University of Texas Southwestern (UTSW) as IRB of Record

Steps:

1. Submit Reliance Request and select, "Request for External Sites to Rely on UTSW IRB"
2. Reliance Consultation – The lead Principal Investigator is encouraged to meet with HRPP Reliance Team to discuss additional responsibilities when other sites rely on UTSW IRB *(see Appendix A)*.
    - Discuss whether the UTSW IRB can act as the sIRB for all or some institutions participating in the study, or whether an external IRB would be more appropriate.
    - Decide which reliance agreements will be utilized between UTSW and the Relying Sites.
    - Identify who will act in the role of coordinating the additional activities when other sites will rely on UTSW. Please note the study team is responsible for conducting activities on behalf of the Relying Sites.
    - Provide the UTSW IRB reliance staff with details about the study, including the study-wide protocol and/or local context information.
    - Identify all sites that will be engaged in human subject's research and may require UTSW IRB coverage.

Initial Study Approval:

3. Submit the study in Velos and eIRB according to the Information Resources Training Tip Sheets and the following items:

- **Required elements to include in Form E – Master Consent: Part 1 and Part 2**
    - *Header*: Insert the names of the affiliated sites
    - *Section "How will your PHI be shared":* insert names of the relying collaborating institutions
- **Required elements of Form H**
    - *Section 2 and 3a:* Insert names of all the affiliates and local sites relying on UTSW IRB
- **Required elements of Form C**
    - Ensure the differences in recruiting and consenting are addressed, or the lack of differences are stated. (e.g., "This is a multi-site study. There are no differences in recruiting or consenting procedures. If the recruitment plan differs in the future, this will be detailed in a modification.")
- **Required elements of the Parent Smartform Application**
    - Item 4.2: Conflict of interest disclosed and associated management plan for internal study team members provided, if applicable
    - Item 5.4: Select "Yes".
    - Item 5.7.1: Select "Yes".
    - Item 5.7.2: Select "Yes".
    - Item 5.7.3: Upload the Lead Monitoring Plan (Form W).
    - Item 5.7.4: Select "Yes" during the initial submission.
    - Item 5.7.4a: Add Site Name as, "Pending" and Research Related Activity as, "Pending". These will be completed when the site(s) are onboarded in Step 4.

After initial study approval, provide Relying Site Study Teams with approved Part 1 consent (no changes to occur) and Part 2 consent template which indicates areas where the Relying Institutions must add site-specific language.

Adding ("onboarding") Relying Sites:

4. Submit a modification to add sites relying on UTSW IRB.

- Relying site documents include the site specific consent form (Part 2), the finalized reliance agreement, and the Institutional Profile and Site Specific Sheet.

- **Modification Smartform Changes:**
  - Item 1.1:
    - Select "Other" and list the site(s) that are being added where the UTSW IRB will serve as the IRB of record.
    - Select "Conflict of Interest Changes" to disclose management plans for relying institutions staff, when applicable
  - Item 15.0:
    - List the site(s) being added and upload the reliance agreement, the institutional profile and study specific sheet for each site.

- **Parent Smartform Changes:**
  - Item 4.2: Conflict of interest disclosed and associated management plan for external study team members provided, if applicable
  - Item 5.7.4: Change to "Yes".
  - Item 5.7.4a: Add Non-UTSW Site(s) and describe their study activities
  - Item 5.7.4b: Upload Reliance Agreement(s) for each site
  - Item 5.7.4c: Upload the attached Institutional Profile and completed Study Specific Sheet

Transitioning from Single-Site to Multi-Site Study with Single IRB

5. If the study was originally as a single site study but will now include site(s) relying on UTSW IRB, use the following instructions:

- **Create a modification to transition study to Single IRB and onboard the relying site(s):**
  - UTSW specific documentation includes the revised master protocol, master consent (Part 1), and site-specific consent (Part 2) for UTSW affiliates.

  - Relying site documents include the site specific consent form (Part 2), the finalized reliance agreement, and the Institutional Profile and Site Specific Sheet.

- **Modification Smartform Changes**
  - Item 1.1:
    - Select "Protocol"
      - Provide revised document that includes the external sites primary investigator and institutions name, and a description of the site activities for each relying site.
    - Select "Consent Form"
      - Provide master (Part 1) consent. See template.
      - Provide site-specific (Part 2) consent for UTSW and relying site.
    - Select "Waivers of Consent and Authorization", if applicable
      - Section 2 and 3a: Insert the names of the collaborating sites.
    - Select "Other" and list the site(s) that are being added where the UTSW IRB will serve as the IRB of record.
  - Item 15.0:
    - List the site(s) being added and upload the site specific consent form (Part 2), the finalized reliance agreement, and the Institutional Profile and Site Specific Sheet.
    - Attach Form C
      - Ensure the differences in recruiting and consenting are addressed, or the lack of differences stated. (e.g., "*This is a multi-site study. There are no differences in recruiting*

or consenting procedures. If the recruitment plan differs in the future, this will be detailed in a modification.")

- Complete and attach the Lead Monitoring Plan (Form W):

- **Parent Smartform Changes**
  - Item 5.4: "Yes" selected
  - Item 5.7.1: "Yes" selected
  - Item 5.7.2: "No" selected
  - Item 5.7.3: Lead PI Monitoring Plan (Form W) uploaded.
  - Item 5.7.4: Change to "Yes".
  - Item 5.7.4a: Add Non-UTSW Site(s) and describe their study activities
  - Item 5.7.4b: Upload Reliance Agreement(s) for each site
  - Item 5.7.4c: Upload the attached Institutional Profile and completed Study Specific Sheet

Continuing Review or Annual Update

- Collect participating site progress data and coordinate submission of the data prior to the parent study expiration date.
- Relying Sites complete Form AC – sIRB Continuing Review Form and send to Study Team Designated Contact.

Appendix A: UTSW Principal Investigator (Lead PI) Additional Responsibilities

☐ Provide Relying Site study teams with UTSW HRPP policies. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints. UTSW HRPP Guidelines and Policies.

☐ Coordinate reports of any participating site protocol event or deviation reports that could qualify as:

- Unanticipated problems posing risks to subjects or others;
- Incidents of serious noncompliance; or
- Continuing noncompliance.

UTSW reporting timelines should be followed for reporting of these events to the UTSW IRB. The participating sites may have different reporting timelines and participating site investigators must adhere to those timelines for reports submitted to their local institution.

☐ Respond to questions or requests for information from study teams and IRB/Human Research Protection Program personnel at institutions who are relying on the single IRB.

☐ Provide participating Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials)

☐ Prepare and submit IRB applications on behalf of all sites, including initial reviews, local amendments, personnel updates, local reportable events, and study wide information for continuing review.

☐ Notify Site Investigators of all Reviewing IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events.

☐ Report to the Site Investigator (or designee on the Relying Site Study Team) any unanticipated problems involving risks to subjects or others research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the research (i.e., the specific study or studies ceded to the Reviewing IRB) at the Relying Institution, when applicable.

☐ If a Relying Site Study Team does not provide the Lead Study Team (or designee) with the required information before the continuing review application is submitted to the Reviewing IRB, report the absence of this information as

part of the continuing review and notifying affected Relying Site Study Team of lapse in approval for their site and any applicable corrective action plans.

- ☐ Provide access, upon request, to study records for audit by the Relying Institution, the Reviewing IRB, and other regulatory or monitoring entities.
- ☐ Follow all requirements of the Relying Institution with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.
- ☐ Work in collaboration with the Reviewing IRB to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions; this includes developing a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).
- ☐ Participate in conference calls regarding a study as requested.
- ☐ Comply with ClinicalTrials.gov requirements set by FDAAA 801 and the National Institutes of Health (NIH) Policy on Dissemination of NIH-funded Clinical Trial Information, when applicable.