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| **UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER**  **INSTITUTIONAL REVIEW BOARD**  **UTILIZATION OF LOCAL RELIANCE AGREEMENTS**  **MAINTAINED BY THE UTHSC IRB** | |
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UTILIZATION OF LOCAL RELIANCE AGREEMENTS MAINTAINED BY THE UTHSC IRB

1. **PURPOSE**

To specify the procedures for utilizing the Local Reliance Agreements for studies conducted by investigators at the University of Tennessee Health Science Center, Campbell Clinic, Methodist Le Bonheur Healthcare, Regional One Health, St. Jude Children’s Research Hospital, and the University of Memphis.

1. **SCOPE**

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

**Personnel responsible**:

IRB administrative staff, IRB members, and investigators.

1. **BACKGROUND**

An IRB Reliance Agreement (or cooperative agreement or authorization agreement) is a contract between two or more organization that delineates and documents the respective responsibilities, roles, and process of communication between an organization that provides ethical and regulatory review of human subjects research (via the reviewing IRB) and the collaborating organizations that accept the determinations of the reviewing IRB (via the relying IRB(s)).

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. In 2022 this agreement was updated via the SMART IRB platform to outline the circumstances and procedures under which St. Jude Children’s Research Hospital and UTHSC may cede IRB review and to include those institutions that UTHSC serves as the IRB of recordfor. . 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:**

**DHHS**: 45 CFR 46.103(b)(2), 45 CFR 46.103(d), 45 CFR 46.109(d), 45 CFR 46.114 [Use of Centralized Institutional Review Board (IRB) (OHRP Letter, 2010)](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-of-a-centralized-irb/index.html)

**FDA:** 21 CFR 56.109)e), 21 CFR 56.114, [Non-local IRB Review – Information Sheet](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/non-local-irb-review), [Cooperative Research – Information Sheet](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cooperative-research)

**NIH**: Policy on the Use of a Single Institutional Review Board for Multi-Site Research (21 June 2016)

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

**IV. PROCEDURES**

**A. Reliance Agreement between University of Tennessee Health Science Center, St. Jude Children’s Research Hospital**

* 1. **Determination of Reviewing IRB**
     1. Joint, collaborative decision making will be used to determine which IRB is to review each study, for example, when the research includes investigators from UTHSC or its affiliate institutions and St. Jude and/or is conducted at UTHSC or its affiliate institutions and St. Jude.
     2. In general, the IRB of the institution that is the primary sponsor or author of the Study is to be the Reviewing IRB, even if the informed consent process is taking place at UTHSC or its affiliate institutions and St. Jude and/or if the study includes researchers from UTHSC or its affiliate institutions and St. Jude.
     3. If the preponderance of research (considering the number of patients and the location of the informed consent process) is being conducted at the institution that is not the primary sponsor and if the parties agree, then the IRB of the institution where the preponderance of the research is to occur may be the Reviewing IRB. If neither institution is the primary sponsor, then the IRB of the institution where the preponderance of research is being conducted generally is to be the Reviewing IRB.
     4. The IRB Reliance Managers or designee at each institution shall communicate to clarify which institution is the reviewing IRB

Each IRB reserves the right not to cede review and retains the right to insist on its own full review of all protocols that are conducted using joint faculty, research associates, or facilities.

* 1. **IRB Responsibility**
     1. The reviewing 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.
     2. 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 50, 56, 312, 600, and 812, as applicable.
  2. **Review Process when the UTHSC IRB is the reviewing IRB**
     1. 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.
     2. 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 reviewing IRB.
     3. The UTHSC IRB will verify that personnel involved in the research have completed required education and training for the protection of human research subjects.
     4. 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).
     5. 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.
     6. The St. Jude IRB will notify the UTHSC IRB in a reasonable amount of time 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.
     7. 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.
     8. 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.
     9. A copy of the correspondence will be retained in the electronic IRB file for the study.
     10. Documentation of IRB review and approval, approval with provisos, and deferrals will be included on the IRB meeting agenda in iMedRIS. 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.
  3. **Review Process when the St. Jude IRB is the reviewing IRB**
     1. The site principal investigator must **register the study with the UTHSC IRB** via iMedRIS, and receive a final acknowledgement letter, before the study is initiated at UTHSC or its affiliate institution(s). Alternatively, if the research will be conducted at St. Jude and less than half of the investigators are from UTHSC or its affiliate institutions, the IRB Reliance Manager or IRB Reliance Liaison will register the study with the UTHSC IRB via iMedRIS.
     2. The iMedRIS application will collect basic study information and ask questions to assess for requisite local ancillary reviews and other procedures (e.g., IBC or IACUC review, execution of data use agreements or material transfer agreements, etc.). The application must include all required components as follows:
        1. Documents that will be submitted to the reviewing IRB, such as the application, protocol, consent form(s), investigator’s brochure, package inserts, recruitment materials, data collection tools, etc., with UTHSC’s local requirements having been incorporated according to (V)(3)(g);

ii. A copy of the most recent IRB approval letter(s) (i.e., initial and continuing) that contain the current approval and expiration dates for the overall study as well as the regulatory categories and/or level of review under which the main study was approved.

* + 1. 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 reviewing IRB and the St. Jude IRB number.
    2. The IRB Chair or other experienced reviewer will be assigned the responsibility for reviewing the Documents from the Reviewing IRB submission form.
    3. 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.
    4. The results of the review will be summarized by the IRB Reliance Manager or designee in a letter to the principal investigator.
    5. 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.
    6. 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.
    7. The UTHSC IRB will comply with the **determinations of the St. Jude IRB** regarding initial review, continuing review, review of revisions, reportable events, as well as DSMB and device reports for studies covered under the reliance agreement. Documentation of these determinations must be provided to the UTHSC IRB via the **Documents from Reviewing IRB** submission form in iMedRIS
    8. 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.
    9. A copy of the correspondence will be retained in the electronic IRB file for the study in iMedRIS.
    10. Documentation of IRB review and acknowledgment will be included on the IRB meeting agenda in iMedRIS.

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

1. **IRB Responsibility**
   1. The Reliance 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, fellow, resident, or a student at UTHSC; or where 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 facilities, etc.
   2. 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**
   1. 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.
   2. 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 reviewing IRB.
   3. The UTHSC IRB will verify that personnel involved in the research have completed required education and training for the protection of human research subjects.
   4. UM should be listed as a research site within the iMedRIS application, and, if appropriate in the consent form(s).
   5. 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 a reasonable amount of time.
   6. 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.
   7. 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 a reasonable amount of time.
   8. 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.
   9. 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.
   10. Documentation of IRB review and approval, approval with provisos, and deferrals will be included on the IRB meeting agenda in iMedRIS. 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. If investigators wish to conduct a research study at another local institution (such as, 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 IRB Reliance Managers at 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 executed between the institutions.