pre-Review as instructed.

3. **EQuIP Pre-meeting Actions**: once a New/Transfer Investigator contacts the EQuIP office, the meeting (approximately 1 hour) will be scheduled. Prior to the scheduled meeting, the EQuIP staff will:

   a. Obtain the CCI/IRB study file.
   b. Complete the General Information on the cover sheet of the **New/Transfer Investigator Meeting Checklist** (template located J:\RPA\EQuIP\New & Transfer Investigators).
   c. Review the protocol with the goal to tailor the pre-review material to best fit the needs of the proposed protocol/investigator (e.g. drug or device study vs. survey study).
   d. Prepare handouts as outlined in **New/Transfer Investigator Meetings: Handouts and Guidance** (located J:\RPA\EQuIP\New & Transfer Investigators).

   EQuIP staff will encourage New/Transfer Investigator to have all study documents, case report forms, files and binders available and/or bring questions pertaining to these topics.

4. **New/Transfer Investigator Pre-Review Meeting**: the goal of this pre-review meeting is to ensure the New/Transfer Investigator has an understanding of all applicable regulations and policies and are aware of the following:

    a. CHB Clinical Research Support Services & Resources
        - CCI/IRB, EQuIP, CRP, CTSU, Research Pharmacy, TRP

    b. CHB/CCI Principal Investigator Responsibilities

    c. CHB/CCI Policies and Procedures (highlighting policies and procedures that maybe unique to CHB, as well as common reporting procedures)

    d. CHB/CCI Reporting and Review structure, requirements and related policies.

    e. CHB/CCI Informed Consent Library

    f. Applicable issues pertaining to Study Documentation, Organization and Storage

    g. Applicable issues pertaining to Informed Consent and Assent

    h. Applicable resources available through CHB intranet (CCI, EQuIP, CRP).

    The EQuIP staff will complete the **New/Transfer Investigator Meeting Checklist** to guide the meeting. Handouts, references and a template Study Regulatory Binder will be provided as outlined in **New/Transfer Investigator Meetings: Handouts and Guidance**.

    Once the Pre-Review is complete, and the QI Specialist feels the New/Transfer Investigator is adequately prepared to conduct the proposed research safely and understands applicable regulations and policies, the QI Specialist and New/Transfer Investigator will sign the **New/Transfer Investigator Meeting Checklist** coversheet.

5. **EQuIP Post-meeting Actions**: once the pre-review is complete, the EQuIP staff will complete the following steps:

    a. Photocopy signed coversheet of the **New/Transfer Investigator Meeting Checklist** and give to CCI/IRB administrator with returned CCI/IRB study file.

    b. Enter information into EQuIP database under *'PI Orientation'* (part of CCI Database: http://chbcfapps.tch.harvard.edu/cfapps/cci/CCI/)

    c. Enter continuing education training for PI and other attendees into *Training*, *'Add New Person to Training List'* (part of CCI Database http://chbcfapps.tch.harvard.edu/cfapps/cci/CCI/AddPersonTrainProgram.cfm)

    d. If applicable, enter information into *'Regulatory Binder Distribution'* for those who accepted template Regulatory Study Binder and *'Guide Book Recipients'* for those who were offered The CRC's Guide to Coordinating Clinical Research.

    e. File hard-copy of checklist in file folder labeled *'Completed New/Transfer PI Pre-Reviews'* in the EQuIP central files.