Reliance Submission Process

PI/Designee Submission Tasks:

1. Submit Reliance Request and select, "Request to Rely on an External IRB"
2. Reliance Consultation (Optional) – Investigators are encouraged to meet with HRPPO Reliance Team prior to submission to discuss the study and reliance process. You can request a meeting when completing the Reliance Request or email SIRB@UTSouthwestern.edu with your availability.
3. 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 will insert local context language on behalf of the study team. Study teams must insert site-specific information such as compensation amount and frequency in Advarra's online application.
    - 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 all other External IRBs, insert the local context language found in the UTSW document.

    Pre-review of consent forms by UTSW HRPP is not required before submitting to the Reviewing IRB provided this information has not been rejected or changed by the CRO or Sponsor.
4. Prepare a separate HIPAA Authorization Form for the UTSW submission if not combined with consent form and Reviewing IRB is not serving as the privacy board (e.g., NCI CIRB, NMDP, etc.).
5. Prepare any site-specific recruitment materials or other documents to the Single IRB for approval.
6. Submit Study to Single IRB: Submit the study as instructed directly to the Single IRB or through the study's CRO, Sponsor, or Lead Institution.
7. Single IRB Approval of Study/Site(s)
    - Study Entry and Submission in eIRB: *Leave the eIRB study in **DRAFT** until the External IRB Approval Letters for the local site(s) (UTSW, Parkland, Children's, etc.) have been uploaded.*
    - Request Performance Site Approval
    - Request all Ancillary Committee Approvals
    - Study smartform mandatory sections for all reliance studies (1, 3, 5, 4, 7, 9, 12)
    - Other sections, as applicable, (cancer studies, study drugs, radiation)
    - Reliance Checklist, Form B, and Form C.

    Key Questions:

    - Item 5.0:
        - Item 5.3.1: Are you requesting to rely on an external IRB? **Yes**
        - Item 5.6: Is this a multisite study? **Yes**
    - Item 12.0: Upload the following where applicable:
        - 12.1.a: Reliance Agreement
        - 12.2.1. Initial Study Approval letter
        - 12.2.2: Site Approval letter that lists all performance sites
        - 12.2.3: Amendment Approval letter
        - 12.2.4: Continuing Review Approval letter
        - 12.3.1: Currently approved Protocol
        - 12.3.2: HIPAA Authorization Form (if applicable)
        - 12.3.3: Approved/Stamped
        - 12.4.3a: Partial HIPAA Waiver from Single IRB, or Form H if UTSW is acting as the privacy board.
        - 12.6 and 12.7: Answer these questions "Yes" to trigger Radiation and Drug/Device sections.

UTSW HRPP

Administrative Review: Once submitted, UTSW HRPP 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: Inform the Reviewing IRB about any training deficiencies
- Conflict of Interest: Disclose conflicts of interests to the Reviewing IRB and management plans.
- Performance Site Review: One performance site approval is required before the study will be activated in eIRB but performance site approval must be obtained prior to beginning enrollment at that site.
- Ancillary Committees: Inform the Reviewing IRB of the results of Ancillary Committee reviews.

Study Acknowledgement: UTSW HRPP will accept the review of the Single IRB.

- Accept the review of the external IRB
- Stamp Consent Form
- Acknowledge and upload study documents under "approved documents"
- Study expiration date in eIRB is set one month after the expiration date assigned by the external IRB
- PI, Research Coordinator, and Primary Administrative Contact receive an acceptance letter. The letter lists all other approvals that are pending (i.e., performance site, coverage analysis, contract, etc.).

Study Activation: UTSW HRPP will issue a study activation letter when these conditions are met:

- The status of one performance site, UTSW Coverage Analysis, and UTSW Clinical Trial Agreement must be "Approved" or "Not Applicable" before the study may be activated.
- Study status in eIRB will be updated to "Awaiting Activation".

PI/Designee Responsibilities for Ongoing Study Management:

- Study activities may begin *only* at sites where performance site approval has been obtained.
- Any change in the study must be submitted with an approval letter from the Single IRB.
- To renew the study in eIRB, submit an Annual Update (AU) by uploading the CR approval letter from the Single IRB.
- Submit Reportable Events to the Single IRB's policies.
- Report to UT Southwestern HRPP via eIRB then submit a follow up to include the Single IRB determination.