# UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE
# INSTITUTIONAL REVIEW BOARD
# UTILIZATION OF COMMERCIAL CIRB

## I. PURPOSE

To specify the procedures for utilizing the Central IRBs for studies conducted by investigators at the Erlanger Health System and University of Tennessee College of Medicine Chattanooga and affiliated institutions.

## II. SCOPE

This SOP applies to 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

Currently, Erlanger Health System has a MOU with the Western Institutional Review Board and the Advarra and Sterling Institutional Review Boards for oversight of certain Industry Sponsored Clinical Trials.

The UTCOM IRB however, 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; 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 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.

***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 utilize a Central IRB for Industry Sponsored Clinical Trials, the following steps must be followed:

a. 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 CIRB, and 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 *UTCOMC IRB Smart Form: Study/Project Application*, Section 2.0, 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. The expiration date of CIRB studies will be the CIRB expiration date;

d. The UTCOMC IRB will issue a letter via the UTCOMC IRB electronic system, IRBNet, acknowledging receipt of the appropriate study documentation and that the 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 CIRB boilerplate language must be incorporated into the CIRB-approved model consent form to create the consent form to use for a specific study:

a. Pages must be numbered 1 of 5, 2 of 5, etc.;

b. The compensation for injury section must include the standard compensation disclaimer contained in the current UTCOMC IRB main consent form template;

c. 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;

d. The signature line section of the consent form must be formatted according to the current UTCOMC IRB main consent form template.

3. 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.

4. The CIRB conducts **continuing review** for all studies on its menu. The local principal investigator will submit to the UTCOM IRB via IRBNet Form D 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 UTCOM IRB will issue an acknowledgement letter.

5. The CIRB reviews **amendments** for all studies on its menu. The local principal investigator will submit to the UTCOM IRB via IRBNet Form C 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 UTCOM IRB will issue an acknowledgement letter.

6. **Changes in local key project personnel** should be submitted to the UTCOM IRB Form C submission form, via IRBNet simultaneous with submission of personnel changes to the CIRB. The following documents should be attached:
   a. Form C and/or updated delegation listing all key study personnel and current online CITI training;
   b. Revised consent form (if applicable);

   Upon receipt of the appropriate documentation, the UTCOM IRB will issue an acknowledgement letter.

7. **Unanticipated problems,** including adverse events, which do not involve study participants at the local study site(s), should **not** be submitted to the UTCOM IRB. Unanticipated problems should be submitted to the IRB only when they involve study participants at UTCOM 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 UTCOM IRB standard operating procedure (See UTCOM IRB SOP Reporting Unanticipated Problems, Including Adverse Events).

9. The UTCOM 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,

a. Ensuring the initial and ongoing qualifications of investigators and research staff;
b. Overseeing the conduct of the research
c. Monitoring protocol compliance;
d. Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;
e. Providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research; and
f. Investigating, managing, and providing notification to the 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 CIRB of a potential unanticipated problem and/or serious or continuing noncompliance, UTCOM must provide a plan to manage the incident, experience, or outcome, including measures to prevent similar occurrences.

10. As a part of ensuring safe and appropriate performance of research, the UTCOM IRB has the authority to observe any aspect of the research process including observing the consent process.

11. The UTCOM IRB will notify the CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the CIRB was responsible for study review.

12. The UTCOM IRB will maintain a regulatory file for each study under CIRB purview as per local institution and sponsor policy.