SMART IRB Guidance for Investigators

General Introduction to SMART IRB

First of all, note that "SMART IRB" is not actually an IRB. SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy. Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status. Basically, SMART IRB is a reliance agreement system in which a "Relying Institution" authorizes and relies upon a "Reviewing IRB" at some other institution. The idea is to minimize multiple reviews for the same study being conducted at several sites.

UNTHSC has signed onto the SMART IRB Reliance Agreement, and is now able to consider relying upon other IRBs *only for the review of multi-site projects funded by NIH and other federal agencies*.

How does SMART IRB function?

Once you, as principal investigator, have agreed to collaborate with an investigator at another institution and intend to use an external IRB for oversight of this study, you should contact the UNTHSC SMART IRB "Point of Contact (POC)" person to discuss whether ceding IRB oversight to an external IRB is appropriate. For UNTHSC, this is Dr. Brian Gladue, Associate VP for Research Administration.

In a detailed memorandum requesting use of SMART IRB, provide Dr. Gladue with the following information and attached documents:

- Details about the study (including your study team's role),
- Name of the proposed reviewing IRB, and the lead investigator's name and institution.
- Obtain and submit a copy of the study-wide protocol and template consent documents(s)
- A copy of the Reviewing Institution's SMART IRB-related documents/agreements, such as:
    - IRB Reliance Exchange Portal Agreement
    - Common Reciprocal IRB Authorization Agreement, etc.

These documents will form the basis for a decision to allow the use of SMART IRB

Who makes the Decision to use a Reviewing IRB?

The POC Official will present the request to the Institutional Official (for UNTHSC, this would be the Vice President for Research), and if approved, appropriate documentation will be developed for UNTHSC to rely upon the Reviewing IRB. In addition, the principal investigator at UNTHSC for that specific project has their own roles and responsibilities as outlined below.

Requirements of an Investigator (to be noted in a project-specific "Written Agreement for SMART IRB Delegation"; see template below):

- *Do not initiate any research activity until Review*ing IRB has approved the protocol
- Maintain all research records (Consent Forms, HIPAA Authorizations, etc.)
- Allow inspection of records by both Relying and Reviewing IRBs
- Notify BOTH IRBs of Unanticipated Problems
- Notify BOTH IRBs of potential non-compliance
- Notify BOTH IRBs of restriction or suspension
- Provide Relying IRB copies of ICF, HIPAA Authorization, assent forms, etc.

Requirements of the Relying IRB (in this case, the North Texas Regional IRB)

- Inform Reviewing IRB of personnel training, education and credentials as requested
- Local Context: Institutional policies, state laws, ancillary reviews
- ICF: Compensation for injury language, local contact information for study team, and local IRB (North Texas Regional IRB)
- Share COI policies on request, conduct COI analyses as needed and share with Reviewing IRB
- Have mechanisms for the North Texas Regional IRB to address complaints made by UNTHSC-based research subjects or others
- Conduct or cooperate in audit of study as requested by Reviewing IRB
- Notify Reviewing IRB of any federal agency audits or communications

Click here for detailed information regarding the SMART IRB Reliance System: https://smartirb.org/

Primary Obligations of UNTHSC Investigators

Duties and Responsibilities of UNTHSC Investigators relying upon another IRB through the SMART IRB Reliance System

Once the UNTHSC Institutional Official (Dr. Ghorpade, VP for Research and Innovation) has approved the use of SMART IRB for a given project, the Principal Investigator has the following document submission and follow-on obligations as described below and in an accompanying "Written Agreement for SMART IRB Delegation":

- Provide the North Texas Regional IRB with the names and roles of all key study personnel on the local study team

- Adhere to any management plans for potential conflicts of interest (COI) relevant to the study that will be ceded to the external IRB, including any new or altered management plans put in place throughout the lifespan of the study.

- Register the study with the North Texas Regional IRB via IRBNet and uploading documents received.

- Promptly respond to questions or requests for information from the Lead Study Team (or their designee) as well as from the Reviewing IRB.

- Participate, as required, in conference calls regarding the study as requested.

Other Obligations of the Principal Investigator

- Become familiar with the reportable event policy of the Reviewing IRB to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the Reviewing IRB to be reported and within the timeframes required.

- Ensure that all local reviews and sign offs , in addition to IRB approval, are in place before a study is activated, such as coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., radiology, nursing, and pharmacy).

- Work with the Lead Study Team and the IRB/HRPP POC at UNTHSC to incorporate locally required language into the consent template to be used by the local study team, such as institutionally required compensation for injury language, local study team contact information, and additional costs that subjects may incur that differ from those identified in the template consent form.

- For externally funded studies, provide the UNTHSC Office of Sponsored Programs with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

Notify the lead PI of:

- Any reportable events that occur locally, according to regulations and the Reviewing IRB's policy.

- Any changes (including those related to funding and personnel) in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.

- Any management plans, including any updates to these plans, as relevant to the study.

- Any applicable information for continuing review progress reports in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.

- Follow all determinations of the Reviewing IRB. Only implement changes of protocol, including local variations, after the Reviewing IRB has approved them, except in cases where a change is required to avoid an apparent immediate hazard to participants.

- Provide, upon request, access to study records for audit by the local institution, the Reviewing IRB's institution, and other regulatory or monitoring entities.

WRITTEN AGREEMENT FOR SMART IRB DELEGATION

NIH Funding Institute/Center: **Insert specific NIH Institute name here**
Project Name (Title): **Complete Title of NIH-funded study**
NIH Award Number: **List funding award (grant) number here**
Lead Principal Investigator: **Insert Overall Project PI name here**
UNTHSC Principal Investigator: **Insert UNTHSC PI name here**

Name of Reviewing SMART IRB: **Insert name of the Reviewing (SMART) IRB here**

The ***University of North Texas Health Science Center*** **in affiliation with the North Texas Regional IRB** agrees to delegate and designate IRB review and authority for continuing oversight of the above-referenced research study to **Insert name of the Reviewing (SMART) IRB here**, as allowed under 21 CFR 56.114 and 45 CFR 46.114. **Insert name of the Reviewing (SMART) IRB here,** in separate document(s), has agreed to the review and oversight of the above-referenced research study.

Delegation of IRB review is made to **Insert name of the Reviewing (SMART) IRB here** with the understanding that the **Principal Investigator** will provide documentation by letter of key elements (described below) of the study to assist with appropriate local research project oversight. This notification will allow the ***University of North Texas Health Science Center*** **in affiliation with the North Texas Regional IRB** to be aware of the relevant clinical research that is ongoing in this project and within ***University of North Texas Health Science Center*** and to undertake appropriate risk management oversight relative to activities occurring at ***University of North Texas Health Science Center*** and by its personnel.

The following documents shall be provided to the North Texas Regional IRB *within ten (10) business days of receipt from the Reviewing (SMART) IRB by Principal Investigator:*

- The names and roles of all key study personnel on the local (UNTHSC) study team
- Copy of **Insert name of the Reviewing (SMART) IRB here** Initial Approval Letter, including protocol and consent documents
- Copies of **Insert name of the Reviewing (SMART) IRB here** Continuing Review approval letters
- Any sponsor, contract research organization or federal agency reports, audits or investigations
- Notice of closure of the study (trial)

The UNTHSC Principal Investigator also agrees to the following:

- *NOT initiate any research activity until Review*ing IRB has approved the protocol
- Maintain all research records (Consent Forms, HIPAA Authorizations, etc.)
- Allow inspection of records by both Relying and Reviewing IRBs
- Notify BOTH IRBs of Unanticipated Problems within 10 business days of occurrence
- Notify BOTH IRBs of potential non-compliance within 10 business days of occurrence
- Notify BOTH IRBs of restriction or suspension within 10 business days of occurrence
- Register the study with the North Texas Regional IRB via IRBNet and uploading documents received.
- Promptly respond to questions or requests for information from the Lead Study Team (or their designee) as well as from the Reviewing IRB.
- Participate, as required, in conference calls regarding a study as requested by any or all parties.

Principal Investigator:

_____
Signature Date

_____
Printed Name of Principal Investigator

UNTHSC Institutional Official:

_____
Signature Date

Once the ***WRITTEN AGREEMENT FOR SMART IRB DELEGATION*** has been signed and submitted by the local site investigator to the UNTHSC Office of Research Compliance, the project will be processed for SMART IRB transfer. A copy of the signed and co-signed (approved) document will be returned to the local (UNTHSC) investigator for their records.

Click here for the Written Agreement for SMART IRB Delegation Form.