
Demystifying Reliance

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Hend Nadim, MBA – Expedited Review Program Manager

Brendan Paulman, MS – Senior Regulatory Analyst

Reliance Terminology



Single IRB (sIRB): IRB of Record is the lead IRB who will oversee the conduct of research-related activities at all research locations. The IRB of Record could also be known as the Lead IRB, a single IRB of Record, reviewing or central IRB.



Relying Institution: The entity that agrees to rely upon the reviewing IRB.



Reliance agreement: A Reliance Agreement is a formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution. Institutions may use different descriptive terms, e.g., reliance agreement, cooperative agreement or IRB authorization agreement (IAA).

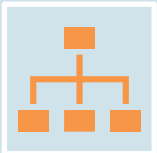
Reliance Terminology



SMART IRB: Is a web-base agreement platform/ Online Reliance System that offers a master IRB reliance agreement

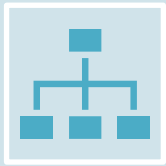


IREx: IRB Reliance Exchange: web-based document/ document management system that uses SMART IRB agreements



The Point of Contact (POC): is generally responsible for being the conduit of information, representing his or her organization, whether it is a lead or a relying institution. The Point of Contact could represent the lead study team coordinator or the IRB staff member identified as the point of contact. The Point of Contact is responsible for facilitation of communication between either the research study team(s) involved in the study or the communication between the IRB of Record and the Relying IRB.

Reliance Terminology



The relying study team (aka Relying site): Study team who relies on review by an IRB outside of their institution. It is the responsibility of the Relying Study Team to designate a single Point of Contact who will serve as the communication portal with other Relying Site IRBs and the Lead Site IRB.

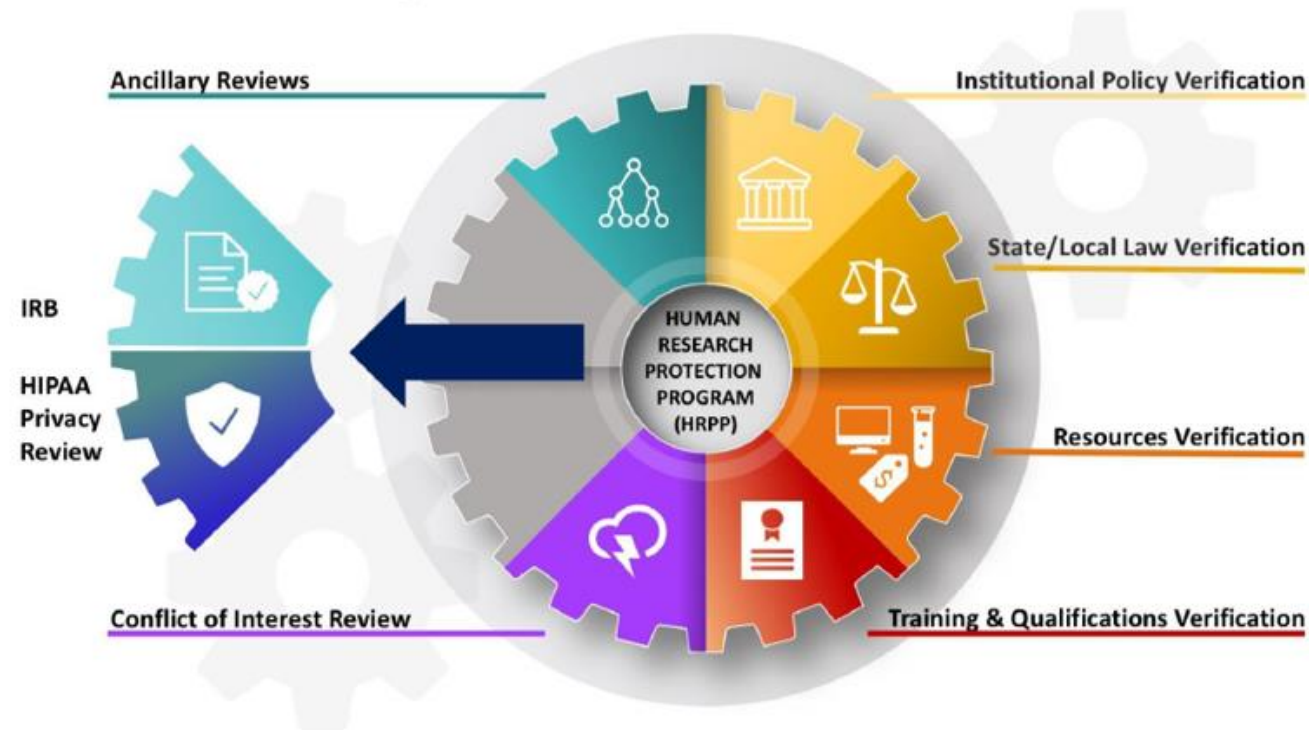


Local context: The language required by UT Southwestern to be present in informed consents for studies reviewed by an external IRB.

What is Single IRB (sIRB)?

- Use of one IRB of record (Reviewing IRB) for the regulatory and ethical review for multiple sites participating in a study.

The Full Picture | HRP



UTSW sIRB versus External IRB (Reliance)



UTSW sIRB

UTSW serves as the IRB of record for external sites. We are responsible for making regulatory determinations. We work with relying study sites to incorporate state/institutional requirements



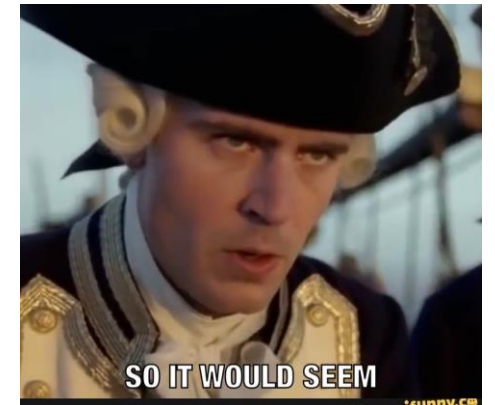
External IRB=Reliance

UTSW relies on an external IRB for regulatory determinations. Local study teams still need to work with IRB Office to confirm state/institutional components are fulfilled

Why Single IRB (sIRB)?

Mandated by regulations to:

1. Foster collaboration among institutions.
2. Streamline reviews with a centralized process to eliminate duplicative efforts.
3. Implement a single IRB review for all participating sites.
4. Ensure uniformity with standardized protocol and informed consent templates across all sites.
5. Enhance subject protections and promote reliability in study data.



When is it required?

NIH POLICY

Required for all multi-site, domestic, non-exempt NIH research for grants submitted on or after January 25, 2018.

COMMON RULE

Required for all domestic, cooperative research that is ready for IRB submission on or after January 20, 2020.

DHHS, DOD, DO Energy, DO Education, NASA, NSF, SSA, DO Homeland Security, USDA, VA, DO Commerce, EPA, Agency for International Development, DOHUD, DO Labor, DO Transportation

FDA Policy on Single IRB

- On September 28, 2022, the Food and Drug Administration (FDA) released two proposed rules, or Notices of Proposed Rule Making (NPRM), intended to partially harmonize its current regulations with the revised Common Rule.
- Proposed rule “[Institutional Review Boards; Cooperative Research](#)” recommends requiring any U.S. located institution conducting cooperative research to rely on sIRB oversight for the research being conducted in the U.S. (with certain exceptions). This would harmonize FDA regulations with the revised Common Rule’s sIRB requirements, as well as similar sIRB policies enacted by the National Institutes of Health (NIH).

■ Single IRB NIH and Federal Policies

When is it not required?



Exempt Research



If the designated SIRB
is unable to meet the
needs of specific
populations



Where local IRB is
required by federal,
tribal, or state laws



Research conducted
under career
development,
research training or
fellowship awards

Engagement in Research

Being the primary awardee for a federal grant that supports human subjects research

Intervening for research purposes with any human subjects of the research by performing invasive or noninvasive procedures or manipulating the environment

Interacting for research purposes with any human subject of the research

Obtaining the informed consent of human subjects for the research

Obtaining for research purposes identifiable private information or identifiable biological specimens from any source for the research

Engagement in Research

Examples of activities that DO NOT engage institutions in human subjects research:

Institutions

- Whose employees or agents
 - perform commercial or other services for investigators
 - inform prospective subjects about the availability of the research
 - provide prospective subjects with information about the research but do not obtain subjects' consent for the research or act as representatives of the investigators;
 - provide prospective subjects with information about contacting investigators for information or enrollment
 - seek or obtain the prospective subjects' permission for investigators to contact them
 - release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research
 - obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information (such as name or social security number); and are **unable** to readily ascertain the identity of the subjects to whom the coded information or specimens
- That permit use of their facilities for intervention or interaction with subjects by investigators from another institution

IRB Authorization Agreement

A formal agreement between Institutional Review Boards (IRBs) from different institutions or entities involved in a specific research project. This agreement outlines the terms of cooperation, outlines responsibilities of each IRB, and aims to streamline the review process while ensuring compliance with ethical and regulatory standards. May cover a single study, multiple studies, a category of studies, are all human subjects research conducted under an institutions Federalwide Assurance.

This agreement provides the permission for the reviewing IRB to make regulatory determinations on behalf of a relying site.

What is a Reliance Agreement?

- After an IAA has been executed, a reliance agreement (aka reliance documentation) is necessary.
- This document is signed by two the relying institution and the reviewing IRB.
- This reliance agreements documents agreement of an institution to rely on the reviewing IRB for a single study and allow for reviewing IRB to collect information that is necessary for the review of the study including:
 - Respective authorities
 - Responsibilities of relying site research team members and the Lead PI responsibilities
 - The communication plan all parties
 - Local context (ICF language, state/institutional components)



Responsibilities of the Reviewing and Relying Institutions

Reviewing IRB

- Regulatory review
- Evaluate relying sites
- Provide the approved study documents
- Develop local context survey
- Ensure that each sites local language is included in the consent
- Reviewing local and study wide amendments, reportable events, and continuing reviews

Relying Institution

- Determine if it is feasibility for the site to conduct the study
- Complete the local context survey and institutional profile
- Perform ancillary reviews
- Disclose conflicts of interest and provide a management plan if required
- Review study personnel training

Responsibilities of the Relying Study Team

- Inform the UTSW HRPP that you want to rely on an external IRB (submit a reliance request).
- Insert the UTSW local language into the template consent form.
- Work with the sponsor/lead site to submit to the IRB of record for site approval.
- Submit the study for acknowledgement eIRB
- Submit modifications and annual updates in eIRB.
- Submit any locally occurring reportable events to the IRB of record and UTSW HRPP

■ Types of IRBs

- **Commercial**

- Advarra and WCG

- **Institutional**

- IRBs at other medical centers and academic institutions

- **Cooperative Groups**

- National Cancer Institute (NCI) and National Marrow Donor Program (NMDP)

Commercial IRBs

- UTSW has a master service agreement (MSA) with Advarra and WCG.
- A reliance request is still required.
- Once the UTSW IRB office has indicated that we are willing to use Advarra or WCG for the study, work with the sponsor/lead site to submit to the IRB for site approval.
 - Instructions on submitting for site approval are included in the reliance acknowledgement email
- The study can be submitted in eIRB after this has been completed.



Institutional IRBs

- UTSW frequently collaborates with other medical centers and academic institutions and will rely on external institutional IRBs when appropriate.
- Each institution's IRB has its own policies and requirements for reliance.
- Site information sheet and institutional profile.
- The lead sites consent template will be used with the UTSW local context language submitted.
 - The required language is available on the UTSW HRPP forms page.
- Once the reliance agreement is completed, the lead site will submit a modification to their IRB to add UTSW as a site.
- Work with study team at the lead site on adding UTSW as a relying site.
- Once UTSW (or our affiliated institutions) have been approved by the IRB of record, the study can be submitted in eIRB.

National Cancer Institute Central IRB (NCI CIRB)

- The NCI CIRB serves as the IRB of record for many cooperative group studies, such as ECOG, NRG, Alliance, and COG.
- Individual reliance requests do not need to be submitted for NCI CIRB studies.
- The NCI consent template approved for the study must be used and have the UTSW language inserted.
 - The required UTSW language for NCI studies is available on the UTSW forms page.
- The UTSW short form templates can be used for NCI CIRB studies.
- All NCI CIRB studies will use a separate HIPAA authorization (form F) and HIPAA waivers will need to be requested from UTSW IRB using form H.



RELYING ON AN EXTERNAL IRB

Submitting a Request to Rely on an External IRB

- Reliance request is submitted via REDCap form on the UTSW HRPP website

Select the option that describes the reason for submitting this request

* must provide value

Request to Rely on an External IRB

- Include the protocol, consent template, local context documents, and any other materials that the lead site or IRB of record provided.
- The request will be reviewed by the UTSW IRB office to determine whether a reliance agreement is appropriate for this study.
- Booking a consultation with a reliance analyst is recommended but not required.
- If the request is approved, the UTSW IRB office will notify the IRB of record and begin working on the reliance agreement.

Including Affiliated Institutions in a Reliance Agreement

- Affiliated institutions, such as Children's Health and Parkland Health, require a separate reliance agreement with the external IRB.
- These can be added through the reliance request form.
- Notify the sponsor/lead site of the inclusion of any UTSW-affiliated institutions and that a separate agreement is required.




■ Reliance and Site Approval with the External IRB


- The UTSW study team adds the site-specific language to the consent form(s) provided by the lead site or sponsor.
 - Available on the forms page of the HRPP website.
- Pre-review of the consent form by UTSW HRPP is not required ***UNLESS*** the UTSW language has been rejected by the Reviewing IRB.
- Local context document is provided to the Reviewing IRB.
- Submit to the Reviewing IRB for site approval.
 - Work with the sponsor, CRO, or lead site to submit for approval.
 - Submit any site-specific recruitment materials or translated forms to the Reviewing IRB for approval.

eIRB Application

- Once UTSW has been approved by the Reviewing IRB, a new study application needs to be submitted in Velos/eIRB.
- Only submit the eIRB application **AFTER** the reliance agreement is executed.
- Request Performance Site Approval and Ancillary Committee Approvals

* 5.3 Are you requesting to rely on a non-UT Southwestern IRB? This review type is applicable when any research-related activities will occur at UTSW or its affiliated institutions under the jurisdiction of an external IRB. (For example, NCI-CIRB or another UTSW approved external IRB.) 

☒ Yes ☐ No [Clear](#)

* 5.4 Multi-Site Research: Is this a multi-site study? 

☒ Yes ☐ No [Clear](#)

- Answer 'Yes' to the above questions in the eIRB application.
- Include approval letters from the IRB of record for all submitted documents.

HIPAA Waivers

- Depending on the terms of the reliance agreement, either UTSW or the external IRB will serve as the Privacy Board and will grant waivers.
- Typically, the external IRB will also serve as the Privacy Board, but not always.
- If the external IRB is the Privacy Board:
 - All HIPAA waivers must be requested from the external IRB
 - The HIPAA authorization language will be embedded in the consent form using the language from the lead site.
- If UTSW is the Privacy Board when relying on an external IRB:
 - All HIPAA waivers will be requested from the UTSW HRPP office using form H.
 - A separate HIPAA authorization (form F) using UTSWs language will be used.

Study Review, Acknowledgement, and Activation

- Once the study is submitted in eIRB, the UTSW IRB Office will perform an administrative review.
 - Study team CITI training, conflicts of interest, consent language, recruitment plan
- Performance Site Review of at least one study site and Ancillary Committee Review
- UTSW IRB Office will accept the review of the external IRB.
- Study can be activated and enrollment can begin once the coverage analysis and clinical trial agreement have been approved (or listed as N/A in eIRB).
- The expiration date in eIRB is set for 30 days following the expiration date assigned by the Reviewing IRB.

Modifications

- Any changes to the study must be submitted as a modification in eIRB.
- All changes to the study must be approved by the Reviewing IRB prior to being submitted in eIRB.
 - Include the approval letter for the amended documents from the Reviewing IRB.
 - Exceptions: changes to study personnel (form B), form C, HIPAA waiver/authorization (if UTSW is the Privacy Board), corrections to the smartform.

Annual Updates

- Studies where we are relying on an external IRB require an annual update to be submitted in eIRB.
- Include the continuing review approval letter from the IRB of record.
 - If CR is not required by the IRB of record, the approval letter stating this should be provided.



Reportable Events

- Investigators relying on a non-UTSW IRB are responsible for reporting events to the reviewing IRB as required. The investigator must be familiar with the reporting policies of the reviewing (external) IRB.
- In addition to reporting to the external IRB, the following LOCAL events must be submitted to the UTSW HRPP:
 - **LOCAL** emergency deviations
 - **LOCAL** events that appear to constitute protocol violations or serious or continuing noncompliance
 - **LOCAL** UPIRSOs
 - **LOCAL** research-related complaints affecting subjects' rights, safety, or welfare.
- Local events must be reported to the reviewing IRB and UTSW HRPP within **5 working days** of discovery.
- The external IRB's response or determination must be submitted to UTSW HRPP within **10 working days** of receipt.



COMMON QUESTIONS



**The study has already been approved by
the central IRB, why does it need to be
approved again at UTSW?**

The study has already been approved by the central IRB, why does it need to be approved again at UTSW?

- While the central IRB reviews the study and makes regulatory determinations, the UTSW IRB Office performs an administrative review to ensure that local policy is being met.
- This is not a second IRB review.
- Consent form is reviewed to ensure that the appropriate local context language has been added.
- UTSW maintains a shadow record of what the Reviewing IRB has approved.
- Other local reviews, such as PRMC, radiation safety, or institutional biosafety committee, may be required.



How do I add a non-English short form for a reliance study?

How do I add a non-English short form for a reliance study?

- Use the approved shortform consent from the lead site/IRB of record.
- If necessary, obtain approval from the IRB of record to use the short form consent.
- Submit a modification in eIRB to use the short form consent.
- For NCI CIRB studies, the UTSW short form can be used.
 - This must still be submitted in eIRB.



**When is the best time to submit the
reliance request?**

When is the best time to submit the reliance request?

- Submit the reliance request as soon as you receive the protocol and the study is approved by the central IRB

Resources

Virtual Open Office Hours

HRPP-OCTM Virtual Open Office Hours

- Every Tuesday & Thursday
- 10:00 am-11:00 am held via virtual Zoom Session

Subscribe to [HRPP-Events](#) listserv for Zoom link!

Still Have Questions?

sIRB/Reliance Inquiries [Email](#)

Consultations:

[Book a meeting with a Reliance Analyst today!](#)

Questions?

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