G-013 - Regulatory Binder- Single IRB Requirements

PBRC is the Relying Institution

Use this tab if your site is ceding review to an outside IRB. Documentation on the following should be maintained by the Relying Institution Site:

- **Copy of Executed Reliance Agreement**

- **Willing to Rely Letter from IRB**

- **Documentation that the following information was provided to the Lead Institution Site Point of Contact (POC);** copies of these items should be maintained in the regulatory binder:
    - Changes in PBRC's investigators or study team.
    - PBRC changes in COI disclosures and COI management plans.

- **Reviewing IRB Policies and Procedures Documents/Manual:** The Relying Institution investigator must adhere to the reviewing IRB's policies and procedures for reporting unanticipated problems, noncompliance, and other important items. The site binder should identify where these policies are. For example, a web address of the lead site's policies or documents provided by the lead site.

- **Copies of communication from the lead site investigator regarding all reviewing IRB determinations.**
    - Initial approval letter
    - Continuing review/progress approval letters
    - Amendment approval letters
    - Final close-out acknowledgement letters

- **Reviewing IRB Approved Study Documents:** Copies of communication from the lead investigator regarding all approved IRB documents.
    - Informed consent forms
    - Authorization forms (if applicable)
    - Recruitment materials
    - Participant handouts, flyers, surveys, etc.
    - Case report forms (if applicable)
    - Amendments (including funding changes)

- **Documentation of communication of local considerations ("local context") through the Point of Contact.**
    - IREx surveys or other reliance platform surveys
    - Local site information documents, etc.

- **Documentation of communication to the Reviewing IRB of communications to and from the Relying Institution and FDA, OHRP, and/or other regulatory agencies.**

- **Documentation showing "prompt reporting" to lead study team of any unanticipated problems, suspension of the study or noncompliance at the local site.**

- **Documentation that the Relying Institution Sponsored Programs Office has Received Relying IRB Approval Documentation.**

- **Relying Institution IRB Materials/Documents Submitted to Lead Investigator.**
    - Initial IRB approval materials
    - Relying institution IRB-approved informed consent form (if applicable)
    - Study staff lists and training documents
    - Continuing review information

PBRC is the Reviewing (Lead) Institution

Use this tab only if your site is the Lead site of a multi-center study utilizing a single IRB. Documentation on the following should be maintained by the Lead Study Team Site about the Relying Sites.

- **Copy of Executed Reliance Agreement with Relying Institutions:** The Lead Investigator should maintain executed reliance agreements for each participating Relying Institution.

- **Willing to Lead Letter from PBRC IRB**

- **COI documents received from Relying Institutions (if applicable):**
    - COI disclosures and, if applicable, COI management plans.

- **Documentation that the reviewing IRB Policies and Procedures documents were provided to each Relying Institution investigator.** Document that relying institutions were informed where to find our Policies and Procedures. For example, if this notification was through email, copies of the email notifying the sites are sufficient.

- **PBRC IRB's determination letter.**

- **Documentation of notifying relevant Point of Contacts from Relying Institutions of findings and actions with respect to Unanticipated Problems or research related subject complaints or injuries or serious and/or continuing non-compliance.**

- **Documentation on Relying Sites local context.** Typically IREx surveys

- **The Lead Investigator should ensure (and document) that each Relying Institution investigator was provided with a copy of PBRC IRB approval letters and IRB-approved study documents:**
    - PBRC IRB initial approval letter
    - PBRC IRB continuing review/progress approval letters
    - PBRC IRB amendments, approval letters
    - PBRC IRB final close-out acknowledgment letter
    - PBRC IRB Informed Consent Form
    - PBRC IRB authorization forms
    - PBRC IRB recruitment materials
    - PBRC IRB participant handouts, flyers, surveys, etc.

- **Documentation of communications with Relying Sites including responses to questions or requests from site investigators/staff at Relying Institutions.**

- **The Lead Investigator should maintain all copies of all Relying Institution IRB documents provided by the Relying Institution investigator:**
    - Initial IRB approval materials
    - Relying Institution approved IRB Informed Consent Form (if applicable)
    - Study staff Lists and Training Documents
    - AE/UP information
    - Other Items