University of Massachusetts Medical School
UMASS

Reliance on National Cancer Institute, Central Institutional Review Board (CIRB)

This guidance reviews the process for use of CIRB for IRB review and oversight of research involving University of Massachusetts-Worcester (UMass) investigators. UMass maintains an Agreement with the CIRB which sets forth understandings, authority, and responsibilities of both institutions.

The University of Massachusetts-Worcester, in an effort to create a framework that will facilitate the review of cooperative group cancer studies, has entered into an agreement with CIRB whereby UMass may rely upon CIRB for IRB review and approval.

In order for the UMass IRB to be able to extend this agreement to include a specific research study, all of the following conditions must apply:

The research is a Phase III Cooperative Group Trial.
A waiver (partial or full) of HIPAA Research Authorization is not required.
If a subject becomes incarcerated, s/he will not remain on the study.

If the study does not meet all of the conditions above, and you wish to rely on CIRB, contact the UMass IRB **before** preparing the submission to CIRB.

Although UMass may rely upon CIRB for review of certain research projects, the Institution is still responsible for the conduct of that research. Therefore, while not responsible for IRB approval of CIRB-submitted studies, the UMass IRB must be aware of and approve of the submission being sent to CIRB through an administrative pre-review. CIRB will not review any UMass study prior to UMass administrative pre-review.

APPROVAL PROCESS:

IN IRB MANAGER: Instructions for completing the worksheets about local context can be found on the CIRB website at https://ncicirb.org/cirb/ Click on Independent Model Information

- Confirm that the Annual Principal Investigator Worksheet about Local Context is Approved by the CIRB.
- Identify the Study: Check the CIRB Website at www.cirb.org and confirm that the study to be opened is on the CIRB Menu.
- Complete the Study-Specific Worksheet About Local Context: This should be completed by the lead researcher (or designee) via IRB Manager (https://irbmanager.becirb.com)

IN eIRB:

- Place "CIRB" in front of the Study Nickname to indicate that the protocol is reviewed by the CIRB.
- Upload the following documents in eIRB:
    - Cooperative Group Master Protocol in place of the Investigator Study Plan
    - Annual Principal Investigator Worksheet About Local Context
    - Draft Study-Specific Worksheet about Local Context
    - CIRB Approved Consent Form
    - Most current CIRB approval letter for study

- Subject Consent Form(s) (**Subject injury language must be taken from the current UMass approved template found at http://www.umassmed.edu/ccts/irb/forms_templates/**
- NOTE: No revisions to the CIRB-approved consent form are allowed except adding the CIRB approved cover sheet and replacing CIRB consent form language with the CIRB-approved UMass specific language, where applicable.
- HIPAA Research Authorization Form
- UMass specific recruitment materials
- Any other required UMass approvals (PRC, IBC, RSC, etc.), which must be obtained before submitting to CIRB

1. Once all required documents have been uploaded into eIRB, the PI has submitted the study, and the submission is in Pre-Review (and is no longer in Pre-Submission), the UMass IRB will conduct an administrative review which includes the following activities:

    - Confirming that the PI is not restricted as per the Investigator's Manual
    - Reviewing the list of active study staff for current CITI human subjects research training
    - Reviewing the uploaded documents to assure that the study meets the conditions of the reliance agreement
    - Notifying the study team of any issues, including required changes to the consent form, through Pre-Review (or Non-Committee Review) Clarifications Requested in eIRB
    - Sending confirmation (via eIRB Modifications Required to Secure Approval [MRSA]) to the study team indicating that the application may be submitted to CIRB

2. Once CIRB has approved the study, the CIRB Approval of Study Specific Worksheet about Local Context (CIRB approval letter) must be uploaded to Section 7.0 Attachments as the response to MRSA. Once the PI responds to the IRB decision, the IRB will issue final "approval"*.

PI POST-CIRB APPROVAL RESPONSIBILITIES:

Once CIRB approval is granted, CIRB will maintain oversight of the study. Therefore, subsequent submissions (e.g., amendments, continuing reviews, reportable events) go directly to CIRB for review. **However, the annual continuing review and other items listed below must also be submitted to UMass through eIRB.**

SUBMIT TO CIRB:

- AEs and SAEs reportable per the cooperative group guidelines
- Any potential unanticipated problem involving risks to subjects or others, and serious/continuing noncompliance
- Renewal and amended protocol documents to the appropriate cooperative group

SUBMIT IN eIRB:

- Changes in personnel as they happen
    - Use Edit Research Staff to report changes to non-PI personnel
    - Submit a Modification to report a change in PI

- Any potential unanticipated problem involving risks to subjects or others, and serious/continuing noncompliance via Reportable New Information
- The annual Continuing Review, including:
    - Current CIRB Approval letter
    - A Modification to submit updated documents (e.g., consent form, recruitment materials, sponsor protocol)
- Final Continuing Review with closing report submitted to CIRB when study closes at UMass

**Note: eIRB is not designed to keep track of protocols for which the UMass IRB relies on an external IRB. Therefore, for those studies for which UMass relies on the CIRB for review and approval, the term "approved" conveys acknowledgement that the study is being conducted at UMass and does not mean that the UMass IRB has reviewed and approved the study for compliance with regulatory criteria*.