University of Texas Southwestern (UTSW)
Submission Process for Studies Relying on an External IRB

PI/Designee Submission Tasks:

1. Create the study in UTSW ETHOS.
    - Complete section **1.0 – Intake Questions / Basic Study Information.**
    - Add personnel who need to receive notifications to section **3.0 – Study Personnel**
    - Add the funding source in section **4.0 – Study Funding and Other Support**
        - If the agreement or grant is not initiated in eAgreements or eGrants, select "External Funding not Managed through UTSW Sponsored Programs Administration (SPA) and describe the type of funding.
    - Add the performance sites to section **5.0 – Performance Sites.**
    - Complete the required fields in **6.0 – Study Summary / Consent Forms**.
        - Upload the protocol to item 5.
        - If available upload the consent form to item 12.
    - **On the main study page, select and complete "Add Reliance Institute Information". This will notify HRPP staff to initiate the reliance agreement.**
    - Forward the **Reliance Package** from the External IRB (this is the Reviewing IRB) to UTSW IRB at sIRB@UTSouthwestern.edu. The **Reliance Package** contains the Reviewing IRB's Reliance Agreement and Local Context Form (protocol-specific document). Send this as soon as possible to avoid delays in the reliance process.
    - If UTSW and/or UTSW Affiliate site(s) will be included as performance site(s), request Performance Site Approval according to "Adding UTSW and Affiliates Sites".
    - For NCI CIRB, see Instructions for Relying on NCI CIRB (CIRB).
2. Reliance Consultation (This is an optional step) – Investigators and study teams are encouraged to meet with IRB Office prior to submission to discuss the study and reliance process using this link: Book a meeting with a Reliance Analyst.
3. Prepare Documents for External IRB:
    - Add Site-Specific Required Language for Consents: (Local context language is UTSW-specific information that needs to be inserted into the consent form template(s) when UTSW agrees to rely on an external IRB).
        - Advarra IRB: Effective December 1, 2023, study teams will insert the local context language found in the UTSW document.
        - WCG IRB will insert local context language once the study team submits the completed WCG ICF Checklist. Study teams must insert site-specific information such as compensation amount and frequency in WCG's online application.
        - Insert the local context language in the documents provided for NCI CIRB and NMDP.
        - For Jaeb Center for Health Research (JCHR) – Use the Adult-Parental ICF Template.
        - For all other External IRBs, insert the local context language found in the UTSW document.

      Pre-review of consent forms by UTSW IRBIRB is *not* required before submitting to the External IRB provided this information has not been rejected or changed by the CRO or Sponsor. In this case, review can be requested by emailing the consent form(s) to Brendan Paulman.
    - Prepare a separate HIPAA Authorization Form for the UTSW submission if ***not*** combined with consent form **and** External IRB is not serving as the privacy board per agreement. This is standard for NCI CIRB

and NMDP but may be applicable to other External IRBs.

- If applicable, prepare any site-specific recruitment materials or other documents for External IRB approval.
- **Parkland Health:** Consent Forms requiring Parkland performance site approval are required to address the areas listed in the Parkland Health Guidelines for Informed Consent Document. All elements in this guide are consistent with the ***UTSW*** document except for the insurance language which also needs to be added to the consent form and local context form.

4. Submit Study to External IRB: Submit the study as instructed directly to the External IRB or through the study's CRO, Sponsor, or Lead Institution.

5. UTSW Study Submission:
   - Submit the study in UTSW ETHOS and Velos
   - Request all Ancillary Committee Approvals

   - **Key Reliance Questions:**

     - 1.0 Intake Questions/Basic Study Information:
       - Item 5: What kind of study is this? **Multi-Site Or Collaborative Study**
       - Item 6: Will an External IRB act as the IRB of record for this study? **Yes**

     - 6.0 Study Summary/Consent form:
       - Item 5: a. Draft Protocol - ***Due before UTSW IRB Pre-review***.
         b. IRB-approved Protocol - ***Due before UTSW IRB Approval.***
       - Item 12:
         a. Draft Consent Form with Site-Specific Required Language for Consents per Item 3 - ***Due before UTSW IRB Pre-review***.
         b. IRB-Approved Consent Form - ***Due before IRB Approval.***
       - Item 12: Upload separate HIPAA Authorization Form if not combined with consent form for UTSW IRB approval (do not submit form to External IRB). This always applies to NCI CIRB and NMDP but may apply to other institutions as defined in the reliance agreement. - ***Due before IRB Pre-review***.

     - 9.0 Relying on a non-UT Southwestern IRB:
       - Item 2.1: Upload Reliance Agreement
         - **NCI CIRB, NMDP and TrialNet Studies:** These studies have an agreement for all studies so a per-study reliance agreement does not need to be uploaded before HRPP pre-review or HRPP approval.
           - **TrialNet** Studies: Email the Local Context Review Form and Protocol to sIRB@UTSouthwestern.edu for addition of applicable state or local laws, regulations, policies, and ancillary review processes relevant to the research that should be considered by the External IRB. Notify Brendan Paulman in Teams to facilitate the request.
         - **Advarra and WCG IRB Studies:**
           - **Advarra:** *UTSW* and *Children's Health* have a Master Service Agreement with Advarra. A reliance email will be sent from sIRB@utsouthwestern.edu to the PI. You are responsible for uploading the reliance email in Advarra IRB CIRBI Initial Investigator Application and UTSW ETHOS smartform Item 2.1. ***Due before UTSW IRB Pre-review.***
             - ✓ *Parkland Health, Scottish Rite for Children* and other affiliated sites will send you a separate, partially signed reliance agreement to submit to an Advarra CIRBI Initial Investigator Application. Once Advarra has approved the sites, the Advarra IRB will sign the reliance agreement(s) and you can download the fully signed agreement(s) from CIRBI. You are responsible for uploading the signed agreement(s) in UTSW

ETHOS smartform Item 2.1. ***Due before UTSW IRB Approval.***

- **WCG**: *UTSW* has a Master Service Agreement with WCG. A reliance email will be sent from sIRB@utsouthwestern.edu to the PI. The PI or authorized designee must upload the reliance email in the WCG IRB Connexus Initial Review or Existing Submission application and in UTSW ETHOS smartform Item 2.1. ***Due before UTSW IRB Pre-review.***
  - ✓ *Children's Health, Parkland Health, Scottish Rite for Children* and other affiliated sites will send you a separate, partially signed reliance agreement to submit to the WCG Connexus Initial Review or Existing Submission application. Once WCG has approved the sites, the IRB will sign the reliance agreement(s) and you can download the fully signed agreement(s) from CIRBI. You can find the agreement(s) by looking under Document Type, "Written Agreement". ***Due before UTSW IRB Approval.***

- **All other External IRBs:** A reliance email will be sent on behalf of UTSW and any applicable affiliated sites with a request to provide a reliance package. The PI or authorized designee must upload the reliance email in UTSW ETHOS smartform Item 2.1. ***Due before UTSW IRB Pre-review.***
  - ➢ The fully signed reliance agreement for each performance site listed in smartform Item 5.0 must be uploaded before the study is sent back to the IRB for final approval. ***Due before UTSW IRB Approval.***

- ➢ Item 2.1. Initial Study Approval letter - ***Due before UTSW IRB Approval.***
- ➢ Item 3: Site Approval letter that lists all performance sites - ***Due before UTSW IRB Approval.***
- ➢ Item 4: Amendment Approval letter, if any. ***Due before UTSW IRB Approval.***
- ➢ Item 5: Continuing Review Approval letter, if applicable. ***Due before UTSW IRB Approval.***
- ➢ Item 6: Respond to the questions on HIPAA Waivers and, if applicable, upload the HIPAA Waiver from the External IRB.

UTSW IRB Review:

1. **Pre-Review Review:** Once submitted, UTSW IRB review will include but not be limited to these items:

   - Study smartform is completed appropriately and as applicable to the study,
   - Study documents include the required local context language,
   - Training is completed according to Training policy and inform the Reviewing IRB about any training deficiencies,
   - Conflict of Interest: Ensure that conflicts of interests and management plans have been disclosed to the Reviewing IRB,
   - Ancillary Committees: Review for pending Ancillary Committee reviews.

   If the External IRB has not approved UTSW and/or affiliates study site(s) or if any required Ancillary reviews are outstanding, the submission will be returned to you in UTSW ETHOS with instructions to resubmit only when approvals are in place.

2. **Administrative Review and Study Acknowledgement:**

   - Once External IRB has approved UTSW/Affiliates as study site(s) and all ancillary reviews have been approved, you may upload final, approved documents and resubmit the study.
   - UTSW IRB will re-review the submission to ensure other updates are not required and accept the review of the External IRB.
   - PI, Research Coordinator, and Primary Administrative Contact receive an **acceptance letter**. The letter lists all other approvals that are pending (coverage analysis, performance site review, contracts, etc.).

3. **Study Activation:** UTSW IRB will issue a study activation letter when these conditions are met:

   - UTSW Coverage Analysis and UTSW Clinical Trial Agreement are "Approved" or "Not Applicable".
   - Performance site review for one site where the study will be conducted is approved.

   The UTSW IRB will do the following tasks to activate the study:
   - ➢ Stamp the consent form(s), if applicable,
   - ➢ Acknowledge and upload study documents under "approved documents",

- Set the expiration date in UTSW ETHOS as one month after the expiration date assigned by the external IRB, and
- Issue the study activation letter that specifies which performance sites may begin enrolling participants.

PI/Designee Responsibilities for Ongoing Study Management:

1. **Enrollment:** Study activities may begin *only* at sites where performance site approval has been obtained.
2. **Modifications:** Any change in the study must be submitted with an approval letter from the External IRB.
3. **Annual Update:** To renew the study in UTSW ETHOS, submit an Annual Update (AU) by uploading the CR approval letter from the External IRB.
4. **Reportable Events:** Submit Reportable Events (Complaints, Noncompliance, Unanticipated Problems Involving Risks to Subjects or Others, and/or Unanticipated Adverse Device Effects) to the External IRB in accordance with their policies.
    - The same Reportable Event must be submitted to UTSW IRB via UTSW ETHOS (Reportable Event) and attach the External IRB's determination or documentation that the event is not required to be reported to the External IRB.