

**National Cancer Institute Central
IRB Initiative**

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Version: 1.0
Date: 06/26/2009
Approved by: Interim Vice Chancellor for Research
AAHRPP REF#: 198
AAHRPP Elements: I.1.A., I.2.B,

INTRODUCTION:

- I. The Central Institutional Review Board (CIRB) Initiative is sponsored by the National Cancer Institute (NCI) in consultation with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP).
- II. UIC has chosen to participate with NCI in this initiative, which is a "facilitated review" process that streamlines local IRB reviews of adult and pediatric national multi-center cancer treatment trials.
- III. The NCI CIRB has two panels:
 - A. The Adult NCI CIRB reviews all Phase 3 Cooperative Group trials from the ACOSOG, CALGB, ECOG, GOG, NCCTG, NCIC, NSABP, RTOG, and SWOG, as well as any other studies opened in the Cancer Trials Support Unit (CTSU).
 - B. The Pediatric NCI CIRB reviews all NCI-approved COG Phase 2, 3, and Pilot protocols.

DEFINITIONS:

- I. **FACILITATED REVIEW:** a review to streamline the review process by accepting the NCI CIRB's responsibility to ensure that a comprehensive review of the research protocol was completed.
 - A. Facilitated review differs from expedited review in that the NCI CIRB makes the initial determinations related to 45 CFR 46, 21 CFR 50, and the regulations related to Subpart D.
 - B. Facilitated review allows the local IRB to retain authority to review the protocol for local context.

POLICY:

- I. UIC has amended its FWA to utilize the NCI CIRB initiative.
- II. UIC IRBs will perform a facilitated review and determine on a protocol-by-protocol basis to accept the NCI CIRB review in lieu of a full board review at UIC or to conduct its own review.

- A. UIC IRB 1 will perform facilitated reviews on adult NCI CIRB approved protocols.
 - B. UIC IRB 3 will perform facilitated reviews on pediatric NCI CIRB approved protocols.
- III. If the UIC IRB accepts the NCI CIRB review,
- A. The CIRB becomes the IRB of Record for the research and is responsible for continuing review as well as review of subsequent amendments and serious adverse events (SAE) as notified by the Group.
 - B. The UIC IRB is responsible for local context and oversight, including the review of:
 - 1. Local unanticipated problems;
 - 2. Local serious adverse events; and
 - 3. Amendments affecting local conduct of the study.
 - 4. Consent documents (local context language)
- IV. Protocols involving JBVAMC as a performance site are NOT eligible for facilitated review.
- V. Protocols involving Rush University Medical Center, John H. Stroger, Jr. Hospital of Cook County, and Mercy Hospital and Medical Center as a performance site are eligible for facilitated review.

PROCEDURE:

- I. Initial Review.
- A. To prepare this request, the investigator will submit the NCI CIRB approved research protocol, informed consent / parental permission / HIPAA document (revised to adhere to the UIC IRB's requirements), and assent document(s), as applicable. The documents are available at www.ncicirb.org. All other relevant NCI CIRB documents (e.g., CIRB application, meeting minutes, reviewer comments, final approval notices, etc) available in the Participants' Area of the NCI CIRB website will be downloaded by the OPRS staff.
 - B. The investigator will prepare a submission to the UIC IRB that includes:
 - 1. UIC OPRS form *UIC Facilitated Review Application: NCI CIRB Approved Research Study*;
 - 2. Applicable appendices;
 - 3. Documentation of Investigational Drug Service (IDS), Cancer Center (CC PRC), Radiation Safety Committee (RSC) and/or Institutional Biosafety Committee (IBC) approval, as appropriate;
 - 4. NCI CIRB Approved research protocol;
 - 5. CIRB Approved Informed Consent Document(s);
 - 6. NCI CIRB Approval letter;
 - 7. Consent/assent/permission form(s) and information sheets (if applicable) that include the local contact information and local liability, injury and/or confidentiality language;
 - 8. HIPAA authorization(s) (if separate from the consent/permission);

9. Recruitment materials;
10. Other relevant documents available from the NCI CIRB;
11. Other relevant documents from performance sites (Mercy, Rush, Stroger).

II. Continuing Review.

- A. The investigator will receive email alerts from the NCI CIRB and from OPRS regarding the need for continuing review of NCI CIRB approved protocols.
- B. Prior to expiration of NCI CIRB/UIC IRB approval, the investigator must seek continuing review or close out the study by submitting a final report. For continuing review or to close the study, the investigator should submit a report of a project to the UIC IRB by using the UIC OPRS form *Facilitated NCI CIRB Continuing Review of Research*. The following information must be included:
 1. A completed UIC OPRS *Facilitated NCI CIRB Continuing Review of Research* application form;
 2. Current NCI CIRB Approved Research protocol;
 3. NCI CIRB Continuing Approval letter;
 4. Current consent/assent/permission form(s) and information sheets (if applicable) that include the local contact information and local liability, injury and/or confidentiality language if enrollment will continue at the UIC site;
 5. Recruitment materials;
 6. UIC Cancer Center Protocol Review Committee submission receipt;
 7. Other relevant documents available from the NCI CIRB.

III. Amendments.

- A. NCI CIRB approved amendments will be forwarded through bi-monthly e-mail alerts to investigators by the NCI CIRB Initiative and subsequently submitted to the OPRS by the investigator.
- B. The investigator should submit two copies of the amendment submission to the IRB.
- C. The amendment submission will include:
 1. A completed UIC OPRS [*Amendments to Previously Approved Research*](#) form that provides a summary of the changes
 2. All revised documents (protocol, consent form, etc.), if applicable
 3. NCI CIRB approval letter that corresponds to the proposed amendment.
- D. If the consent form is amended, the submitted consent should include local contact information, and other local language previously required by the UIC IRB (unless the amendment is also requesting a change to this local language). A tracked-changes consent document, as well as a clean (unmarked) consent document, should be submitted along with a completed UIC OPRS [*Amendments to Previously Approved Research*](#) form to the UIC IRB.

IV. Unanticipated problems or other events requiring prompt reporting.

- A. At the time of continuing review, the investigator must report a summary of all unanticipated problems and any local serious-related adverse events.
- B. For any unanticipated problems or other events requiring prompt reporting connected with a UIC IRB/NCI CIRB approved study that is from a non-UIC study site, the NCI CIRB Initiative will notify investigators. Such reports will be processed according to UIC HSPP policies and procedures.
- C. Unanticipated problems or other events requiring prompt reporting and/or serious or continuing non-compliance that involve the UIC study site must be promptly reported to the UIC IRB using the Prompt Reporting Form and should not be reported to the CIRB. The investigator should continue to report SAEs to the Cooperative Group as per the Cooperative Group Guidelines.
- D. Unanticipated problems within the purview of the CIRB are those unexpected incidents, events or outcomes which the sponsor identifies and which impact the trial nationally. These are reviewed by the CIRB and the CIRB accepts the responsibility to ensure reporting to the appropriate agency, i.e. OHRP and/or FDA.

V. Facilitated Review Process.

- A. A review of the submission (initial, continuing, amendment) will be undertaken by the IRB Chair/Vice-Chair or designee through facilitated review procedures. The designated reviewer will receive all submitted materials as well as any documents available on the restricted NCI CIRB web site. Access to the NCI CIRB restricted web site requires a user ID and password and is only available to IRB administrators, IRB chairs and/or IRB members. OPRS staff will facilitate the review process by downloading and making available to the reviewers all protocol specific additional materials (such as minutes and NCI CIRB reviewer comments) from the NCI IRB site.
- B. The role of the UIC IRB reviewer is to determine whether local concerns exist that need to be addressed and whether the NCI CIRB review should be accepted by UIC. Such a review will ensure UIC compliance with OHRP's guidance that "...an institution relying upon another institution's IRB has a responsibility to ensure that the particular characteristics of its local research context are considered through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other members of its local IRB." [Guidance document *IRB Knowledge of Local Research Context*, dated August 27, 1998]. The UIC investigator and the UIC IRB may modify the NCI CIRB-approved consent language as needed to comply with state and local laws and requirements or add clarifying language. These changes do not have to be submitted to NCI CIRB. However, no sections may be removed from the NCI CIRB-approved consent and no changes can be made which would alter the meaning of any content.
- C. The reviewer's scope of authority, while restricted, is more than the mere authority to accept or reject the NCI CIRB approval. If the UIC IRB requires substantive changes to the protocol or revisions to the informed consent document that would alter content, then the UIC IRB will communicate with the UIC investigator that NCI CIRB approval is not accepted.

- D. The UIC IRB may:
 - 1. Add stipulations or local requirements to protocols, particularly to increase subjects' safety, to clarify procedures, etc., but may not delete or contradict any protocol contents.
 - 2. Require additions or deletions to the informed consent, dealing with state and local law, institutional requirements, or UIC IRB policies.
 - 3. Require minor word substitutions or additions in the informed consent document, particularly to facilitate better comprehension by the local population, as long as the proposed changes do not alter the meaning of the CIRB approved contents.
- E. The UIC IRB reviewer's requested changes, stipulations, and requirements will be given to the OPRS staff and subsequently communicated to the UIC investigator who will need to respond to the concerns before CIRB approval is accepted.
- F. The investigator's response (and any modified documents) will be processed as a modification through the facilitated process. Any UIC IRB imposed requirements to the NCI CIRB approved protocol and/or consent form will constitute a request placed only on the local investigator (UIC, Rush University Medical Center, Mercy Hospital, Stroger Hospital of Cook County) and will not become a formal part of the protocol.
- G. If the NCI CIRB approval is not accepted at initial review, continuing review or during the review of an amendment and if the UIC investigator still wants to conduct the trial, then a new initial UIC Health and Biological Sciences Application Form for convened IRB review will need to be completed and submitted to the UIC IRB according to standard procedures governing submission of new studies that require review by the convened UIC IRB. For continuing review or review of an amendment, the submission will be referred to the convened board for review. The UIC IRB may accept the NCI CIRB approval or alternatively withdraw from the NCI CIRB collaboration, in which case the UIC IRB would become the primary IRB of record.
- H. If the NCI CIRB approval is accepted for initial review, OPRS will notify the UIC investigator and the NCI CIRB Initiative of the acceptance decision. OPRS must notify the NCI CIRB Initiative each time the UIC IRB accepts the NCI CIRB review and approval of a protocol. OPRS does not need to notify the NCI CIRB Initiative if the UIC IRB accepts NCI CIRB continuing review approval or approval of an amendment. The OPRS will, however, notify the PI about the acceptance decision. Both the UIC IRB and investigator will keep appropriate records of all such decisions and communications on file.
- I. The decision to accept NCI CIRB approval will be conveyed to IRB #1 or #3 as a line item on the next agenda.
- J. Projects for which the UIC IRB accepts NCI CIRB approval may also need to be submitted and reviewed by the institution's Radiation Safety Committee (RSC) and Institutional Biosafety Committee (IBC). In such situations, no project-related activities may take place before appropriate RSC and/or IBC approvals are obtained. NCI CIRB review and approval will be formally accepted only after RSC and/or IBC approvals are on file with OPRS.

VI. Final Report.

- A. When the NCI CIRB or investigator has completed a research protocol (including no further data analysis and any publications are in press with no possibility for requests for additional data analysis), a final report must be submitted to the IRB/OPRS.
- B. The investigator should submit the “Final Research Report” form to be reviewed via facilitated review procedures. A final report must be submitted even if the research was never initiated, no subjects were enrolled, or the investigator is terminating the research earlier than originally planned.
- C. A review of the final report will be undertaken by the IRB Chair/Vice Chair or designee through facilitated review procedures. The reviewer may accept the NCI CIRB approval of the closure as is, accept it with minor modifications, or not accept the final report.
- D. Once a study has been closed via a final report, it cannot be re-opened. If a later use for the research data is identified, then the investigator must submit a new research application for the use of the previously collected data. This use of the data may qualify for an exemption, if the data is existing and recorded without identifiers.

VII. Transferring of ongoing studies to NCI CIRB.

- A. Investigators with studies which were previously approved by the UIC IRB and who wish to be transferred to the NCI CIRB may do so at the time of continuing review by submitting a request for continuing review on the UIC OPRS form *Facilitated NCI CIRB Continuing Review of Research*. Under the study progress section, the investigator should check that a transfer to the NCI CIRB is being requested. The submission to the UIC IRB include revised consent forms in the NCI CIRB format (if the study is still open to enrollment), a copy of the latest NCI CIRB approved protocol, and any other relevant documents. The investigator would also need to submit a final report for the study to be transferred to the NCI CIRB, as the same protocol cannot be open under two different protocol numbers.
- B. A review of the continuing review submission will be undertaken by the IRB Chair/Vice-Chair or designee through facilitated review procedures. All other relevant NCI CIRB documents (e.g., NCI CIRB application, meeting minutes, reviewer comments, final approval notices, etc) available in the Participants’ Area of the NCI CIRB website will be downloaded by the OPRS staff. The reviewer may accept the NCI CIRB approval as is, accept it with minor modifications or not accept the NCI CIRB approval.
- C. If the NCI CIRB approval is not accepted, and if the UIC investigator still wants to continue the trial, then the study will remain with the UIC IRB as the primary IRB of record, and the OPRS continuing review process for studies that do not utilize the NCI CIRB will need to be followed.
- D. If the NCI CIRB approval is accepted, UIC IRB will notify the investigator and NCI CIRB Initiative about the acceptance decision. The UIC IRB and the investigator will keep appropriate records of such a decision on file. The decision to accept NCI CIRB approval will be conveyed to IRB #3 as a line item on the agenda.

REFERENCES:

<http://www.ncicirb.org/>
OHRP guidance document *IRB Knowledge of Local Research Context*, dated August 27, 1998