

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
UTILIZATION OF COOPERATIVE AGREEMENTS**

I. PURPOSE

To specify the procedures for utilizing the Cooperative Agreement for studies conducted by investigators at the University of Tennessee Health Science Center, Le Bonheur Children's Hospital, St. Jude Children's Research Hospital, and the University of Memphis.

II. SCOPE

This SOP applies to all IRB administrative staff, board members, and investigators.

Personnel responsible:

IRB administrative staff, IRB members, and investigators.

III. BACKGROUND

Cooperative research studies/projects involve more than one institution. Both the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) regulations permit institutions involved in multi-institutional studies to use reasonable methods of joint or cooperative review. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects.

The regulatory provision for cooperative review arrangements may be applied to different types of cooperative clinical investigations. For example, an institution may rely upon the review of another qualified IRB or make similar arrangements to avoid the duplication of IRB effort.

To avoid such a duplication of effort, the University of Tennessee Health Science Center, St. Jude Children's Research Hospital, and Le Bonheur Children's Hospital, a Division of Methodist Healthcare – Memphis Hospitals, entered into a memorandum of agreement on 22 November 2003 to outline the specific circumstances and procedures under which each entity may defer to the other's IRB for primary review of designated pediatric research protocols. A similar memorandum of agreement exists between the University of Tennessee Health Science Center and the University of Memphis, dated 8 January 2013.

In Accordance With:

45 CFR 46.114 and 21 CFR 56.114

Use of Centralized Institutional Review Board (IRB) (April 30, 2010)
<http://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-of-a-centralized-irb/>

Cooperative Research – Information Sheet
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126422.htm>

Non-local IRB Review – Information Sheet
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126423.htm>

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

IV. PROCEDURES

A. Cooperative Agreement between University of Tennessee Health Science Center, Le Bonheur Children’s Hospital, and St. Jude Children’s Research Hospital

1. Determination of Reviewing IRB

- a. The UTHSC IRB shall be the primary IRB for all pediatric protocols when the preponderance of the research or all the research is conducted at UTHSC governed sites, or at sites for which the UTHSC IRB is the designated IRB, such as Le Bonheur Children’s Hospital.
- b. The St. Jude IRB shall be the primary IRB for all pediatric protocols when the preponderance of the research or all of the research is conducted at St. Jude governed sites or within space leased by St. Jude.
- c. Each IRB shall have the option of deferring to the other as the primary IRB. However, each IRB retains the right to insist on its own full review of all protocols that are conducted using joint faculty, research associates, or facilities.

2. IRB Responsibility

- a. The primary IRB shall have full responsibility for the protection of human subjects, including the initial review, ongoing and continuing review, and oversight regarding amendments and safety reports.
- b. St. Jude and UTHSC IRB have the responsibility for protecting the rights and welfare of human subjects and for complying with all applicable

principles of respect for persons, minimization of risk, maximization of benefits, and fairness as stated in the Belmont Report, and will apply such in compliance with Federal regulations (45 CFR 46 and 21 CFR Parts 50 and 56).

3. **Review Process when the UTHSC IRB is the primary IRB**
 - a. All IRB applications will be prepared, submitted, and reviewed via iMedRIS following the IRB review processes outlined in the appropriate UTHSC IRB SOPs for initial review, continuing review, revisions, safety reports, protocol deviations, etc.
 - b. The IRB number will be assigned with the extension “STJUDE” and the study title listed within the electronic application will indicate that UTHSC is the primary IRB.
 - c. The UTHSC IRB will verify that personnel involved in the research have completed required education and training for the protection of human research subjects.
 - d. St. Jude Children’s Research Hospital should be listed as a research site within the iMedRIS application, and, if appropriate in the consent form(s).
 - e. The findings of the UTHSC IRB regarding full board, expedited, and exempt status including administrative provisos or reasons of deferral will be transmitted to the investigator via iMedRIS and to the St. Jude Children’s Hospital designated representative via e-mail.
 - f. The St. Jude IRB will notify the UTHSC IRB in writing within 10 working days as to whether it accepts the review by the UTHSC IRB or whether it shall insist on its own full review. If accepted, the St. Jude IRB will approve the research by its own administrative review process.
 - g. The UTHSC IRB shall immediately forward to the St. Jude Children’s Hospital designated representative any information regarding studies covered under this policy that has been determined through the UTHSC IRB’s review to alter the assessment of risk to subjects or others.
 - h. At the time of re-approval, all documentation, including any amendments, will be forwarded by the UTHSC IRB to the St. Jude Children’s Hospital designated representative. The St. Jude IRB shall notify the UTHSC IRB in writing within a reasonable amount of time as to whether it accepts its re-approval review. If accepted, the St. Jude IRB will approve the research continuation by its own administrative review process.
 - i. A copy of the correspondence will be retained in the electronic IRB file for the study.
 - j. Documentation of IRB review and approval, approval with provisos, and deferrals will be included on the IRB meeting agenda. Also included will be the satisfaction by the investigator of conditions for IRB approval of research reviewed under full board, expedited, or exempt review procedure, including the date when the IRB Chair, Director, or designee

determines that all conditions of IRB approval have been satisfied, the date when initial approval becomes effective, and the date by which continuing review (if applicable) must occur.

4. Review Process when the St. Jude IRB is the primary IRB

- a. At the request of the principal investigator or the UTHSC IRB, the St. Jude IRB shall forward electronically a copy of the approved documents, including the research protocol with all attachments, any approved advertisements/recruitment documents, and the informed consent document(s) to the UTHSC IRB.
- b. Upon receipt of the documents from the St. Jude IRB, the Director or designee will complete the IRB application, adding him/herself as a study contact, and attaching the appropriate documents.
- c. The IRB number will be assigned with the extension “STJUDE” and the study title listed within the electronic application will indicate that St. Jude is the primary IRB.
- d. The IRB Chair or other experienced reviewer designated by the Chair will be assigned the responsibility for reviewing the Documents from the Primary IRB application.
- e. The assigned reviewer(s) will review the application and all attachments according to the applicable ethical principles, federal regulations, and local IRB policies, and will complete the reviewer’s form.
- f. The results of the review will be summarized by the IRB Director or designee in a letter to the principal investigator.
- g. The UTHSC IRB shall apprise the St. Jude Children’s Hospital designated representative, within a reasonable amount of time, as to whether it accepts the review by the St. Jude IRB or whether it shall require insist on its own regular review of the study.
- h. The St. Jude IRB shall immediately forward to the UTHSC IRB any information regarding studies covered under this policy that has been determined through the St. Jude IRB’s review to alter the assessment of risk to subjects or others, including local and external adverse events.
- i. At the time of re-approval, all documentation, including any amendments, will be forwarded by the St. Jude IRB to the UTHSC IRB for review. The UTHSC IRB shall notify the St. Jude IRB in writing within a reasonable amount of time as to whether it accepts its re-approval review. If accepted, the UTHSC IRB will acknowledge the research continuation via the use of the Documents from the Primary IRB form.
- j. The findings of the UTHSC IRB will be transmitted to the investigator via iMedRIS and to the St. Jude Children’s Hospital designated representative via e-mail.
- k. A copy of the correspondence will be retained in the electronic IRB file for the study.

1. Documentation of IRB review and acknowledgment will be included on the IRB meeting agenda.

B. Cooperative Agreement between University of Tennessee Health Science Center (UTHSC) and University of Memphis (UM)

1. IRB Responsibility

- a. The Cooperative Agreement between UTHSC and UM applies to all human subject research protocols where at least one of the key study personnel listed on the protocol is faculty, staff, or a student at UTHSC; or where the preponderance of the research or all of the research is conducted at UTHSC or at UTHSC governed sites for which the UTHSC IRB is the designated IRB (Methodist-Le Bonheur Healthcare facilities, Regional One Health, or UT Medical Group, Inc.).
- b. The review performed by the UTHSC IRB will comply with the appropriate federal, state, local or institutional laws, regulations and policies pertaining to human subjects research [e.g., HHS regulations and guidance at 45 CFR 46 (Subparts A, B, C, and D) and the Food and Drug Administration regulations and guidance at 21 CFR 50, 56, 312, 600, and 812].

2. Review Process

- a. All IRB applications will be prepared, submitted, and reviewed via iMedRIS following the IRB review processes outlined in the appropriate UTHSC IRB SOPs for initial review, continuing review, revisions, safety reports, protocol deviations, etc.
- b. The IRB number will be assigned with the extension “UM” and the study title listed within the electronic application will indicate that UTHSC is the primary IRB.
- c. The UTHSC IRB will verify that personnel involved in the research have completed required education and training for the protection of human research subjects.
- d. UM should be listed as a research site within the iMedRIS application, and, if appropriate in the consent form(s).
- e. Upon approval of the research protocol by the UTHSC IRB, the UTHSC IRB will forward a copy of the approved documents, including but not limited to the study application, research protocol, any approved advertisements/recruitment documents, and the informed consent document(s) to the investigator and the UM IRB via the IRB electronic system, iMedRIS. The UM IRB shall acknowledge receipt of the review by the UTHSC IRB within ten (10) working days.

- f. The Principal Investigator must also contact the University of Memphis IRB and obtain their acknowledgment of the UTHSC IRB's approval in writing before the principal investigator may begin his/her research project.
- g. Upon the approval of continuing review and amendments, the UTHSC IRB will forward a copy of all documentation to the UM IRB. Further, the UTHSC IRB will forward any documentation via iMedRIS that has been determined through IRB review to alter the assessment of risk to subjects or others, including but not limited to local and external adverse events, protocol deviations/violations, Data and Safety Monitoring Board (DSMB) reports, and audit reports. The UM IRB shall acknowledge receipt of the reviews by the UTHSC IRB within ten (10) working days.
- h. The UTHSC IRB will provide the UM IRB and the Principal Investigator(s) a copy of the UTHSC IRB review and determinations concerning the research (e.g., proviso letters, approval letters, deferral, or other appropriate documents) via iMedRIS.
- i. The UTHSC IRB will maintain copies of the IRB approved research protocol (initial review, continuing review, amendments, adverse event reports, termination report, etc.), in the electronic IRB file for the study.
- j. Documentation of IRB review and approval, approval with provisos, and deferrals will be included on the IRB meeting agenda. Also included will be the satisfaction by the investigator of conditions for IRB approval of research reviewed under full board, expedited, or exempt review procedure, including the date when the IRB Chair, Director, or designee determines that all conditions of IRB approval have been satisfied, the date when initial approval becomes effective, and the date by which continuing review (if applicable) must occur.

C. Other Institutions

1. The UTHSC IRB does not currently hold Cooperative Agreements with any other institutions. If investigators wish to conduct a research study at another institution (for instance, Baptist Memorial Hospital, Memphis VA Medical Center, St. Francis Hospital, etc.), they must contact each of the institution's IRBs (Institutional Review Boards) to find out what to do at each institution in order to obtain approval for the conduct of the research study there. In addition, investigators will also need to simultaneously contact the UTHSC IRB to inquire about whether they should submit their application to the UTHSC IRB *before or after* they submit their application to each of the other IRBs and about whether an Institutional Review Board Authorization Agreement should be pursued between the institutions.