Boston Children's Hospital

New/Transfer Investigator

New/Transfer Investigator: General Info

Principal Investigator	☐ Co-Investigator
Protocol #	
Protocol Title	

Protocol Status	☐ Submitted for IRB review: *ancillary review triggered* ☐ Pending IRB Submission: *ancillary review not triggered* ☐ Amendment for PI change: *ancillary review triggered*
Date of Meeting	Time: Location:
EQuIP Staff	☐ Tonya Ferraro ☐ Eunice Newbert

Notes and PI Follow-up (e.g. send handouts, templates)

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EQuIP Tasks (after NEW PI training completed)

☐ Update Continuing Education Training under 'Account Profile' in CHeRP

☐ Submit EQuIP Ancillary Review in CHeRP protocol

☐ Enter New PI into EQuIP Activity spreadsheet

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EQuIP & IRB: Programs and Services

- **EQuIP**
  - ☐ Program and Services
  - ☐ Study Tools and Templates

- **IRB**
  - ☐ Guidelines and Policies – Table of Contents
  - ☐ Principal Investigator Responsibilities (*reference in PI Oversight*)
  - ☐ Reporting, Unanticipated Events and Non-compliance Policies
    - ↳ External Reports (e.g. Monitoring, Data Safety Monitoring, FDA)
    - ↳ Non-compliance and Subject Complaints
    - ↳ Define Significant and Minor deviations (Non-compliance policies)
      - ↳ Minor Deviation Tracking Templates

IRB Reviews: CHeRP, Types of IRB Review, Ancillary Reviews

☐ **Scientific Review:** department/division review required through CHERP **prior** to Initial IRB submission

☐ **New Protocol Submission:** Initial Review

☐ **Continuing Reviews:** within one year of approval date (vs. activation date)
- if more frequent reviews are required, IRB will specify in approval letter
- recommend to submit ~2 months prior to expiration

☐ **Amendments**: all changes must be incorporated into the protocol, consent/assent forms, study documents and recruitment materials, reviewed and IRB- approved before implementing into study, unless intended to eliminate immediate harm to subject

Staff Amendments can update CHERP without IRB review

** CHERP only allows one review at a time, so recommended to submit as many changes as once if possible. This includes continuing review and amendments, so ensure all staff training up to date.

☐ **Hint:** can reference IRB Reviewer Worksheets in CHERP
-available for New Protocol/Deferral, Continuing Review and Amendments

Ancillary Reviews (list types and define)

☐ **Sponsor-Investigator Orientation (Ancillary Review)**
If PI is also the Sponsor, holding the IND for Investigational Drug or IDE for Devices (SR or NSR)

☐ CTBO

☐ **Reliance Agreements and Multicenter Research and Engagement in Research**
- ☐ Other sites relying on BCH IRB
- ☐ Relying on another IRB

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Principal Investigator Responsibilities and Oversight

☐ Discuss importance of developing plan to ensure adequate oversight
- create PI-specific SOP (naming conventions, where to file documents)
- Roles and Responsibilities Template
- Study Document template ("document map")
- Make a pro-active plan to ensure availability to research staff (e.g. regular staff meeting)

☐ Availability to Research Staff
- pro-active approach(e.g. regular staff meeting, office hours)
- ensure staff roles and responsibilities
- develop culture of openness/approachability

Recruitment ☐ n/a

☐ **Appropriate recruitment practices (avoiding undue influence, protecting privacy)**
- ☐ know what approved protocol AND protocol application (smart form) outlines
- ☐ review IRB Guidelines for recruitment

Contacts and Resources

☐ IRB Newsletters

☐ BCH Research Contacts Handout (add offices and contacts below)

☐ Educational Opportunities:

ICCTR - Introduction to Clinical Research, Coordinator Rounds, Orientation for New Study Coordinators

Miscellaneous: Special Considerations

Sponsor-Investigators

☐ Register trial on www.clinicaltrials.gov

☐ Add required consent language regarding clinicaltrials.gov registration

Drug Studies (all studies using Research Pharmacy)

☐ Register each subject on CHERP to verify consent. Must be entered prior to Pharmacy dispensing study drug for that subject

☐ **Data Security and Privacy**
- General Computing Concern - Help Desk at ext. 5-4357
- Privacy Incidents – Privacy Officer at ext. 5-4934
- Security Incidents – ISD Help Desk at 5-HELP/4357
- Information Security Concern – Information Security Officer at ext. 4-4013

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Informed Consent and Assent ☐ n/a

☐ **Adequate plan to safely obtain consent/assent (trained staff, location, timing)**
- ☐ know what approved protocol AND protocol application (smart form) outlines
  - ☐ review IRB Guidelines for process and documentation of consent/assent
  - ☐ review IRB Guidelines for obtaining consent/assent via phone and mail (if applicable)
  - ☐ review IRB Guidelines for waivers and alterations of consent/assent (if applicable)

☐ **Subjects/Parent/ Court-Appointed Legal Guardian must receive a copy of the SIGNED consent form**
- ☐ may have subject/parent/guardian sign two copies, but photocopy preferred

☐ **Assent: must have signature OR reason**
- ☐ always read IRB approval letter – specifies if assent is required or waived
- ☐ if separate assent form, ensure consent form clearly indicates a separate assent or reason
- ☐ 'Specify Relationship to Child': never assume, have parent/legal guardian complete.

☐ **Signatures**
- ☐ ensure each required signature is on correct line and dated correctly
- ☐ tailor signature section to fit specific study (e.g. 2 parent signatures, 2 parent lines)

☐ **Never date another person's signature**
- ☐ check that each person correctly dated their signature before they leave

☐ **Always ensure all consent and assent forms are 'active', not expired**
- ☐ check the footer of approved consent/assent form for each subject: approval vs. activation date

☐ **Always obtain most recent consent/assent version from Informed Consent Library**

Obtain link through CHERP. Note: no access outside BCH firewall, so non-BCH staff will not have access

☐ **Consents must be in the subject/family's primary language:**
- ☐ Interpreter/Translation Services @ CHB Information
  - → CCI Link: Info for Researchers, Informed Consent link, towards end of page (2nd last topic)
- ☐ Translation of Informed Consent Request Form
  - → CCI Link: Info for Researchers, Forms – under 'Miscellaneous'

☐ **Short Form Translations –**
- ☐ Short Form Translations: Policy & Questions and Answers documents
  - → Use of Short Forms for Informed Consent
  - → CCI Link: Info for Researchers, Informed Consent link, 2nd topic of page

Study Documentation, Organization and Storage

1. **Determine what documents are required and what you need throughout study**

2. **Determine where to file/store required documents for easy reference but that ensures safe and secure storage**

3. **Who will be responsible for maintaining and updating each document? Who will 'own' the document? Clinical Trial Study Documents (handout)**

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