

GUIDELINES for NCI CENTRAL IRB (CIRB) Reviewed/Approved Studies

The SUNY Upstate Medical University Institutional Review Board (Upstate IRB) participates in the National Cancer Institute's Central Institutional Review Board (CIRB) Initiative. Local investigators who wish to enroll patients onto CIRB-approved protocols are asked to utilize this service. However, the Upstate IRB must review each protocol on an individual, expedited basis to determine if CIRB oversight is appropriate. What follows are the instructions for submitting these protocols to the Upstate IRB for facilitated review.

NCI CIRB WEBSITE: <http://www.ncicirb.org/> includes general information and access to all study documents.

IRBNet WEBSITE: <http://www.irbnet.org> The Upstate Medical University IRB uses IRBNet for the electronic administration and management of its IRB.

INITIAL SUBMISSION:

1. Follow the Instructions to Create a New Study (Initial Application) found in the "Read Me First~ IRBNet for Upstate Researchers" on IRBNet in the "Forms and Templates" Library. **Include the cooperative group name & study number** (e.g., "CALGB 70401") **as the internal reference #** (project information section of the registration form).
2. Prepare the documents you will submit.
 - Use the IRB forms and templates located on IRBNet and save them to your computer.
 - Upload electronic versions of study documents from the CIRB Web site
 - Revise the consent form to conform to include the Upstate standard required statements.
3. Use the following checklist to make sure that the submission is complete.
 - Registration Form, (IRBNet wizard). **Include the cooperative group name & study number** (e.g., "CALGB 70401") **as the internal reference #** (project information section of the registration form).
 - Upstate Application form for NCI CIRB approved Studies (forms & Templates Library)
 - Complete Study Protocol (from NCI CIRB website)
 - Most current NCI CIRB Application Form (from NCI CIRB website)
 - NCI CIRB approval Letter (from NCI CIRB website)
 - Consent/Assent Forms(s), revised as noted above
 - Pharmacy Worksheet (for studies involving drugs/biologics)
 - Any local recruitment materials
4. Share the study with the research team, especially those who will need to sign the application.
 - Share the Study (Read Only) with Melissa Reale if a pharmacy worksheet is required
 - Share the study (Read Only) with Joseph Spadaro, if Radiation Safety Committee (RSC) review is required

5. Confirm that all study team members have complete the required CITI training- [CITI INFORMATION](#) (studies will not be approved until this requirement has been met).
6. Assure that all needed signatures are completed. The Dept. Chair should only sign when your documents are finalized for submission, i.e., just before you are ready to submit to the IRB.
7. Submit to the IRB- choose submission type “**New Project**” and in the “**Additional Comments**” section please write, “**NCI CIRB Study**”

From the NCI CIRB Handbook for Local Sites:

As part of facilitated review, the local IRB Chair/subcommittee may:

- Apply local boilerplate requirements to the informed consent document to comply with state or local laws, institutional requirements, or IRB policies.
- Make minor word substitutions or additions in the informed consent document to facilitate better comprehension by the local population as long as the proposed changes do not alter the meaning of the CIRB- approved contents and the changes comply with the Cooperative Group guidelines regarding informed consent document changes. The informed consent text may not be otherwise deleted or contradicted.
- Revisions/changes to the informed consent document other than those described above require full Board review at the local level, and facilitated review may not be used.
- The translation of the informed consent form is the responsibility of the local institution.

UPSTATE IRB REVIEW:

The Upstate IRB chairperson, Vice Chairperson or a designated IRB member will conduct a facilitated review of the study materials . There are three possible outcomes:

1. Deferred (Protocol Not Accepted): Local IRB oversight is required. You must complete the IRB Registration and Application form for IRB Review and submit materials to the IRB office by the deadline date for full board review. The CIRB will not be involved in overseeing the protocol.
2. Minor Modifications Required: Specific stipulations must be addressed before the CIRB can be designated as the IRB of record.
3. Approved (Protocol Accepted): The CIRB will be designated as the IRB of record.
 - a. An Approval Letter will be posted on IRBNet.
 - b. The approved Consent/assent Form(s) will be posted on IRBNet

POST-APPROVAL RESPONSIBILITIES

Once the CIRB is designated as the IRB of record, your interaction with the Upstate IRB will be minimal, but very important.

Consent Form Revisions: Consent forms must always be the most current CIRB approved version. The CIRB will notify the PI and coordinator (by e-mail) when changes to the consent have been made and posted on the CIRB website. Make all changes on

the local consent, update the header to match the CIRB approved consent and submit to IRB. An acknowledgement letter will be posted on IRBNet.

Continuing Reviews: Continuing review will be conducted by the CIRB. The PI and the coordinator will receive e-mail notification of these reviews. Please submit the DSMB report (if any) and the CIRB approval letter along with a completed *NCI CIRB Progress Report Form* (available in the Forms & Templates Library) and the updated (new expiration date) local consent form(s). An acknowledgement letter will be posted on IRBNet.

Unanticipated Problems & Adverse Events (AEs): Submit **only local** Unanticipated Problems and AEs to the Upstate IRB per the Upstate IRB Policy at: http://www.upstate.edu/researchadmin/document/adverse_event_guidelines.pdf

The Upstate IRB will review the Unanticipated Problem at the next IRB meeting and post on IRBNet any action needed.

Personnel Changes: Submit any local personnel or site changes to the Upstate IRB ("Amendment Request Form" & Upstate the IRB Registration Form) as they arise. An IRB decision letter will be posted on IRBNet.

Other Local Amendments, Alterations or Updates: Any locally initiated alterations/updates (e.g., advertisements) should be submitted to the Upstate IRB for review. An IRB decision letter will be posted on IRBNet.

Study Closure: To close a CIRB study at this site, submit a completed "NCI CIRB Study Closure Form". The Upstate IRB will notify the NCI CIRB and post a termination letter on IRBNet.

Protocol Amendments (*don't send to the Upstate IRB*): Whenever the Cooperative Group makes protocol amendments; you must use only the CIRB approved version. These can be downloaded from the CIRB website through the investigator log-in access. These should not be submitted the Upstate IRB.

The Upstate IRB will maintain files (either on paper or on IRBNet) of locally approved CIRB protocols with access to all subsequent reviews and other CIRB documentation.

Contact Information:

The CIRB Toll-free Number is **888-657-3711** or e-mail-ncicirbcontact@emmes.com
The Upstate IRB Number is **315-464-4317**