### EQuIP: Programs and Services

- **New Investigator**
- **EQuIP Education and Quality Improvement Program**

### Principal Investigator Responsibilities

- **CCI/IRB Policy: Principal Investigator Responsibilities** – Review policy
- **CCI/IRB: Institutional Guidelines and Policies** – Table of Contents
- **Clinical Research Map**

### Protocol Reviews & Reporting: Scientific, IRB & Other/Outside Reviews

#### Reviews

<table>
<thead>
<tr>
<th>Scientific Review</th>
<th>department/division review required through CHERP prior to Initial IRB submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Protocol Submission</td>
<td>Initial Review</td>
</tr>
<tr>
<td>Ancillary Review</td>
<td>required depending on nature of research and resources used; e.g. radiation, EQuIP, CTO, drug/device, etc.</td>
</tr>
<tr>
<td>Continuing Reviews</td>
<td>recommend to submit ~2 months prior to expiration</td>
</tr>
</tbody>
</table>

#### Amendments

- Reliance Agreements
  - Daniel Alderson [Daniel.Alderson@childrens.harvard.edu](mailto:Daniel.Alderson@childrens.harvard.edu)
  - 617-919-1918

### Reporting

#### Conflict of Interest

- **Unanticipated Problems and Events Involving Risk to Subjects** submit CHeRP Reportable Event Form or Deviation Log and Alternate Deviation Log

#### Protocol Exception Requests

- **External Reports**: submit copies of external reports to CCI (Monitoring, Data Safety Monitoring, FDA annual IND report)
### Recruitment

<table>
<thead>
<tr>
<th>Appropriate recruitment practices (avoiding undue influence, protecting privacy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Know what approved protocol AND protocol application (smart form) outlines</td>
</tr>
<tr>
<td>Review CCI Guidelines for recruitment</td>
</tr>
</tbody>
</table>

### Informed Consent and Assent

<table>
<thead>
<tr>
<th>Adequate plan to safely obtain consent/assent (trained staff, location, timing) know what approved protocol AND protocol application (smart form) outlines; review IRB General Information: Informed Consent and Parental Permission, and Special Considerations: Assent and Parental Permission.</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td>Always obtain most recent consent/assent version from Informed Consent Library and ensure all consent and assent forms are ‘active’, not expired; Obtain link through CHERP.</td>
</tr>
</tbody>
</table>

**Informed Consent with Non-English Speakers**
## Study Documentation, Organization and Storage

| Determine what documents are required and what you need throughout study:  
IRB and Regulatory Documents  
Case Report Forms and Source Documents  
Storage of Research Data and Informed Consent Documents  
Providing Remuneration to Research Subjects  
Research Finance Remuneration FAQs |
|---|
| Determine where to file/store required documents for easy reference but that ensures safe and secure storage?  
general rule, behind 2 locks (e.g. locked cabinet behind locked door); common sense (who can access documents?) |
| Study and Subject Records & Files: Clinical Trial Study Documents  
CATALYST REGULATORY BINDER TEMPLATE  
Electronic Storage of Study Data and Documents CHERP |
| 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 |
| Adequate resources & facilities |

## Research Staff, Training and Resources

<table>
<thead>
<tr>
<th>Qualified Research Staff: Ensure all staff are listed and approved by IRB; Required training: CITI, from other institutions and continuing education (every 3 years); Ensure each staff training still valid before each submission</th>
</tr>
</thead>
</table>
| Available to research staff  
EQuIP Resources |
| Educational Opportunities: Clinical Research Center Education Core - Introduction to Clinical Research, Coordinator Rounds, Orientation for New Study Coordinator, also Research Practice Guidelines |
### Clinical Research Support Services

- **Institutional Review Board** (CCI/IRB)
- **CHERP Help or CHeRP How Do I? documents**
- **Clinical Research Center**
  Erin Deneen Education Program Coordinator 21 Autumn Street Ext: 857-218-4724
- **Education and Quality Improvement Program** (EQuIP): 
- **Translational Research Program** (TRP): Regulatory/FDA Services
- **Clinical Trials Business Office** (CTBO)

### Miscellaneous: Special Considerations

- CCI/IRB Guidelines [ClinicalTrials.gov](https://clinicaltrials.gov)
- June 2014 Special Communication Newsletter – [ClinicalTrials.gov](https://clinicaltrials.gov)
- Register trial on [www.clinicaltrials.gov](http://www.clinicaltrials.gov); Add required consent language regarding clinicaltrials.gov registration
- **ICH E6 Good Clinical Practice Guidelines**
- **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