CIRB Questions from CPN Consortium Participating Organizations

1. How can I find out if my institution is a CIRB signatory institution?
   Contact the CIRB at this email address: ncicirbcontact@emmes.com

2. How can we find out who are the individuals at our institution who are most knowledgeable about the CIRB, specifically CIRB procedures for non-CTEP (i.e. consortia) studies?
   Contact the CIRB at this email address: ncicirbcontact@emmes.com

3. How can we find out the status of a consortium study prior to activation?
   Go to the CIRB website: https://www.ncicirb.org

4. What will we have to submit to our local IRB?
   - For each CIRB study you plan to open at your institution, you will have to submit to your local IRB a request to use an external IRB. That process varies from institution to institution, and your local IRB probably has a CIRB specialist who can help.
   - If there are any committee approvals, i.e. Scientific Review, Biospecimens Review, or Biosafety Committee reviews, that are required prior to or in addition to IRB approval, you will still have to obtain those approvals.
   - For example, at Mayo:
     - The Mayo Clinic electronic IRB application has to include all Mayo staff members who will be involved in the study. The Mayo IRB confirms they have Human Subjects Protections training, they are qualified to perform the tasks required for study implementation (PI, sub-I, study coordinator, nurse, statistician, etc.), and that they have disclosed all potential conflicts of interest.
     - We have to submit documentation of CIRB approval of the protocol, recruitment plans and materials, and participant materials.
     - We have to paste the CIRB-approved informed consent language into the Mayo-approved consent form template.
     - We have to link electronically to an approved budget, and that application links to an executed contract.
     - Finally, we have to list and describe the risks and benefits of participation.
     - From that point forward, we have to submit documentation of CIRB approval of protocol modifications, and we have to submit documentation of CIRB approval of the annual continuing review.

5. What does the CIRB review and approve?
   - Overall, the CIRB has responsibility for approving the protocol, all recruitment and on-study materials, the recruitment plan, and the template informed consent language.
   - The CIRB approves translations of documents into other languages. Additionally, the translations for any documents that the participants will see (consent, questionnaires, etc.) must be certified.
   - Annual Signatory Institution Worksheet About Local Context
   - Annual PI Worksheet About Local Context
   - Study-Specific Worksheet About Local Context
   - Study Closure or Transfer of Review
   - Unanticipated Problems and Serious and/or Continuing Non-Compliance

- An overview of the process can be found here:

https://ncicirb.org/institutions/institution-quickguides/overview-of-the-study-review-process

6. Where can we find the information needed by our local IRB to cede responsibility for a study to the CPC CIRB?
   - FWA? The CIRB does not hold an FWA since they do not conduct research themselves.
   - Contact information for the CIRB Signatory official or the CPC CIRB chairperson? CIRB Membership can be found here: https://www.ncicirb.org/about-cirb/about-the-boards
   - Accreditation for the CIRB? The CIRB has been accredited by AAHRPP since 2012. More information can be found here: https://ncicirb.org/about-cirb/history
   - Registration number for the CIRB? The CIRB Registration Numbers are as follows:
     NCI CIRB Adult Late Phase Emphasis: IRB00000781
     NCI CIRB Pediatric: IRB 00004296
     NCI CIRB Adult Early Phase Emphasis: IRB00009430
     NCI CIRB Cancer Prevention & Control: IRB00010018

     You can also find them here:

https://ncicirb.org/institutions/becomingsignatoryinstitution/documenting-local-context

   - Is the CPC CIRB a member of SmartIRB or IRBChoice? No

7. What is the first step in obtaining CIRB approval for opening a study at our institution?
   For a CIRB-approved institution, the first step is to contact the CIRB Helpdesk to request access to IRBManager. Next, a PI Worksheet should be submitted in IRBManager to establish your Principal Investigator

https://ncicirb.org/institutions/institution-quickguides/managing-site/establishing-principal-investigator

   After the PI Worksheet is approved, a Study-Specific Worksheet should be submitted in IRBManager to open the study

https://ncicirb.org/institutions/institution-quickguides/managing-study/opening-study

8. Where can I find the forms required to request approval to open a study at our institution?
   All forms are completed electronically and are located in IRBManager:

https://nci.my.irbmanager.com/xForms/StartForm.aspx?Dashboard=1

9. After activation, what are the CLO responsibilities for reporting to and communicating with the CIRB?
   The CLO (CPN in this case), will submit the initial application and all continuing review applications for a given protocol to the CIRB. After approval, the approved documents, the approval letter, and the approved informed language will be distributed via the CPN website.

The CLO will also submit any reportable events (SAEs, incidents, safety alerts, deviations, and misconduct) that apply across all sites participating in the study.

If there are any deviations or misconduct events that occur at a single site and do not affect the other sites, the report must be submitted by that single site, not the CLO.

10. After activation, what are PO responsibilities for reporting to and communicating with the CIRB?
    Signatory Institution responsibilities are outlined in section 3.2 of the CIRB SOPs (available here:

https://ncicirb.org/system/files/CIRB_SOPs_101817.pdf

11. Among other reporting responsibilities, a Signatory institution is responsible for:
    Providing updates in a timely manner to the NCI CIRB whenever a Signatory Institution Principal Investigator is replaced;
    Notifying the CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the CIRB was responsible for study review;
    Reporting locally-occurring unexpected incidents, experiences, or outcomes that meet the criteria of an unanticipated problem or serious or continuing non-compliance.