

**RESTATED AND AMENDED IRB RECIPROCITY AGREEMENT
MEMORANDUM OF UNDERSTANDING**

This Restated and Amended IRB Reciprocity Agreement Memorandum of Understanding ("Master Reciprocity Agreement"), having an effective date of July 1, 2015 ("Effective Date"), is between the **Participating Institutions** (as defined below) listed as signatories and certain **Affiliated Organizations** (as defined below) who may be added to this Master Reciprocity Agreement at a future date (each a "Party" or, collectively, "Parties").

RECITALS

- A. The Original MOU set forth the agreement between participating The University of Texas System ("UT System") Institutions ("Participating Institutions") concerning the reciprocal use of each other's Institutional Review Boards ("IRBs") for research that will be conducted by investigators at those institutions.
- B. The Parties now wish to amend and restate the Original MOU through this Master Reciprocity Agreement to, (a) clarify specific language throughout this Master Reciprocity Agreement and (b) to extend the term for an additional five (5) years from July 1, 2020 to June 30, 2025. This Master Reciprocity Agreement will amend, replace and supersede the Reciprocity Agreement and Memorandum of Understanding ("Original MOU") executed between the Parties on and around June 2010.
- C. Additionally, the Parties may wish to further revise this Master Reciprocity Agreement in the future to include additional Participating Institutions (see **APPENDIX 1** and as defined below), hospitals and clinical care centers ("Affiliated Organizations", see **APPENDIX 2**) by executing an amendment hereto.

NOW, THEREFORE, in consideration of the mutual promises set forth herein and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the Parties hereto promise and agree as follows:

I. DEFINITIONS

- A. **Affiliated Organizations** – an entity, for example a business, society, association, hospital or clinical care center who agrees to rely on a Participating Institution's IRB and agrees to formally participate in this Master Reciprocity Agreement by completing and executing an amendment substantially in the form of **APPENDIX 2**. An Affiliated Organization shall not serve as a Reviewing IRB under this Master Reciprocity Agreement.
- B. **Human Research Protection Program (HRPP)** – encompasses the entities within the Participating Institution that contribute to the mission to protect the rights and welfare

of participants who take part in human subject research, including but not limited to the institutional officials, IRB, and research staff.

- C. **Human Subject Research** – activities that meet the United States Department of Health and Human Services (DHHS) definition of research set forth in 45 CFR § 46.102(d) and involve human subjects as set forth in 45 CFR § 46.102(f), or activities that meet the United States Food and Drug Administration (FDA) definitions of research/clinical investigation set forth at 21 CFR § 50.3(c) and § 56.102(c) that involve human subjects as set forth at 21 CFR § 50.3(g), § 103(e), § 312.3(b) and § 812.3(p).
- D. **Institutional Official** – the Institutional Official (IO) who is the signatory on the Federal Wide Assurance (FWA) filed with DHHS Office of Human Research Protections (OHRP) to assure compliance with regulations governing protection of human subjects. OHRP requires the Institutional Official to be a high-level official who has the authority to represent the institution named in the FWA.
- E. **Participating Institutions** – any Texas institution of higher education who, in addition to serving as a Reviewing IRB (as defined below), are signatories to this Master Reciprocity Agreement (and agreed to extend the Agreement through June 20, 2025) and may also agree to rely on another Participating Institution's IRB (see definition below for Relying Institution). Additional Participating Institutions may be added to this Master Reciprocity Agreement by completing and executing an amendment substantially in the form of **APPENDIX 1**. UT System will provide timely notification to all Participating Institutions when new Participating Institutions enter into and execute this Master Reciprocity Agreement.
- F. **Relying Institution** – a Participating Institution or Affiliated Organization who agrees to rely on another Participating Institution's IRB for a specific study.
- G. **Reviewing IRB** – a Participating Institution who agrees to serve as the IRB of record for a specific study for one or more of the other Participating Institution(s) or Affiliated Organization(s).
- H. **Site Activation** – consists of all other approval requirements required by the institution before human subject research can begin (e.g., safety committee approval, research credentialing, conflict of interest committee approval, etc.).

II. SCOPE

- A. Each Participating Institution to this Master Reciprocity Agreement may rely on each other's IRBs for review, approval and continuing oversight of human subject research as defined by federal regulations.
- B. Each Participating Institution shall maintain a separate, active FWA with OHRP. Each Participating Institution shall also recognize OHRP's current policy guidance on defining when an institution is engaged in research covered by the Common Rule and each institution's FWA. The review and continuing oversight performed by the Reviewing IRB

will meet the human subject protection requirements of each Relying Institution's OHRP-approved FWA. Relevant minutes of IRB meetings will be made available to the Relying Institutions upon written request. The Relying Institutions remains responsible for ensuring compliance with the Reviewing IRB's determinations and with the terms of its OHRP-approved FWA. This document must be kept on file at all Relying Institutions and provided to OHRP upon written request.

III. NAMES OF PARTICIPATING INSTITUTIONS

The names of the Participating Institutions to this Master Reciprocity Agreement are listed as signatories at the end of this Master Reciprocity Agreement. The Parties agree and understand that additional Participating Institutions may be added to this Master Reciprocity Agreement by completing and executing an Amendment substantially in the form of **APPENDIX 1**.

IV. AMENDING MASTER RECIPROCITY AGREEMENT TO ADD PARTICIPATING INSTITUTIONS

This Master Reciprocity Agreement may also be amended from time to time (using **APPENDIX 1** template) to add an additional Participating Institution who agrees to rely on any of the Participating Institution's IRB.

V. AMENDING MASTER RECIPROCITY AGREEMENT TO ADD AN AFFILIATED ORGANIZATION

This Master Reciprocity Agreement may also be amended from time to time (using **APPENDIX 2** template) to add an Affiliated Organization to this Master Reciprocity Agreement.

VI. COMPLIANCE WITH OFFICE OF HUMAN RESEARCH PROTECTION'S GUIDANCE

This Master Reciprocity Agreement meets the federal requirements for designation of another institution's IRB as the Reviewing IRB, as set forth in guidance issued by the OHRP "Terms of the Federal-wide Assurance for the Protection of Human Subjects", March 20, 2002.

VII. AUTHORITY

The following is a list of authorities for the federal requirements for designating another institution's IRB as the Reviewing IRB.

1. 45 CFR Part 46 Subparts A (Common Rule), B, C & D
2. 21 CFR Parts 50, 56, 312, and 812
3. 45 CFR Parts 46.160 & 164 (HIPAA Privacy Rule)

VIII. RIGHTS, DUTIES, AND RESPONSIBILITIES OF THE REVIEWING IRB

The Reviewing IRB will establish and follow its written policies and procedures to comply with federal and state laws pertaining to the protection of human participants in research. Some rights, duties and responsibilities of the Reviewing IRB are listed in **APPENDIX 3**.

IX. RIGHTS, DUTIES, AND RESPONSIBILITIES OF THE RELYING INSTITUTION

The Relying Institution will establish and follow its written policies and procedures to ensure compliance with federal and state laws pertaining to the protection of human participants in research. Some rights, duties and responsibilities of the Relying Institution are listed in **APPENDIX 4**. **APPENDIX 4** also includes some rights, duties and responsibilities of the Relying Institution when the Relying Institution is an Affiliated Organization.

X. MASTER RECIPROCITY AGREEMENT TOOLKIT

A “toolkit” (see Toolkit attached as **APPENDIX 5** hereto) was prepared to facilitate Participating Institutions and researchers at the various Texas institutions of higher education to effectively and efficiently use this Master Reciprocity Agreement. Several years ago, UT System institutional IRB subject matter experts developed standard operating procedures (SOPs) for initial review, continuing review and reporting. These SOPs are included in this Toolkit to provide guidelines and some suggested steps to researchers and administrators so they can more effectively use the Master Reciprocity Agreement. Also included in this Toolkit are sample templates/forms, as well as contact information for all UT System IRB offices.

XI. MODIFICATION

No amendment to this Master Reciprocity Agreement shall be valid unless it is reduced to writing and signed by authorized representatives of all Parties. Participating Institutions and/or Affiliated Organizations may be added to this Master Reciprocity Agreement by using the template set forth in **APPENDIX 1** or **APPENDIX 2** (respectively) attached hereto.

XII. CONFIDENTIALITY

- A. Each Party shall hold in confidence any information obtained from the other Party within the scope of this Master Reciprocity Agreement. The recipient Party's obligation shall not apply to information that:
1. is already in the recipient Party's possession at the time of disclosure;
 2. is or later becomes part of the public domain through no fault of the recipient Party;
 3. is received from a third party with no obligation of confidentiality to the disclosing Party;
 4. is independently developed by the recipient Party;
 5. is ethically required to be disclosed to participants because of any unforeseen risk identified by either Party during or after completion of the study; or

6. is required by law or regulation to be disclosed.

B. In the event that information is required to be disclosed pursuant to subsection 6 above, the Party required to make disclosure shall notify the other to allow that Party to assert whatever exclusions or exemptions may be available to it under such law or regulation.

XIII. TERM AND TERMINATION

A. The term of this Master Reciprocity Agreement is five years (5) from the Effective Date, from July 1, 2015 to June 30, 2025. If the termination date falls on a weekend or designated holiday, then the Master Reciprocity Agreement shall terminate on the next business day.

B. The term of this Master Reciprocity Agreement may be extended if the Parties agree in writing to renew it for additional five-year periods.

C. Any Party may terminate its participation in this Master Reciprocity Agreement, with or without cause, by giving the other Parties at least 6 months advance written notice of its intent to terminate and any such termination will not affect the Master Reciprocity Agreement with regard to the remaining Participating Institutions. Termination shall be without penalty.

XIV. INDEMNIFICATION

Each Party, to the extent authorized by law, shall indemnify and hold the other Parties harmless from any and all liability, losses, damages, claims, or expenses of any kind, that result from a Party's willful misconduct or negligent acts or omissions.

XV. NOTICES

Any Party giving or making any notice, request, demand, or other communication (each, a "notice") pursuant to this Master Reciprocity Agreement must give the notice in writing by one of the following means: personal delivery; registered or certified mail (in each case, return receipt requested); mailing by US Postal Service; nationally recognized overnight courier; electronic mail (receipt must be confirmed); or facsimile. Any Party giving notice must address the notice to the appropriate person at the receiving Party using the information listed in the appropriate signature box.

XVI. MASTER RECIPROCITY AGREEMENT SUPERSEDES ORIGINAL MOU

This Master Reciprocity Agreement and its Appendices amends, replaces and supersedes the Reciprocity Agreement and Memorandum of Understanding ("Original MOU") executed between

the parties, having an effective date of June 8, 2010 and is hereby extended by certain parties through June 30, 2025.

XVII. COMPLETE MASTER RECIPROCITY AGREEMENT

This Master Reciprocity Agreement includes the following Appendices which are each incorporated herein:

- Appendix 1 Amendment Template to Add Participating Institutions to Master Reciprocity Agreement
- Appendix 2 Amendment Template to Add Affiliated Organizations to Master Reciprocity Agreement
- Appendix 3 Rights, Duties, and Responsibilities of the Reviewing IRB
- Appendix 4 Rights, Duties, and Responsibilities of the Relying Institution
- Appendix 5 Toolkit for Using The University of Texas System Institutional Review Board Network and the Master IRB Reciprocity Agreement

The undersigned have read and agreed to all of the terms above, and have the authority to bind their respective Participating Institutions. Written concurrence is required for this Master Reciprocity Agreement to have legal effect, as memorialized by signature below.

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APPENDIX 1

Template to Add a Participating Institution to this Master Reciprocity Agreement

ADDENDUM TO MASTER RECIPROCITY AGREEMENT

(Adding a Participating Institution)

This Addendum to the Master Reciprocity Agreement (“Addendum”) is made and entered into as of [date] by and between the Participating Institutions named in the Master Reciprocity Agreement and _____, a Texas institution of higher education, the purpose of which is to add _____ as a Participating Institution to this Master Reciprocity Agreement.

RECITALS

A. The Participating Institutions of the Master Reciprocity Agreement having an Effective Date of July 1, 2015 as extended through June 30, 2025 wish to add _____ as a Participating Institution to this Master Reciprocity Agreement.

NOW, THEREFORE, it is hereby agreed as follows:

1. The Master Reciprocity Agreement is amended to add _____ as a Participating Institution hereto.
2. Except as expressly provided in this Addendum, all other terms, conditions and provisions of the Master Reciprocity Agreement shall continue in full force and effect as provided therein.

IN WITNESS WHEREOF, Participating Institutions (signed by an authorized representative of The University of Texas System) and _____, a new Participating Institution to the Master Reciprocity Agreement have entered into this Addendum effective as of the date first set forth above.

THE UNIVERSITY OF TEXAS SYSTEM

(UT System signatory signing on behalf of all Participating Institutions)

Signature: _____

Name: _____

Title: _____

Date: _____

PARTICIPATING INSTITUTION:

IRB Organization #: IORG _____

Federalwide Assurance #: FWA _____

IRB Registration #: IRB _____

Signature: _____

Name: _____

Title: _____

Date: _____

IRB Contact Information:

Phone:

Fax:

Email:

Website:

APPENDIX 2

Amendment Template to Add an Affiliated Organization to the Master Reciprocity Agreement

ADDENDUM TO MASTER RECIPROCITY AGREEMENT

Adding an Affiliated Organization

This Addendum to the Master Reciprocity Agreement (“Addendum”) is made and entered into as of [date] by and between the Participating Institution, _____, an institution named in the attached Master Reciprocity Agreement and _____, a _____ [e.g., an entity (e.g., business, society or association), a hospital or clinical care center] (“Affiliated Organization”) relying on any of the Participating Institution’s IRB and agreeing to participate in the Master Reciprocity Agreement as an Affiliated Organization.

RECITALS

A. The undersigned Participating Institution of the Master Reciprocity Agreement dated July 1, 2015 as extended through June 30, 2025 wishes to add _____, as an Affiliated Organization to the Master Reciprocity Agreement.

NOW, THEREFORE, it is hereby agreed as follows:

1. The Master Reciprocity Agreement is amended to add _____ as an Affiliated Organization.
2. Except as expressly provided in this Addendum, all other terms, conditions and provisions of the Master Reciprocity Agreement shall continue in full force and effect as provided therein.

IN WITNESS WHEREOF, the undersigned Participating Institution and _____, a new Affiliated Organization to the Master Reciprocity Agreement have entered into this Addendum effective as of the date first set forth above.

Signatures blocks on next page

PARTICIPATING INSTITUTION:

IRB Organization #: IORG _____

Federalwide Assurance #: FWA _____

IRB Registration #: IRB _____

Signature: _____

Name: _____

Title: _____

Date: _____

AFFILIATED ORGANIZATION:

Federalwide Assurance #: FWA: _____

Signature: _____

Name: _____

Title: _____

Date: _____

HRPP Contact Information:

Phone:

Fax:

Email:

Website:

For Office Use Only: Send a copy of the fully executed **APPENDIX 2** to the OFFICE OF GENERAL COUNSEL OF THE UNIVERSITY OF TEXAS SYSTEM. These documents will be maintained on the UT System website.

APPENDIX 3
Rights, Duties and Responsibilities of Reviewing IRB

Some, but not all, rights, duties and responsibilities of the Reviewing IRB are listed below:

- A. The Reviewing IRB shall ensure that each Relying Institution has agreed to rely on the Reviewing IRB for a specific study prior to initiating a review to add it as a study site. The Reviewing IRB will consider conflicts of interest using the Reviewing IRB's conflict of interest policy. For conflicts involving investigators from Relying Institutions (if any), the Reviewing IRB will consider the Relying Institution's conflict of interest policy as defined in that institution's management plan in the study approval.
- B. The Reviewing IRB will notify Relying Institution of (a) any unanticipated problems involving risks to subjects or others, (b) serious or continuing non-compliance with the regulations or determinations of the IRB, and (c) termination or suspension of IRB approval of research and collaborate with the Relying Institution to draft a joint notification letter to OHRP and FDA (as applicable).
- C. The Reviewing IRB will make its records, including any relevant communications with investigators, available upon written request in a timely manner to appropriate officials at the Relying Institution and to regulatory and accrediting entities.
- D. The Reviewing IRB and the Relying Institution will develop a mutually agreeable process to ensure that the Reviewing IRB communicates to the Relying Institution all initial and continuing approvals, disapprovals and/or closures of the proposed research.
- E. The Reviewing IRB may require the Relying Institution to conduct a monitoring visit and/or require the Relying Institution to observe the consent process at the Relying Institution.
- F. The Reviewing IRB will collaborate with the Relying Institution on the investigation,
- G. management, and reporting to regulatory agencies and appropriate institutional officials of serious or continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions and terminations of IRB approval.
- H. Right to Decline to be IRB of Record. A Reviewing IRB may decline, on a case-by case basis, to act as the Reviewing IRB for research conducted at other Participating Institutions.
- I. Right to Terminate Serving as the IRB of Record. After initial approval of a study, the Reviewing IRB may terminate serving as the IRB record for a study with at least six months advance written notice to the Principal Investigator (PI) and the Relying Institutions, in order to provide time for the protocol to be transferred to another IRB.

APPENDIX 4
Rights, Duties and Responsibilities of Relying Institution

Some, but not all, rights, duties and responsibilities of the Relying Institution are listed below:

- A. The Relying Institution bears responsibility for the conduct of all human subject research in which it is engaged. This includes the following:
 - 1. Maintain a Federalwide Assurance (or equivalent federal assurance) and human research protection program if engaged in federally funded or support research.
 - 2. Ensure that the relying institution's investigators and other research personnel are appropriately qualified and meet the relying institution's standards for eligibility to conduct research. This includes, but is not limited to, having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the research.
 - 3. Promptly report to the Reviewing IRB any proposed changes in the research and ensure that the researchers will not initiate changes in the research (including changes in the consent form) without prior review and approval by the Reviewing IRB, except where necessary to eliminate apparent immediate hazards to the subjects.
 - 4. Ensure that the researchers will not enroll individuals in research prior to review and approval by the Reviewing IRB.
 - 5. Ensure that the researchers when responsible for enrolling participants will obtain, document and maintain records of consent for the each subject as stipulated by the Reviewing IRB.
 - 6. Ensure that the researchers will provide to the Reviewing IRB any data safety monitoring board reports they receive at continuing review or upon request by the Reviewing IRB.

- B. The Relying Institution grants the reviewing IRB the authority to:
 - 1. Approve, require modifications to secure approval, and disapprove the research. The Relying Institution shall not approve specifically related research that has not been approved by the Reviewing IRB.
 - 2. Suspend or terminate approval of the research when not being conducted in accordance with the Reviewing IRB's requirements or that has been associated with unexpected serious harm to subjects.
 - 3. Observe, or have a third party observe, the consent process and the conduct of the research.

- C. Prior to Site Activation, the Relying Institution will ensure that each initial submission to the Reviewing IRB complies with any applicable local policies (including but not limited to conflict of interest policies) and procedures of the Relying Institution. Site Activation may not occur prior to IRB approval.

- D. The Relying Institution will comply with the prompt notification requirements of the Reviewing IRB.
- E. The Relying Institution will collaborate with the Reviewing IRB on the investigation, management, and reporting to regulatory agencies and appropriate institutional officials of serious or continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions and terminations of IRB approval.
- F. The Relying Institution will accept or decline, on a case by case basis, in its sole discretion, to rely on the Reviewing IRB. The Relying Institution shall notify the Reviewing IRB of its decision.
- G. The Relying Institution may suspend or terminate the conduct of research at its local organization. If this occurs, the Relying Institution shall promptly notify the Reviewing IRB in writing.
- H. The Relying Institution may terminate, on a case by case basis, its reliance on the Reviewing IRB. If this occurs, the Relying Institution will notify both the site PI and the Reviewing IRB and ensure that the research has been reviewed and approved by another IRB prior to termination of reliance.
- I. When the Relying Institution is an Affiliated Organization, the Affiliated Organization agrees that it will:
 - 1. Maintain an FWA if conducting federally funded research.
 - 2. Ensure that the researchers who are involved in the research are appropriately qualified and meet the standards for eligibility to conduct research at the Affiliated Organization. This may include, but is not limited to, having the required professional staff appointments, credentialing, and insurance coverage for their assigned role in the research.
 - 3. Assume as its joint responsibility with the Relying Institution in the identification and interpretation of the requirements of its applicable state or local laws, regulations, policies, and ancillary review processes as are relevant to research.
 - 4. Provide the Relying Institution with all language needed to complete the identified Affiliated Organization's site-specific sections of the template consent forms and/or HIPAA authorization forms.
 - 5. Maintain research records as per federal and state regulations and laws, as well as any institutional policies or additional requirements.
 - 6. Report all information required under this Master Reciprocity Agreement to the Relying Institution who will in turn report such information to the Reviewing IRB.
 - 7. Cooperate fully with the Relying Institution and the Reviewing IRB to implement the terms and intent of this Master Reciprocity Agreement.

APPENDIX 5

**Toolkit for Using The University of Texas System Institutional Review Board Network and the
Master IRB Reciprocity Agreement**



THE UNIVERSITY *of* TEXAS SYSTEM
Nine Universities. Six Health Institutions. Unlimited Possibilities.

**Toolkit for Using
The University of Texas System
Institutional Review Board Network**

July 2020

Toolkit for Using The University of Texas System Institutional Review Board Network

Contents

I.	Purpose	1
II.	Initial Review	2
III.	Modifications	2
IV.	Continuing Review	5
V.	Reporting to the Reviewing IRB	7

Appendices

Appendix A: IRB Network Process Flow Chart

Appendix B: Contact Information for UT System Institutional Review Board Offices

Appendix C: UT System Centralized IRB Review – Notification to Relying Institution

Appendix D: UT System IRB Master Reciprocity Agreement Application for Addition of Site Investigators

Appendix E: Sample IRB of Record Letter

Appendix F: Sample Permission to Rely Letter

I. Purpose

Purpose of the Toolkit

This toolkit (Toolkit) was prepared to facilitate Institutional Review Board (IRB) staff and researchers from Participating Institutions in using the UT System Restated and Amended Institutional Review Board Reciprocity Agreement Memorandum of Understanding (Master Reciprocity Agreement). This Toolkit provides basic information that each institution can use to develop its own processes at its own site. Defined terms in this Toolkit are the defined terms used in the Master Reciprocity Agreement.

In 2010, the UT System IRB Reciprocity MOU (MOU) was signed by all 15 UT System institutions. In addition to the MOU, stakeholders also developed Standard Operating Procedures (SOPs) for Initial Review, Continuing Review and Reporting; these SOPs were agreed to by all UT System institutions. The SOPs are included in this Toolkit to provide researchers with the necessary steps to effectively use the Master Reciprocity Agreement. Also included are sample templates/forms, as well as contact information for each Participating Institutions. For institutional specific forms, you are encouraged to contact your local IRB office directly.

In mid-2015, the MOU was restated and amended to include the University of Texas Rio Grande Valley (UTGRV), expand the scope of institutions eligible to participate in the IRB Network to any Texas institution of higher education and to more clearly distinguish between Participating Institutions and Affiliated Organizations (entitled “Restated and Amended Institutional Review Board Reciprocity (IRB) Agreement Memorandum of Understanding” (Master Reciprocity Agreement)). This Master Reciprocity Agreement replaces and supersedes the MOU.

In July 2020, the term of the MOU was extended for an additional 5 years so that the Agreement shall remain effective and expire June 30, 2025 for those parties agreeing to the extension.

Purpose of the IRB Network

This UT System IRB Network is composed of Texas academic institution IRBs and was created to reduce the regulatory burden on researchers and institutions conducting regulated human subjects research. The key component is the ability for the IRB Network institutions and affiliated organizations to rely on a single IRB to review and approve multi-center studies for all of the institutions engaged in the research.

The following factors are necessary before proceeding with an application:

- a. A Texas multi-center study with a researcher at each location willing to serve as the Principal Investigator (PI) for the site (Site PI as defined below).
- b. One investigator willing to assume the responsibility for obtaining and maintaining approval from the designated Reviewing IRB for all of the relying institutions.
- c. One of the participating institution IRBs willing to serve as the Reviewing IRB.
- d. At least one participating institution willing to rely on the Reviewing IRB.
- e. Institutional support and approval of the study from each study site.

See **APPENDIX A** for a comprehensive process flow chart.

Key Terms

Affiliated Organization – an entity, for example a business, society, association, hospital or clinical care center who agrees to rely on a Participating Institution's IRB and agrees to formally participate in this Master Reciprocity Agreement. An Affiliated Organization shall not serve as a Reviewing IRB under the Master Reciprocity Agreement.

Participating Institution – any Texas institution of higher education who, in addition to serving as a Reviewing IRB (as defined below), may also agree to rely on another Participating Institution’s IRB (see definition below for Relying Institution). Additional Participating Institutions may be added to this Master Reciprocity Agreement.

Relying Institution - A Participating Institution or Affiliated Organization who agrees to rely on another Participating Institution’s IRB for a specific study.

Reviewing IRB - A Participating Institution who agrees to serve as the IRB of record for a specific study for one or more of the other Participating Institution(s) and/or Affiliated Organization(s).

Overall PI - The lead principal investigator for a single multi-center study who is responsible for obtaining and maintaining approval from the designated Reviewing IRB.

Site PI - The principal investigator at the Relying Institution(s) who is responsible for the conduct of the research at the site(s) and reporting to the Overall PI.

Unanticipated Problem – A problem that is unanticipated or unexpected, related to the research and places the subjects or others at a greater risk of harm than was previously known or recognized. Unanticipated Problems may include adverse events (related, unexpected, place subjects or others at risk of harm), protocol deviations and other problems.

Noncompliance – Conducting research in a manner that disregards or violates federal regulations, failure to follow the requirements and determinations of the IRB, or institutional policies and procedures applicable to human research.

II. INITIAL REVIEW

Policy

A research project may be approved by the [Reviewing IRB](#) under the scope of the Master Reciprocity Agreement with permission from the [Relying Institution](#). Either parties may decline triggering the reciprocity for any particular protocol.

Procedure

1. A research project is reviewed and approved at one [Participating Institution](#). The PI at this Participating Institution is called the [Overall PI](#). The IRB that reviewed and approved the research proposal is called the Reviewing IRB.
2. When a research project falls under the oversight of more than one UT System member IRB, either the Overall PI or the Site PI may trigger the reciprocity agreement. Both the Overall PI and Site PI must understand and accept the additional responsibilities they would have if the research project is reviewed under the reciprocity agreement.

Triggering the Master Reciprocity Agreement

3. To avoid error, it is recommended that the Overall PI & Site PI(s) contact their respective IRB offices (see **APPENDIX B**) to verify that the project is eligible for review under the reciprocity agreement before initiating the formal approval process. ([View the list of offices and contact information \(see Appendix B\)](#) for the participating institutions and affiliated organizations.)
4. The process is initiated by the Site PI at a Relying Institution. The Site PI must follow the Relying Institution's procedure for seeking permission to rely on a network IRB. At most Participating Institutions, this process is handled by the Relying Institution's IRB office.
5. The Site PI must submit supporting documentation according to the Relying Institution's policy/procedure. When the Relying Institution has an electronic IRB system, the institution may require the Site PI to complete an electronic application or registration and attach the supporting documents. At a minimum, the supporting documentation should include:
 - a. Completed "Permission to Rely" form
 - b. Site-specific consent form (Site PI & local IRB contact information) and HIPAA authorization, if applicable.
 - c. Protocol (if required by the Relying Institution)

Permission to Rely from Relying Institution

6. The Relying Institution should consider the following before agreeing to rely:
 - a. Whether the research proposal falls within the scope of the UT System Master Reciprocity Agreement.
 - b. Whether study team members from the relying institution:
 - a. Are current on human subjects training,
 - b. have significant financial interest in the research,
 - c. Have appropriate credentials to conduct the research
 - c. Any concerns about the research submission.
 - d. Any concerns about the qualifications of the Site Investigator / Site research team.
 - e. Any concerns about the resources available at the site.
7. If the Relying Institution disapproves the request to rely, the site PI will submit a regular application to that Institution's IRB. (The study would not continue as part of this IRB Network)
8. If the Relying Institution agrees to rely, the Relying Institution should notify the Site PI (e.g., a written permission letter or a signed 'Permission to Rely' form).
9. Preferably, all the communication from the Site PI with the Reviewing IRB should be through the Overall PI. The Site PI should submit the following documents to the Overall PI.
 - a. Permission to Rely form with Relying Institution's Signature (or equivalent documentation)
 - b. Completed 'Addition of Site' form, if applicable
 - c. CV of the Site PI; and
 - d. Site specific Consent Document (or site specific information to be added to the master consent).

Review by Reviewing IRB

10. If the research project had already been approved by the Reviewing IRB at the time of the Site PI's submission, the Overall PI will submit these documents as a protocol amendment/addition of

site/change request submission. The Overall PI should clearly indicate that approval is being sought for inclusion of the Relying Institution as a study site. If the research project has not yet been approved by the Reviewing IRB, the Overall PI will include the Site PI documents with the initial application to the Reviewing IRB.

11. The Reviewing IRB screens the request to rely and may decide to accept or decline the request to rely. If the Reviewing IRB declines, the Overall PI and Relying Institution are notified.
12. If the Reviewing IRB accepts the request to rely, in addition to the regulatory criteria for approval, the Reviewing IRB should consider** the following:
 - a. Investigator Qualifications - The Site PI should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial.
 - b. Adequacy of the research site – depending on the study, resources such as availability of medical procedures, qualified healthcare providers, and equipment
 - c. Study team - The Site PI should have available an adequate number of qualified staff for the foreseen duration of the trial to conduct the trial properly and safely. Significant research - related duties may be delegated only to adequately qualified individuals.
 - d. Recruitment plan and consent process – If the plan for recruitment and consent process is different from the strategy outlined by the Overall PI, the Reviewing IRB should assess whether the Site PI’s plan is appropriate.
 - e. Conflict of interest disclosures and management plans, if any, by the Site PI and study team.

**IRB may obtain this information in many different ways – through experience, reliance on the Relying Institution, or collecting the information from the investigator.

13. If the Reviewing IRB requires more information, the Reviewing IRB may seek help from appropriate offices/officials from the Relying Institution.

Post Initial Review Communication

14. If the addition of the site is approved, the Reviewing IRB should notify the Overall PI and send the IRB approved consent document (if applicable). The approval notice should include information or a link to the information for the reporting requirements of the Reviewing IRB. If the Relying Institution stipulated that direct communication as a condition to participation, the Reviewing IRB must send a copy of the approval notice to the Relying Institution.
15. Reviewing IRB staff should review the notification arrangement stipulated by the Relying Institution to make sure they can meet the requirements of the Relying Institution before forwarding the request to add the site to the IRB. If there is disagreement, the Reviewing IRB staff will communicate with the Relying Institution staff to come to a mutually acceptable arrangement.
16. The Site PI must submit the approval notice, IRB approved consent form(s) and HIPAA authorizations (if applicable) and any other documents requested by the Relying Institution. The Site PI must also submit relevant documents to any Affiliated Organization involved in the research. Research may not begin until all necessary approvals are on file. Relying Institution may issue an Activation Letter.

Responsibility

This guidance applies to those members of the clinical research team involved in conducting the clinical research. This includes the following:

- Overall Principal Investigator;
- Local Principal Investigator;
- Reviewing IRB and IRB Office;
- HRPP Staff at Relying Institution; and
- Staff at Affiliated Organization.

III. MODIFICATIONS TO APPROVED RESEARCH

Policy The [Overall PI](#) is responsible for coordinating the submission of any modifications (amendment) to the [Reviewing IRB](#). The [Site PI](#) must submit necessary information to appropriate offices/officials at the [Relying Institution](#) and [Affiliated Organization\(s\)](#) (as appropriate).

Procedure

1. The Overall PI is responsible for submitting any modifications to the IRB approved protocol to the Reviewing IRB before the changes are implemented at any of the sites (unless it's to eliminate an immediate hazard).
2. The Overall PI will communicate the proposed changes to the study with the Site PI(s). The Site PI will determine whether the changes affect other institutional issues at the Relying Institution and Affiliated Organizations (as applicable); For example:
 - a. New or modified COI disclosures
 - b. Changes that affect local safety committee approvals
 - c. Changes in study staff that require research privileging or credentialing
 - d. Changes that affect research coverage analysis, billing or participant payments
 - e. Changes that affect grants, sub-awards or contracts
 - f. Changes that affect the resources at the relying institution or an affiliated site

IV. CONTINUING REVIEW

Policy

The [Overall PI](#) is responsible for coordinating the submission of the renewal application to the [Reviewing IRB](#). The [Site PI](#) must submit necessary information in a timely fashion to the Overall PI.

Procedure

1. The Overall PI is responsible for submitting a renewal application to the Reviewing IRB in a timely manner. Continuing review will occur at the same time for all the sites even if the sites were added after the original site had received approval earlier.
2. The Overall PI is responsible for submitting the continuing review application prior to the Reviewing IRB's deadline.

Submission of Continuing Review Application

3. The Overall PI will inform the PI's at all sites of the nature of the information required to complete the continuing review application (e.g., provide a copy of the form). In addition, the Overall PI will establish a deadline for the sites to provide the information. The deadline should provide sufficient time to allow the Overall PI to meet the Reviewing IRB's deadline for Continuing Review.
4. The Overall PI will communicate with the Site PI to resolve any issues related to delinquent reports. The Overall PI may also communicate with the [Relying Institution](#) as needed.
5. The Overall PI will consolidate information from all the sites into a single continuing review application. The Overall PI will submit the consolidated continuing review application to the Reviewing IRB. The Overall PI must indicate the names of the sites whose information is included in the application and indicate whether any of the sites failed to submit the required information. The Overall PI may attach the individual forms from the Site PIs to the continuing review application.
6. The Site PI will provide the required information not later than the deadline established by the Overall PI.

Review by the Reviewing IRB

7. The Reviewing IRB is responsible for the review of the continuing application for all the sites. In addition to the criteria for approval and other issues considered at continuing review, the Reviewing IRB should also determine whether all the sites have provided information about the conduct of research at their site.

Post Review Communication

8. If the continuing review application is approved, the Reviewing IRB should send the approval notice and other IRB approved documents to the Overall PI. The approval notice should include the list of all the sites for which continuing approval has been granted. If the Relying Institution stipulated direct communication, the Reviewing IRB will send a copy of the approval notice to the Relying Institution. The overall PI must send a copy of the approval notice and other IRB approved documents to the Site PIs.

Special Consideration – Study Expiry

9. If the continuing approval is not granted by the Reviewing IRB before study expiry, research activity must stop at all the sites (unless the IRB authorized continuation of specific treatments and procedures to avoid harm to the enrolled participants according to their policies and procedures).
10. If one or more sites participating in the research study did not submit information to the Overall PI for the continuing review application, the Reviewing IRB should conduct continuing review for the sites that did submit their information. For the sites that did not submit information, the study will expire. The Reviewing IRB should issue a letter asking the sites where approval has expired to stop all research activities.
11. The Reviewing IRB must communicate information to the Relying Institution when a study's approval has expired at the Relying Institution. If any Affiliated Organizations are involved, the Relying Institution must communicate this information to them.

Responsibility

This guidance applies to those members of the research team involved in conducting the research. This includes the following:

- Overall Principal Investigator;
- Local Principal Investigator;
- Reviewing IRB and IRB Office;
- HRPP Staff at Relying Institution; and
- Staff at Affiliated Organization.

V. REPORTING TO IRB

Policy

Each of the PIs at the sites must comply with the problem reporting requirements of the [Reviewing IRB](#). The Reviewing IRB must communicate problem reporting requirements at the time of initial approval. At a minimum, problem reporting will include [unanticipated problems](#) and [noncompliance](#).

Procedure

1. The Reviewing IRB is responsible for communicating problem reporting requirements to the PIs at all the approved sites. The Reviewing IRB must also communicate timelines for problem reporting either by listing them in the initial approval notice and the site specific approval notice (when the sites are added on after initial approval of the research) or referencing the problem reporting policy along with the approval notice.

Submission of Problem Reports

2. When a site becomes aware of a problem that needs to be reported to the IRB as per the Reviewing IRB's policy, the [Site PI](#) must submit the required information to the [Overall PI](#). The Overall PI must submit the information to the Reviewing IRB using the relevant forms. Both the Site PI and Overall PI must ensure that the problem reporting timelines are met.

Review by the Reviewing IRB

3. The Reviewing IRB is responsible for the review of the problem report and determining if the problem meets the definition of:
 - a. An Unanticipated Problem involving risks to subjects or others; or
 - b. Serious or continuing noncompliance
4. The Reviewing IRB must follow its own policy and procedure for making these determinations and creating an action plan. When a problem is restricted to one site, the Reviewing IRB may decide to stipulate actions from the affected site. When the problem may affect the entire study, the Reviewing IRB may decide to issue stipulations for all the approved sites. The Reviewing IRB may suspend or terminate its approval for one or more sites without affecting its approval for conduct of the research at the other sites.

Post Review Communication

5. The Reviewing IRB must communicate its findings and stipulations in writing to the Overall PI. The Overall PI must send a copy of the communication to the Site PIs. When the Reviewing IRB makes a determination of an unanticipated problem involving risks to subjects or others or serious or continuing noncompliance, or issues a suspension or termination, the Reviewing IRB must also communicate this information to the Relying Institution. When Affiliated Organizations are involved, the Relying Institution is responsible for informing them in a timely manner.
6. It is the responsibility of the Reviewing IRB to report unanticipated problems, serious or continuing noncompliance and suspensions and terminations of IRB approval to federal agencies. The Reviewing IRB should copy the institutional official at all of the Relying Institutions on these letters.

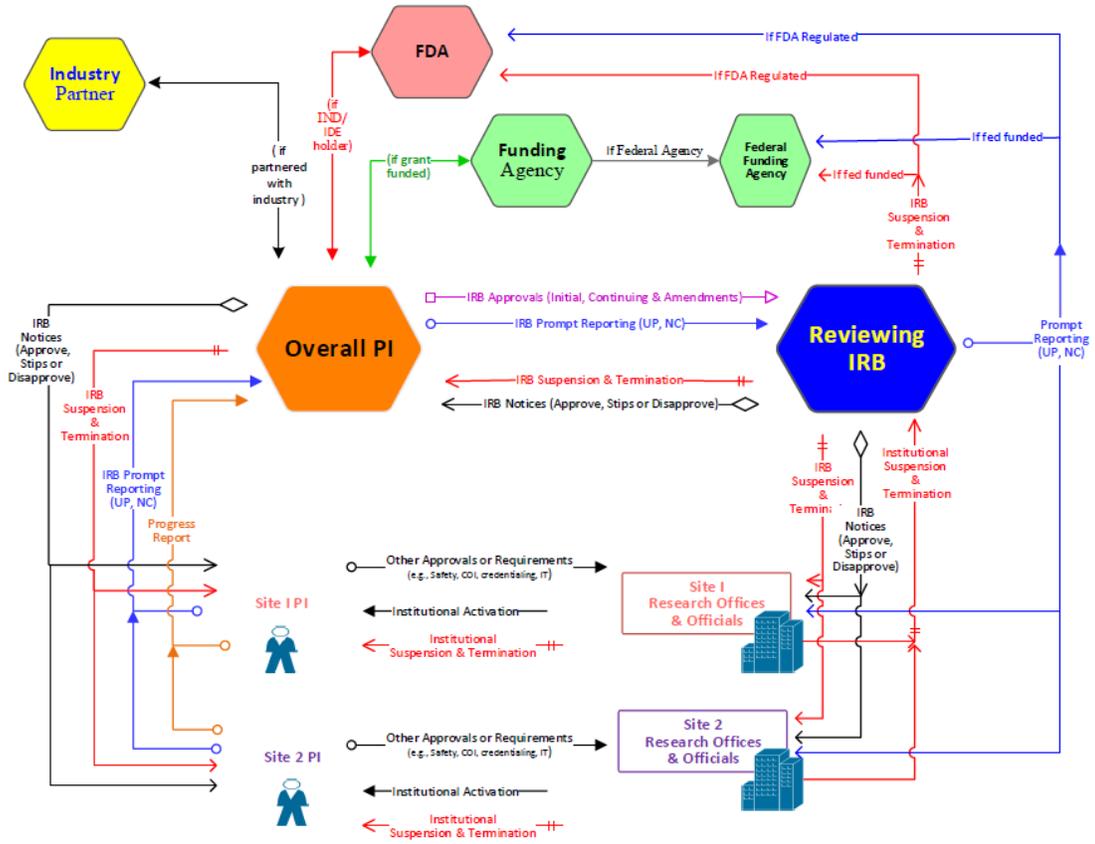
Responsibility

This guidance applies to those members of the clinical research team involved in conducting the research. This includes the following:

- Overall Principal Investigator;
- Local Principal Investigator;
- Reviewing IRB and IRB Office;
- HRPP Staff at Relying Institution; and
- Staff at Affiliated Organization.

APPENDIX A

IRB Network Process Flow Chart



UT IRB Network

APPENDIX B

Contact Information for UT System Institutional Review Board Offices

Health-Related UT System Institutions

The University of Texas Health Science Center at Houston
Point of Contact: Sujatha Sridar
Phone 713.500.7943
Fax: 713.500.7951
Email: cphs@uth.tmc.edu
<https://www.uth.edu/CPHS/>
[Affiliates to be added via APPENDIX 2](#)

The University of Texas Health Science Center at Tyler
Point of Contact: Corrinne Warren
Phone: 903.877.7649
Fax: 903.877.5513
Email: corrinne.warren@uthct.edu

The University of Texas MD Anderson Cancer Center
Point of Contact: Cindy Lee
Phone: 713.792.2933
Fax: 713.794.4589
Email: IRB_help@mdanderson.org

The University of Texas Medical Branch at Galveston
Point of Contact: Anne Clark
Phone: 409.266.9475
Fax: 409.266.9499
Email: akclark@utmb.edu
<http://research.utmb.edu/IRB/Default.aspx>

Academic UT System Institutions

The University of Texas at Arlington
Point of Contact: Kirstin Morningstar
Phone: 817.272.3723
Fax: 817.272.5808
Email: regulatoryservices@uta.edu
<http://www.uta.edu/research/administration/departments/rs/human-subjects-irb/>
[No affiliates](#)

The University of Texas at Austin
Point of Contact: Michelle Stickler
Phone: 512.471.8871
Fax: 512.471.8873
Email: orsc@uts.cc.utexas.edu
<http://www.utexas.edu/research/rsc/humansubjects/>

The University of Texas at Dallas
Point of Contact: Amanda Boone
Phone: 972.883.4579
Fax: 972.883.4569
<http://www.utdallas.edu/research/orc/irb/>

The University of Texas at El Paso
Point of Contact: Athena Fester
Phone: 915.747.8841
Email IRB.ORSP@utep.edu
<http://research.utep.edu/Default.aspx?tabid=72130>

The University of Texas Permian Basin
Point of Contact: Lisa Cline
Phone: 432.552.2361
[http://www.utpb.edu/research-grants/institutional-review-board-\(irb\)](http://www.utpb.edu/research-grants/institutional-review-board-(irb))

The University of Texas Rio Grande Valley
Point of Contact: Kimberly Fernandez
Phone: 956-665-2093
Email: Kimberly.fernandez@utrgv.edu
Dept Email: irb@utrgv.edu
Website: www.utrgv.edu/irb
[Affiliates](#)

The University of Texas at San Antonio
Point of Contact: Michelle "Mickey" Stevenson
Phone: 210.458.6473
Fax: 210.458.6966
Email: irb@utsa.edu
Website: <http://vpr.utsa.edu/oric/irb/>

The University of Texas at Tyler
Point of Contact: David Pearson
Phone: 903.5565.5858
Email: research@uttyler.edu
<https://www.uttyler.edu/research/compliance/irb/>

APPENDIX C

UT System Centralized IRB Review - Site Investigators Pre-Notification Letter- Intent to Submit for Centralized Review

Information for the Overall Principal Investigator (Overall PI) – In addition to submitting an application to your organization’s Institutions’ IRB (designated the “Reviewing IRB”), an “Intent to Submit for Centralized Review” form must be submitted to the IRB office at each Relying participating Institution.

Information for the Site Principal Investigator – The purpose of this form is to request centralized review at your organization institution (designated the “Relying Institution”). This request will be considered by your organization institution and a decision made on a case-by-case basis. The IRB office from your organization institution will forward the final decision to the Reviewing IRB.

If your organization institution agrees to Centralized IRB Review, you will still be required to submit institutional additional materials applications in accordance with local policy. The review of local issues by your organization institution is a separate process from the IRB approval being sought by the Overall PI. Reminder: you are not authorized to initiate research at your organization institution until both processes are completed: 1) the study is approved by the Reviewing IRB and an *approval* letter is issued, and 2) the local policy issues have been resolved and an *activation* letter has been issued by your institution.

Study Title:	
---------------------	--

1. Name and Address of Site Principal Investigator (PI):

Site PI’s Name (Last Name, First Name, MI): _____

Department: _____

PI’s Telephone#: _____ PI’s Cell Number: _____

PI’s e-mail address: _____ PI’s FAX Number: _____

2. Name of the Overall Principal Investigator (PI):

Overall PI’s Name (Last Name, First Name, MI): _____

Institution: _____

3. Which Texas Participating Institution will serve as the Reviewing IRB?

Select only one					
<input type="checkbox"/>	UT at Arlington (UTA)	<input type="checkbox"/>	UT Medical Branch (UTMB)	<input type="checkbox"/>	Texas Tech HSC El Paso (Texas Tech HSC El Paso)
<input type="checkbox"/>	UT Austin (UT Austin)	<input type="checkbox"/>	UT MD Anderson (UTMDACC)	<input type="checkbox"/>	The University of Houston (UH)
<input type="checkbox"/>	UT at Dallas (UTD)	<input type="checkbox"/>	UT Health Science Center Tyler (UTHSCT)	<input type="checkbox"/>	Texas Christian University
<input type="checkbox"/>	UT at El Paso (UTEP)	<input type="checkbox"/>	Angelo State University (ASU)	<input type="checkbox"/>	The University of North Texas Health Science Center (UNT HSC)
<input type="checkbox"/>	UT Permian Basin (UTPB)	<input type="checkbox"/>	Baylor College of Medicine (BCM)	<input type="checkbox"/>	The Methodist Hospital System (Methodist)
<input type="checkbox"/>	UT Rio Grande Valley (UTRGV)	<input type="checkbox"/>	Rice University (Rice)	<input type="checkbox"/>	
<input type="checkbox"/>	UT San Antonio (UTSA)	<input type="checkbox"/>	Texas A&M University (TAMU)	<input type="checkbox"/>	
<input type="checkbox"/>	UT Tyler (UTT)	<input type="checkbox"/>	Texas Tech Univ (Texas Tech)	<input type="checkbox"/>	
<input type="checkbox"/>	UT HSC at Houston (UTHealth)	<input type="checkbox"/>	Texas Tech Univ. Health Sciences Center (Texas Tech HSC)	<input type="checkbox"/>	

4. Which Texas Participating Institution will be engaged in this research?

Select the Participating Institution(s) that will be engaged in the research	Indicate the affiliated organization(s) with the participating institution that will also be engaged in the research
<input type="checkbox"/> UT at Arlington (UTA)	
<input type="checkbox"/> UT Austin (UT Austin)	
<input type="checkbox"/> UT at Dallas (UTD)	
<input type="checkbox"/> UT at El Paso (UTEP)	
<input type="checkbox"/> UT Permian Basin (UTPB)	
<input type="checkbox"/> UT Rio Grande Valley (UTRGV)	
<input type="checkbox"/> UT San Antonio (UTSA)	
<input type="checkbox"/> UT Tyler (UTT)	
<input type="checkbox"/> UT Health Science Center at Houston (UTHealth)	
<input type="checkbox"/> UT Medical Branch (UTMB)	
<input type="checkbox"/> UT MD Anderson (UTMDACC)	
<input type="checkbox"/> UT Health Science Center Tyler (UTHSCT)	
<input type="checkbox"/> Baylor College of Medicine (BCM)	
<input type="checkbox"/> Texas Tech University (Texas Tech)	
<input type="checkbox"/> Texas Tech University Health Sciences Center (Texas Tech HSC)	
<input type="checkbox"/> Texas Tech University HSC El Paso (Texas Tech HSC El Paso)	
<input type="checkbox"/> Angelo State University (ASU)	
<input type="checkbox"/> Texas Christian University	
<input type="checkbox"/> The University of North Texas HSC (UNT HSC)	
<input type="checkbox"/> Rice University (Rice)	
<input type="checkbox"/> The Methodist Hospital System (Methodist)	
<input type="checkbox"/> Texas A&M University (TAMU)	
<input type="checkbox"/> The University of Houston (UH)	
<input type="checkbox"/>	
<input type="checkbox"/>	

FOR IRB ADMINISTRATOR USE ONLY

1. The Investigator's intention to include our institution as part of the Centralized IRB Review by the IRB designated in item 3 is:

<input type="checkbox"/> Acceptable	<input type="checkbox"/> Not Acceptable
-------------------------------------	---

2. Notification Preference – the Reviewing IRB must notify this institution of approvals and study closure using the following method(s):

<input type="checkbox"/> send a copy of the IRB letter	<input type="checkbox"/> send a monthly statement of listing the protocols approved in the previous month
<input type="checkbox"/> send a weekly statement of listing the protocols approved in the previous week	<input type="checkbox"/> send a copy of the IRB letter to the Site PI at this organization who is then responsible to provide this information to the Institution

3. Federalwide Assurance Information – select the applicable statement(s)

<input type="checkbox"/> The box that applies Subpart A to all research is checked
<input type="checkbox"/> The box that applies Subparts B, C, and D to all research is checked

[Signature page to follow]

4. Signature of the Official Authorized by the Institution:

Printed Name/Title Date

<input type="checkbox"/>	UT at Arlington (UTA)	<input type="checkbox"/>	UT Health Science Center Tyler (UTHSCT)	<input type="checkbox"/>	Texas A&M University (TAMU)
<input type="checkbox"/>	UT Austin (UT Austin)	<input type="checkbox"/>	UT Medical Branch (UTMB)	<input type="checkbox"/>	Texas Christian University
<input type="checkbox"/>	UT at Dallas (UTD)	<input type="checkbox"/>	UT MD Anderson (UTMDACC)	<input type="checkbox"/>	The University of North Texas Health Science Center (UNT HSC)
<input type="checkbox"/>	UT at El Paso (UTEP)	<input type="checkbox"/>	Angelo State University (ASU)	<input type="checkbox"/>	The University of Houston (UH)
<input type="checkbox"/>	UT Permian Basin (UTPB)	<input type="checkbox"/>	Baylor College of Medicine (BCM)	<input type="checkbox"/>	The Methodist Hosp. System (Methodist)
<input type="checkbox"/>	UT Rio Grande Valley (UTRGV)	<input type="checkbox"/>	Rice University (Rice)	<input type="checkbox"/>	
<input type="checkbox"/>	UT San Antonio (UTSA)	<input type="checkbox"/>	Texas Tech Univ (Texas Tech)	<input type="checkbox"/>	
<input type="checkbox"/>	UT Tyler (UTT)	<input type="checkbox"/>	Texas Tech Univ. Health Sciences Center (Texas Tech HSC)	<input type="checkbox"/>	
<input type="checkbox"/>	UT HSC at Houston (UTHealth)	<input type="checkbox"/>	Texas Tech HSC El Paso (Texas Tech HSC El Paso)	<input type="checkbox"/>	

APPENDIX D

UT System IRB Master Reciprocity Agreement Application for Addition of Site Investigators

Information for Overall Principal Investigator (Overall PI) – In addition to submitting an application to your organization’s IRB (designated as “Reviewing IRB”), an application for addition of site investigator must be submitted for each Participating Institution. This application may be submitted at the time of initial review or after the initial submission has been approved.

Information for Site Investigator – The purpose of this form is to give enough information to the Reviewing IRB to allow them to make a determination about addition of your site. You may not submit this application form to the Overall PI unless your institution has agreed to rely on the Reviewing IRB.

Reminder – You are not authorized to initiate research at your organization until you have received approval for addition of your site from the Reviewing IRB **as well as** all the other applicable approvals from your institution.

1.0 GENERAL INFORMATION

1.1 Study Title:
Text Field

1.2 Site Principal Investigator:
Text Field

1.3 Site Name:
Text Field

1.4 Address:
Text Field

1.3 Office Phone:
Text Field

1.3 Cell Phone or Pager:
Text Field

1.4 Email Address:
Text Field

2.0 STUDY POPULATION

2.1 How many subjects will you recruit at your site?
Text Field

- 2.2 How will you recruit subjects for this research?
- Existing patients in investigator / co investigator's practice
 - Database of potential subjects (who have agreed to be contacted for future research)
 - Referrals
 - Advertisements
 - Other, please specify *Text Field*

2.3 Describe the recruitment process.
Text Field

2.4 Describe the consent process at your site (who will conduct the consent discussion, when and where it will take place).
Text Field

2.5 Will vulnerable subjects be recruited at your site?

- Children
- Pregnant women
- Cognitively impaired persons
- Prisoners

Text Field

3.0 INVESTIGATOR AND RESEARCH TEAM QUALIFICATIONS

3.1 Do you and your research team members have current human subjects / GCP training at your institution?

- CITI Human Subjects Training
- CITI GCP Training
- Others, please specify *Text Field*

3.2 How long have you been conducting research?
Text Field years

3.3 How many active research studies are you involved in currently?

Text Field years

3.4 Do you or any of the research team members have any significant financial interest related to this research?

Yes No, if yes please describe *Text Field* and include a copy of the approved COI management plan.

4.0 Acknowledgement by Site Principal Investigator

- *I will obtain informed consent from participants before enrolling them into the research unless informed consent has been waived by the Reviewing IRB.*
- *I will follow the protocol and not implement any changes without prior approval from the Reviewing IRB.*
- *I will report Unanticipated Problems involving risks to subjects or others within the timeframe specified by the Reviewing IRB.*
- *I am aware of my institutional policies and procedures in the conduct of research at my institution.*
- *I will cooperate with monitoring oversight visits by the Reviewing IRB and my institutional representatives*

Signature of Site Principal Investigator

Signature Date

APPENDIX E - Sample IRB of Record Letter

<INSTITUTION'S IRB LETTER HEAD>

<Date of Letter>

< SITE PI Name>

<SITE PI ADDRESS>

Protocol Title: <Protocol Title>

Protocol Number: <Protocol Number>

Sponsor: <Sponsor Name>

Approval Date: <Approval Date>

Expiration Date: <Expiration Date>

<Reviewing IRB Name> has approved the conduct of the above research study at <Name of Relying Institution>. The approval includes:

<Protocol Version Number>

<Consent Document Version Number>

<Recruitment Materials and Version Number>

This research study should not be initiated until all other ancillary approvals have been obtained.

<List Conditions of Approval. Examples –

- 1. Changes may not be initiated without approval of the <Reviewing IRB Name> unless a change was necessary to prevent immediate hazard to a subject.*
- 2. Informed Consent must be obtained before any study specific procedures are initiated. Only copies of approved and stamped consent documents must be used.*
- 3. Report the following to the IRB within 10 days <List events that must be reported such as protocol deviations that placed a subject at risk of harm, adverse events that are related and unexpected, unanticipated device affects etc. >*
4. Submit an application for renewal of IRB approval at least 60 days before the expiration of the IRB approval listed above.

If you have questions regarding this process, contact <IRB Office Contact>.

Sincerely,

<Name of IRB Chairperson>

<Title and Address of IRB Chairperson>

APPENDIX F

SAMPLE PERMISSION TO RELY LETTER

<INSTITUTION'S IRB LETTER HEAD>

<Date of Letter>

< SITE PI Name>

<SITE PI ADDRESS>

Protocol Title: <Protocol Title>

Protocol Number: <Protocol Number>

Sponsor: <Sponsor Name>

<Institution IRB Name> has reviewed the above submission and determined that its meets the criteria for being reviewed under the UT System IRB Reciprocity Agreement by <Name of the Reviewing IRB>. Please proceed to submit the necessary documents for review and approval by the <Name of the Reviewing IRB>.

This research study should not be initiated until <Name of the Reviewing IRB> has approved the conduct of the research study at <Name of Relying Institution> and all other ancillary approvals have been obtained.

If you have questions regarding this process, contact <IRB Office Contact>.

Sincerely,

<Name of IRB Chairperson>

<Title and Address of IRB Chairperson>