### New/Transfer Investigator: General Info

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<tr>
<th>Principal Investigator</th>
<th>□ Co-Investigator</th>
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<tr>
<td>Protocol #</td>
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<td>Protocol Title</td>
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### Protocol Status

- □ Submitted for IRB review: **ancillary review triggered**
- □ Pending IRB Submission: **ancillary review not triggered**
- □ Amendment for PI change: **ancillary review triggered**

### 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
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/Admin Update**: 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
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

- 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. 4-013
### Informed Consent and Assent

- **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)**