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

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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