

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
UTILIZATION OF THE NCI CIRB**

I. PURPOSE

To specify the procedures for utilizing the NCI CIRB for studies conducted by investigators at the University of Tennessee Health Science Center and affiliated institutions.

II. SCOPE

This SOP applies to all investigators performing research under the auspices of the University of Tennessee Health Science Center 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 participating institutions.

The UTHSC 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. 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 investigator/research staff will complete the Form 1: 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;
 - b. In the Form 1: 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.
 - c. In the Form 1: Study/Project Application, Section (415), list the contact information for the Principal Investigator(s) and all Study Contacts listed in Section 3.0 and indicate who will obtain informed consent and have access to the research records. For all other key study personnel listed in Section 3.0, indicate in this section who will obtain informed consent and who will have access to research records.
 - d. The expiration date of CIRB studies will be the CIRB expiration date;

- e. The principal investigator (PI) must complete and submit to the NCI CIRB the Study-Specific Worksheet About Local Context;
 - f. The UTHSC IRB will issue a letter acknowledging receipt of the appropriate study documentation and that the NCI CIRB is the IRB of record for the specific study via the UTHSC IRB electronic system, iMedRIS; and
 - g. 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 to use for a specific study:
- a. The consent form must be prepared on UTHSC letterhead according to the current UTHSC IRB consent form template;
 - b. The confidentiality section of the consent form must include the Authorization to Use and Disclose Information for Research Purposes template utilized by the UTHSC IRB (see UTHSC SOP HIPAA Authorization for the Use of PHI in Research);
 - c. The compensation for injury section must include the standard compensation disclaimer contained in the current UTHSC IRB main consent form template;
 - d. Contact information for the local investigator and the UTHSC IRB must be included as outlined in the Questions section of the current UTHSC IRB main consent form template;
 - e. The signature line section of the consent form must be formatted according to the current UTHSC IRB main consent form template; however, the NCI CIRB requires the use of their consent statement rather than the UTHSC IRB consent statement; and
 - f. The assent pages of the template should 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. The local principal investigator will submit to the UTHSC IRB via the iMedRIS submission form, "Documents from Primary IRB," 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 UTHSC IRB will issue an acknowledgement letter via iMedRIS.

6. The CIRB reviews **amendments** for all studies on its menu. The local principal investigator will submit to the UTHSC IRB via the iMedRIS submission form, "Documents from Primary IRB," the following documents from the CIRB website:
 - a. Revised study protocol;
 - 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 UTHSC IRB will issue an acknowledgement letter via iMedRIS.

7. **Changes in local key project personnel** should be submitted to the UTHSC IRB via iMedRIS submission form, "Documents from Primary IRB," simultaneous with submission of personnel changes to the CIRB. The following documents should be attached:
 - a. Revised Form 1 and/or updated spreadsheet 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 UTHSC IRB will issue an acknowledgement letter via iMedRIS.

8. **Unanticipated problems**, including adverse events, which do not involve study participants at the local study site(s), should **not** be submitted to the UTHSC IRB. Unanticipated problems should be submitted to the IRB only when they involve study participants at UTHSC 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 UTHSC IRB standard operating procedure (See UTHSC IRB SOP Reporting Unanticipated Problems, Including Adverse Events).
9. Cooperative Group studies currently approved by the UTHSC 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 UTHSC IRB will comply with the CIRB requirements and directives.
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 Institution;
 - ii. The FWA 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 UTHSC 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 the Signatory Institution and at all Component and Affiliates. 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, UTHSC 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 UTHSC 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 UTHSC IRB to perform such inspections as necessary to assure adequate regulatory compliance.

14. The UTHSC IRB will complete or will notify 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.

15. The UTHSC 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.
16. The UTHSC 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.
17. The UTHSC IRB will remind CIRB-approved Principal Investigators to complete and submit the Study-Specific Worksheet About Local Context to an open study.
18. The UTHSC 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 UTHSC IRB will make not changes to the consent form(s) with the exception of the CIRB-approved boilerplate language;
 - b. The UTHSC IRB will obtain CIRB approval of changes to the boilerplate language prior to implementation; and
 - c. The UTHSC IRB will obtain CIRB approval of translations of the consent form prior to implementation.
19. The UTHSC IRB will maintain a regulatory file for each study under NCI CIRB purview as per local institution and sponsor policy.
20. The NCI CIRB will make the determination whether **assent** of the child is required. Procedures for obtaining and documenting assent should follow the UTHSC IRB policies and procedures outlined in SOP: Additional Protections: Children.
21. Compliance with **HIPAA** regulations are considered an institutional requirement and remain the purview of the local institution. The UTHSC IRB requires the inclusion of HIPAA Authorization as part of the CIRB approved boilerplate language in the consent form, as the CIRB does not function as Privacy Board.
22. 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 UTHSC IRB policies and procedures outlined in the SOPs regarding informed consent.

23. The UTHSC 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 UTHSC IRB must follow the procedures outlined in SOP: Procedures for Full Board Review. Inclusion of prisoners in a previously-initiated, CIRB-approved study requires submission of a “Form 2: Change Request/Amendment” via iMedRIS for review and approval by the UTHSC IRB.

24. The NCI CIRB’s review is designed to meet the requirements of for review by an Institutional Review Board. Requirements for review by other committees such as a **Radiation Safety Committee** or **Institutional Biosafety Committee** are the responsibility of the local institution.