

**UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE
CHATTANOOGA INSTITUTIONAL REVIEW BOARD
IRB EXPEDITED REVIEW OF NEW STUDIES**

I. PURPOSE

To specify the procedures for utilizing the NCI CIRB for studies conducted by investigators at the University of Tennessee College of Medicine Chattanooga and affiliated institutions.

II. SCOPE

This SOP applies to all investigators performing research under the auspices of the University of Tennessee College of Medicine Chattanooga IRB and its affiliated institutions.

Personnel responsible:

IRB administrative staff, IRB members, and investigators.

III. BACKGROUND

The NCI CIRB Initiative is a cooperative venture with FWA institutions that is intended to create a more effective and efficient mechanism for IRB oversight of NCI-sponsored Cooperative Group clinical trials. Specifically, the NCI CIRB is designed 1) to improve access to NCI-sponsored Cooperative Group clinical trials for potential study participants and their physicians by enabling rapid approval of clinical trials through the use of the CIRB review process; 2) to enhance the protection of study participants by providing consistent expert IRB review at the national level; and 3) to reduce the administrative burden for local IRBs and research staff. Under an authorization agreement with the NCI CIRB, the CIRB is the sole IRB of record responsible for the review of cooperative group oncology studies performed at enrolled Signatory Institutions.

The UTCOMC IRB maintains responsibilities for local oversight of performance of CIRB-approved studies. These responsibilities involve ensuring the safe and appropriate performance of the research at its affiliated institutions including, but not limited to, ensuring the initial and ongoing qualifications of investigators and research staff; ensuring adequate resources to perform the research including proper facilities and equipment to conduct research procedures; overseeing the conduct of the research; monitoring protocol compliance, maintaining compliance with state, local or institutional requirements related to the protection of human subjects; providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research; and investigating, managing, and providing notification to the NCI CIRB of any study-specific incidence,

experience, or outcome that seems to rise to the level of an unanticipated problem and/or serious or continuing noncompliance.

In accordance with:

National Cancer Institute Central Institutional Review Board

<https://www.ncicirb.org/about-cirb>

Compliance with this policy also requires compliance with state or local laws and regulations that provide additional protections for human subjects.

IV. DEFINITIONS

1. **Affiliate Institutions** are defined by the CIRB as meeting all of the following criteria:
 - a. The local context considerations of the Affiliate Institution are the same as the Signatory Institution;
 - b. The boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution; and
 - c. The conduct of research at the Affiliate Institution is monitored by the same office as the Signatory Institution.
2. **Boilerplate language** is the information added by the Signatory Institution Principal Investigator to the CIRB-approved consent form after the CIRB approves it. Boilerplate language provides information that is institution-specific and addresses local context considerations for the Signatory Institution and its Component and Affiliate Institutions. This information may include contact information for the Signatory Institution Principal Investigator, institution-specific injury language, institution-specific pregnancy language, and other institution-specific information. Updates to boilerplate language must also receive CIRB approval prior to implementation.
3. **CIRB** refers to all four CIRBs unless otherwise stated.
4. **Component Institutions** are defined by the CIRB as meeting all the following criteria:
 - a. The Component Institution operates under a different name than the Signatory Institution, but the Signatory Institution has legal authority for the Component Institution;
 - b. The FWA number for the Component Institution are the same as the Signatory Institution;
 - c. The boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution; and

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- d. The conduct of research at the Component Institution is monitored by the same office as the Signatory Institution.
 5. **Continuing Noncompliance** is a pattern that, if unaddressed, could jeopardize the rights and welfare of research participants or the integrity of the study data due to noncompliance with the protocol, Federal regulations, and/or the requirements of the CIRB. (See [SOP: Investigator Noncompliance](#))
 6. **Serious Noncompliance** is noncompliance that adversely affects the rights and welfare of study participants or results in any untoward medical occurrence that meets the criteria of “serious” or significantly impacts the integrity of study data. (See [SOP: Investigator Noncompliance](#))
 7. **Signatory Institution** is the institution that signs the Authorization Agreement and Division of Responsibilities document and has a direct relationship with the CIRB. The responsibilities of the Signatory Institution are listed on the Authorization Agreement and Division of Responsibilities document. Signatory Institution Principal Investigators must be “employed by” or “have a relationship with” the Signatory Institution to be eligible to open studies.
 8. **Signatory Institution Primary Contact** is the person who acts as the point of contact for the CIRB should the CIRB have any questions about the research being conducted at the Signatory Institution, Component Institution(s), or Affiliate Institution(s). The Signatory Institution Primary Contact receives or is copied on all correspondence from the CIRB to the Signatory Institution and the Signatory Institution Principal Investigator(s). This individual is also responsible for the submission of Annual Signatory Institution Worksheet About Local Context, and may also assist with other Worksheet completion.
 9. **Signatory Institution Principal Investigator** is an investigator at the Signatory Institution who is a member of the group coordinating the study and therefore is able to open studies with the CIRB. The Signatory Institution Principal Investigator is responsible for the research at their institution and all research activities conducted by the research staff (including any research activity at Component or Affiliate Institutions) for all studies opened in their name.
 10. **Unanticipated Problem** is defined as follows:
 - a. The incident, experience, or outcome is unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol or the investigator’s brochure and the characteristics of the subject population being studied while the protocol was followed as written;
 - b. There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and

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- c. Subjects or others are at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized due to the incident, experience, or outcome.

V. PROCEDURES

1. When an investigator wishes to register a Cooperative Group clinical trial that has been approved by the NCI CIRB, the following steps must be followed:
 - a. The principal investigator (PI) must complete and submit to the NCI CIRB the Study-Specific Worksheet About Local Context;
 - b. The investigator/research staff will complete the *UTCOMC IRB Initial Smart Form: Study/Project Application*, requesting to register a research study that was approved by the NCI CIRB, and submit one copy of each of the following documents obtained from the CIRB Website (www.ncicirb.org):
 - i. Study protocol;
 - ii. CIRB final approval letter (CIRB initial approval letter);
 - iii. Most recent CIRB approval for continuation (if applicable);
 - iv. CIRB approval of the Study-Specific Worksheet About Local Context; and
 - v. CIRB-approved informed consent document modified to include required local elements.
 - c. In the *UTCOMC IRB Smart Form: Study/Project Application*, Section 3.0, list all key study personnel associated with the research study. Alternatively, list the principal investigator, study coordinator/contact, and if applicable, list the appropriate Research Administrative Specialist. In addition, upload a spreadsheet of all key study personnel associated with the study, including who will have access to the research records, who will be obtaining informed consent, and the dates of completion of the online CITI course.
 - d. The expiration date of CIRB studies will be the CIRB expiration date;
 - e. The UTCOMC IRB will issue a letter via the UTCOMC IRB electronic system, IRBNet, acknowledging receipt of the appropriate study documentation and that the NCI CIRB is the IRB of record for the specific study; and
 - f. A copy of the initial review documents will be maintained in the local IRB study file.
2. The following NCI CIRB-approved boilerplate language must be incorporated into the NCI CIRB-approved model consent form to create the consent form(s) to use for a specific study:
 - a. The consent form must be prepared on UTCOMC letterhead;
 - b. Pages must be numbered 1 of 5, 2 of 5, etc.;
 - c. A line must be inserted for the research subject's initials or initials of the LAR (_____) at the bottom of all pages except the signature page (where the line for the initials is permitted but not necessary);
 - d. The compensation for injury section must include the standard compensation disclaimer contained in the current UTCOMC IRB main consent form template;
 - d. Contact information for the local investigator and the UTCOMC IRB must be included as outlined in the Questions section of the current UTCOMC IRB main consent form template;

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- e. The signature line section of the consent form must be formatted according to the current UTCOMC IRB main consent form template; however, the NCI CIRB requires the use of their consent statement rather than the UTCOMC IRB consent statement; and
 - f. The assent pages of the template should include include the following additional instructions to the author of the consent form when assent is not obtained but a pediatric or adult subject is enrolled anyway: *[Delete if this option does not apply to your study. Note that in limited and specific circumstances, assent can be waived if “the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.” These waivers are only appropriate when the study intervention is likely to be more effective than other treatments available outside the trial and should only apply to those components that are judged to be more beneficial. To waive assent under 46.408, the PI would be required to submit an Assent Waiver request to the CIRB explaining the reason for waiving assent. The decision to waive assent under this circumstance would be determined by the CIRB.]*
3. No changes should be made to the NCI CIRB-approved model consent form with the exception of the NCI CIRB-approved boilerplate language; the UTHSC IRB will obtain CIRB approval of changes to the boilerplate language prior to implementation; and NCI CIRB approval of translations of the consent form will be obtained prior to implementation.
 4. For CIRB approved studies, the CIRB is responsible for conducting review of the initial application, continuations, and amendments, as well as review of any other study-specific documents submitted by the Study Chair to the NCI CIRB.
 5. The CIRB conducts **continuing review** for all studies on its menu, as UTCOMC has no regulatory responsibilities for continuing review from the perspective of the CIRB. The local principal investigator will submit to the UTCOMC IRB via the IRBNet submission form, “Checklist of Documents for Submission,” the following documents related to the continuing review from the CIRB website:
 - a. CIRB application for continuing review;
 - b. Report of study (if applicable);
 - c. DSMC meeting minutes (if applicable); and
 - d. CIRB approval for continuation.

Upon receipt of the appropriate documentation, the UTCOMC IRB will issue an acknowledgement letter via IRBNet.

6. The CIRB reviews **amendments** for all studies on its menu, as UTCOMC has no IRB review responsibilities when an amendment is provided for use from the perspective of the CIRB. The local principal investigator will submit to the UTCOMC IRB via the IRBNet submission form, “Documents from Reviewing IRB,” the following documents from the CIRB website:
 - a. Revised study protocol;

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- b. Summary of changes memo;
 - c. CIRB revised consent form (if applicable); and
 - d. CIRB approval of revision.

Upon receipt of the appropriate documentation, the UTCOMC IRB will issue an acknowledgement letter via IRBNet.

7. **Changes in local key project personnel** should be submitted to the UTCOMC IRB via IRBNet submission form, “Documents from Reviewing IRB,” simultaneous with submission of personnel changes to the CIRB. The following documents should be attached:
 - a. Revision Change Form C and/or updated delegation log listing all key study personnel and current online CITI training;
 - b. Revised consent form (if applicable);
 - c. If the Principal Investigator (PI) is replaced, the CIRB requires submission and approval of the Annual Principal Investigator Worksheet About Local Context prior to finalizing the replacement PI.

Upon receipt of the appropriate documentation, the UTCOMC IRB will issue an acknowledgement letter via IRBNet.

8. **Unanticipated problems**, including adverse events, which do not involve study participants at the local study site(s), should **not** be submitted to the UTCOMC IRB. Unanticipated problems should be submitted to the IRB only when they involve study participants at UTCOMC clinical sites and satisfy the criteria for “unanticipated problems” as specifically defined in OHRP guidance. These reports should be submitted in the usual manner per the UTCOMC IRB standard operating procedure (See [UTCOMC IRB SOP Reporting Unanticipated Problems, Including Adverse Events](#)).
9. Cooperative Group studies currently approved by the UTCOMC IRB may be **transferred** to the NCI CIRB. For studies transferred to the CIRB, a note-to-regulatory file should state that the protocol was transferred to the NCI CIRB, including an effective date of the transfer. In addition, the Principal Investigator must submit a Study-Specific Worksheet About Local Context to the CIRB. Enrolled study participants do not have to be re-consented.
10. The UTCOMC IRB, Signatory Institution Principal Investigator, and research staff must comply with the CIRB requirements and directives as defined in the [CIRB SOPs](#) and in correspondence from the CIRB.
11. The UTHSC IRB will report to the NCI CIRB the names of any Component or Affiliate Institution that meet the following definitions:
 - a. Component Institutions are defined by the CIRB as meeting all of the following criteria:
 - i. The Component Institution operates under a different name than the Signatory Institution, but the Signatory Institution has legal authority for the Component

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- Institution;
 - ii. The FWA number for the Component Institution is the same as the Signatory Institution;
 - iii. The local context considerations of the Component Institution are the same as the Signatory Institution;
 - iv. The boilerplate language and institutional requirements of the Component Institution are the same the Signatory institution; and
 - v. The conduct of research at the Component Institution is monitored by the same office as the Signatory Institution.
- b. Affiliate Institutions are defined by the NCI CIRB as meeting all of the following criteria:
- i. The local context considerations of the Affiliate Institution are the same as the Signatory Institution.
 - ii. The boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution; and
 - iii. The conduct of research at the Affiliate Institution is monitored by the same office as the Signatory Institution.
12. The UTCOMC IRB maintains responsibilities for local oversight of performance of CIRB-approved studies. These responsibilities involve the Signatory Institution Principal Investigator ensuring the safe and appropriate performance of the research at the Signatory Institution and at all Component and Affiliate Institutions. This includes, but is not limited to:
- a. Ensuring the initial and ongoing qualifications of investigators and research staff;
 - b. Ensuring adequate resources to perform the research including proper facilities and equipment to conduct research procedures;
 - c. Overseeing the conduct of the research;
 - d. Monitoring protocol compliance;
 - e. Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects. When in conflict with CIRB determinations, the most restrictive requirement applies;
 - f. Providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research; and
 - g. Investigating, managing, and providing notification to the NCI CIRB of any study-specific incidence, experience, or outcome that seems to rise to the level of an unanticipated problem and/or serious or continuing noncompliance. When notifying the NCI CIRB of a potential unanticipated problem and/or serious or continuing noncompliance, UTCOMC must provide a plan to manage the incident, experience, or outcome, including measures to prevent similar occurrences.
13. As a part of ensuring safe and appropriate performance of research, the UTCOMC IRB has the authority to observe any aspect of the research process including observing the consent process. The CIRB retains the authority to direct the UTCOMC IRB to perform such inspections as necessary to assure adequate regulatory compliance.

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14. The NCI CIRB will report determinations of unanticipated problems and/or serious or continuing noncompliance to OHRP and FDA, as applicable. Individuals included on the original correspondence will also be included on the report to OHRP and FDA.
 15. The UTCOMC IRB will provide or will notify the investigators to provide updates in a timely manner to the NCI CIRB whenever a Signatory Institution Principal Investigator is replaced. The CIRB requires submission and approval of the Annual Principal Investigator Worksheet About Local Context prior to finalizing the replacement of the Principal Investigator.
 - a. Local context considerations for UTCOMC include, but are not limited to:
 - i. State and local laws;
 - ii. [Conflict of interest policy](#);
 - iii. Boilerplate language for inclusion in the consent form;
 - iv. Any other institutional requirements; and
 - v. Catchment area, where the institution's study participant population for NCI-sponsored studies is located.
 - b. Local context considerations for the Signatory Institution Principal Investigator include, but are not limited to:
 - i. Resources available to support research;
 - ii. Extent of existing populations eligible for enrollment;
 - iii. Safeguards used to protect those populations;
 - iv. Privacy and confidentiality protections; and
 - v. Any unique study-specific considerations.
 16. The UTCOMC IRB will notify the NCI CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for study review.
 17. The UTCOMC IRB will complete or will notify the investigators to complete and submit the Annual Signatory Institution Worksheet About Local Context, the Annual Principal Investigator Worksheet About Local Context, and any other worksheets/forms required by the NCI CIRB for participation.
 18. The UTHSC IRB will update or will notify the investigator to update the Annual Signatory Institution and Principal Investigator Worksheets on an ongoing basis if there are changes to the Component or Affiliate Institutions, boilerplate language, other institutional requirements, or any other changes. Per the CIRB's implementation of an **Annual Worksheet Review** process, UTCOMC and the Principal Investigators will review the Worksheets at least annually to verify the Worksheets reflect the current policies and procedures for UTCOMC and the Principal Investigator. This is not part of the regulatory-required continuous review process.
 19. The UTHSC IRB will remind CIRB-approved Principal Investigators to complete and submit the Study-Specific Worksheet About Local Context to open a study.

20. The UTCOMC IRB will notify the investigators to incorporate the NCI CIRB-approved boilerplate language into NCI CIRB-approved model consent form(s) to create the consent form(s) to use for a specific study:
 - a. The UTCOMC IRB will make no language changes to the consent form(s) with the exception of the NCI CIRB-approved boilerplate language, removal of instruction/notes from the coordinating Group, and dates embedded to track changes;
 - b. The UTHSC IRB will obtain NCI CIRB approval of any changes to the boilerplate language prior to implementation, including information captured in the consent form header and footer; and
 - c. The UTCOMC IRB will obtain NCI CIRB approval of translations of the consent form prior to implementation.
21. The UTCOMC IRB will follow the instructions in the outcome letter from the CIRB for obtaining re-consent upon the Study Chair or CIRB's determination that study participants are required to be consented using the most recent amendment. If local policy requires re-consent when the Study Chair or CIRB do not, those local policies should be followed.
22. The UTCOMC IRB will maintain a regulatory file for each study under NCI CIRB purview as per local institution and sponsor policy.
23. The NCI CIRB will make the determination of whether **assent** of the child is required. The Principal Investigator must comply with the determinations of the NCI CIRB regarding the assent process and age range. The NCI CIRB does not make a determination regarding the requirement for the documentation of assent. Principal Investigators must follow local institutional policy regarding how to document assent. Procedures for obtaining and documenting assent should follow the UTCOMC IRB policies and procedures outlined in [SOP: Additional Protections: Children](#).
24. Compliance with **HIPAA** regulations are considered an institutional requirement and remain the purview of the local institution. The CIRB does not function as a Privacy Board and therefore does not review or approve HIPAA authorization language nor does the CIRB permit HIPAA language to be included as boilerplate language. HIPAA requirements must be addressed by the institution in a separate document. The UTCOMC IRB accordingly requires the use of a separate HIPAA Research Authorization form that incorporates the standard Authorization to Use and Disclose Protected Health Information for Research Purposes language contained in the current UTCOMC IRB main consent form template.
25. The NCI CIRB will determine whether individuals with **impaired decision-making capacity** as a category are eligible for a study. Procedures for obtaining consent from a legally authorized representative and assent should follow UTCOMC IRB policies and procedures outlined in the [SOPs regarding informed consent](#).
26. The UTCOMC IRB will conduct full board review of any study enrolling **prisoners**, as

the NCI CIRB is not constituted to review studies enrolling prisoners, per 45 CFR 46 Subpart C. Submission of a study for full board review by the UTCOMC IRB must follow the procedures outlined in [SOP: Procedures for Full Board Review](#). Inclusion of prisoners in a previously initiated, CIRB-approved study requires the submission of a *Form C: Change Request/Amendment* via IRBNet for review and approval by the UTCOMC IRB.

27. The NCI CIRB's review is designed to meet the requirements of for review by an Institutional Review Board.