THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
Institutional Review Board (IRB)
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Healthy Tennesseans. Thriving Communities.

Researcher Reliance Checklist

(For use when the UTHSC IRB will be asked to rely on an external IRB's review under an IRB Authorization/Reliance Agreement)

To be completed *before* submitting documents to the Reviewing (External) IRB:

**Schedule a consult with either of the UTHSC the IRB Reliance Manager, Lisa Hagen, via email at lhagen1@uthsc.edu

** **Please do not** move further into this checklist until after this step has been completed and you receive approval from one of the IRB Reliance Manager to proceed.

- Revise all consent form(s) to include the required **UTHSC boilerplate language**.
- Review & retain the UTHSC Local Context Information Sheet that the UTHSC IRB Reliance Manager will send you and complete the reviewing IRB's Local Context Form that they will give you.
- Obtain the signature on the Reliance Agreement or SMART IRB Letter of Acknowledgement from the Reviewing IRB.
- Contact any UTHSC ancillary committees and contract office if necessary (e.g., IBC, IACUC, OSP).
- Obtain separate, written institutional (site) approval to conduct research there and to rely on an external IRB, including from UTHSC affiliate institutions' Le Bonheur Children's Hospital, Methodist Healthcare-Memphis Hospitals, and/or Regional One Health. Affiliate institutional contacts are available at https://uthsc.edu/research/compliance/irb/about/affiliates.php .
- Submit an IRB reliance request in iMedRIS via a *UTHSC IRB Form 1: Study/Project Application* with all study documents attached (e.g., consent form(s) with UTHSC boilerplate language incorporated, surveys, recruitment materials, approved protocol, Investigator's Brochure, reliance agreement signed by reviewing IRB, reviewing IRB's local context form, etc.).
- In the *UTHSC IRB Form 1: Study/Project Application* be sure to list **all local** key study personnel (e.g., Principal and Co-/Sub-Investigators, individuals listed on a grant/contract, individuals listed on FDA Form 1572, individuals who obtain informed consent, individuals who perform study interventions/interactions, individuals who administer study medication, individuals who are responsible for overall conduct of study, etc.).
- In the *UTHSC IRB Form 1: Study/Project Application* be sure to list **all** local study sites (e.g., where any of the following will take place: recruitment of study participants, performance of screening procedures, informed consent, performance of interventions/interactions, administration of study medication, follow-up visits, research record storage, specimen storage, etc.).
- The inclusion of the UTHSC logo or name in any local recruitment materials will require approval from the UTHSC Office of Communications and Marketing prior to production (see UTHSC Logo Usage Policy located at

https://uthsc.policymedical.net/policymed/home/index?ID=de47aa28-16aa-408b-9c96-cb04f232964f&).

- Review the UTHSC IRB Reliance Agreement policy located at https://uthsc.edu/research/regulatory-support/irb/researchers/standard-operating-procedures.php to ensure you are aware of and understand UTHSC reliance procedures.
- Submit the relying IRB review fee to UTHSC IRB, if applicable. Consult the Fees page for more information on IRB fees when UTHSC IRB is the relying IRB.
- Answer all recommendations outlined in UTHSC IRB outcome letter(s) you may receive regarding your IRB reliance request that you submitted in iMedRIS via the *UTHSC IRB Form 1: Study/Project Application*.
- Receive acknowledgement letter from the UTHSC IRB stating that you may now submit to the Reviewing IRB (DO NOT submit to the Reviewing IRB until this is received!).

To be completed *after* submitting documents to the Reviewing (External) IRB:

- Submit all study documents that were approved by Reviewing IRB to UTHSC IRB via the PI Response Form for the *UTHSC IRB Form 1: Study/Project Application* for UTHSC review. The UTHSC IRB will verify that all documents to be used locally contain UTHSC contacts and UTHSC boilerplate language.
- Receive final acknowledgement letter from UTHSC IRB acknowledging the reviewing IRB's determination regarding the study – **ONLY AFTER RECEIVING THIS LETTER may you begin local research activities!**
- Obtain, and educate your key study personnel regarding, the reviewing IRB's policies and procedures (P&P), as you must adhere to their P&P as well as UTHSC IRB's reliance procedures.

To be completed *for the life of the study*:

- **Each time** the reviewing IRB reviews revisions, continuations, unanticipated problems, study closures, etc., the reviewing IRB's outcome letters and supporting documents must be submitted to the UTHSC IRB **within 10 business days** via the *Documents from Reviewing IRB* form in iMedRIS. The UTHSC IRB will acknowledge receipt of these documents via iMedRIS.
- When there are changes in any local key study personnel, you must submit a *Documents from Reviewing IRB* submission form to the UTHSC IRB that includes a revised *UTHSC IRB Memphis Form 1: Study/Project Application*. The UTHSC IRB will verify their CITI training, any required expertise, etc. and issue an acknowledgement letter via iMedRIS. The new key study personnel may not work on the study in any way until you receive the UTHSC IRB acknowledgement letter.