

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER AT EL PASO (TTUHSC El Paso) SINGLE IRB (sIRB) PROCESS

A Single IRB means one IRB of record (or Reviewing IRB), selected on a study-by-study basis, which provides the regulatory and ethical review for all sites participating in a specific multisite study.

sIRB Requirement

At TTUHSC El Paso, a single IRB will be required for the following types of *non-exempt* cooperative (multisite) research carried out within the United States:

New studies approved on or after January 20, 2020 supported by an agency that has signed on to the Common Rule. For a full list of HHS Departments and Agencies that follow the Common Rule, please click [here](#).

Research supported by NIH. Click here for the official notice from NIH: [NOT-OD-16-094](#). There are some exceptions. For more about the NIH exceptions and additional information on the single IRB requirement for NIH supported research (in effect since January 25, 2018) click [here](#).

For projects that are not funded or supported by federal funds, the requirement does not apply.

IRB Reliance Agreements

Agreeing to be the sIRB for a Multi-Site Study (MSS) is much like a contract negotiation. If applicable, each institution must sign an agreement that outlines the responsibilities and expectations of the reviewing and relying IRBs. All studies require a signed agreement, unless 1) the project is deemed exempt, or 2) TTUHSC El Paso has a standing agreement in place with the organization(s). Please contact the IRB and Contracting/Sponsored Programs to engage in the agreement process at the earliest opportunity, as it may take time to negotiate the terms.

How long it may take to finalize an agreement depends on several factors, including the responsiveness of the other IRB and its experience with reliance agreements, as well as, whether language in the agreement requires negotiation. At a minimum, this may take *at least* 30 days. Study teams should keep this in mind when considering sIRB review. The Assistant Vice-President for Research must sign reliance agreements prior to submission to an external IRB.

TTUHSC El Paso has standing agreements in place with the following entities regarding sIRB review:

- National Cancer Institution Central IRB ([NCI CIRB](#)) for Children's Oncology Group studies
- [SMART IRB](#) - a platform for IRBs to share IRB approval for single IRB review. TTUHSC El Paso is a member of the SMART IRB
- UT System
- StrokeNet
- WCG IRB

Requirements before TTUHSC El Paso will agree to sIRB review by another site.

The TTUHSC El Paso IRB must verify that the project is eligible for review under a reliance agreement.

While developing your grant, contact the TTUHSC El Paso IRB to ask if TTUHSC El Paso will be the IRB of record (reviewing IRB) or if an external IRB is necessary (relying IRB), which will require a reliance agreement. Email the following information to Myrna Arvizo, Sr. Director, at myrna.arvizo@ttuhsc.edu:

- The TTUHSC El Paso PI and external Site PI name and contact information
- The study title and IRB number locally (if available) and from the other institution
- The protocol
- Identification of the research procedures (from the protocol) that will take place on this campus, along with the roles of the research personnel
- Identification of the Reviewing IRB

If eligible, email confirmation with further instructions, will be provided. The following may also be needed depending on the sIRB:

- A Request to Rely Authorization form, flexibility form or other acknowledgment
- The TTUHSC El Paso Institutional Official's signature
- The sIRB Institutional Official's signature

What does the TTUHSC EP IRB require when I use an External IRB?

The use of an external IRB does not exempt TTUHSC El Paso from human research activity oversight. TTUHSC El Paso remains accountable for the conduct of human research by TTUHSC El Paso personnel. The PI and study personnel are required to comply with **BOTH** TTUHSC EP research policies **AND** the external IRB policies. Please note: ***TTUHSC El Paso written IRB approval is required prior to initiating research activities at the local site(s) and prior to initiating amendment changes at the local site.***

Therefore, the following is required:

- Completion of TTUHSC El Paso IRB Education and Training for all study personnel: <https://ttuhscep.edu/research/committees/irb/resources/educational-req.aspx>
- iRIS accounts for all study personnel <https://ttuhscep.edu/research/committees/irb/resources/educational-req.aspx>
- Initial Review of supporting documents submitted via [iRIS](#) with the following attached:
 - IRB application
 - Protocol
 - Investigator Brochure (if applicable)
 - Signed Request to Rely form, flexibility addendum, or acknowledgment
 - External (Reviewing) IRB approval letter, **including approval and expiration dates, risk level. The TTUHSC El Paso IRB does not issue approval periods for External IRB**
 - Site -specific consent form which includes approved boilerplate language; this will be stamped for use on our campus (as applicable)
 - Recruitment material to be used at TTUHSC El Paso with local contact information

- Any other documents that are relevant to the review and will be used for the research procedures
- Ancillary approvals from other research committees and/or affiliates
- **During the conduct of the Research, it is the responsibility of the PI to submit the:**
 - Continuing Review Form via [iRIS](#) (frequency as required by the External IRB)
 - External IRB Continuing Review Approval Letter **with approval and expiration dates. The TTUHSC El Paso IRB does not issue approval periods for External IRB reviews.**
 - Unanticipated Event Reports via [iRIS](#) (as required by TTUHSC El Paso for local subjects)
 - Amendments submitted via [iRIS](#)
 - External IRB amendment approval letter
 - Any revised documents

Definitions

Reliance agreement

A formal, written document that provides a mechanism for an institution engaged in research to delegate IRB review to an IRB of another institution. Institutions may use different descriptive terms, (e.g., reliance agreement, cooperative agreement, IRB authorization agreement (IAA), or memorandum of understanding (MOU)). Agreements may cover single studies, categories of studies, or all human subjects research under an organization's Federalwide Assurance (FWA).

Reviewing IRB

The IRB that is responsible for the review, approval and regulatory oversight of a multi-center research study and serving more than one site. Sometimes referred to as the IRB of Record. The IRB that conducts initial and continuing reviews, and will review modification to approved protocol and unanticipated problems or adverse events that may arise. The Reviewing IRB will have the authority to suspend the research for failure to comply with conditions of approval or regulatory requirements.

The Reviewing IRB will notify the federal or funding agencies of these events consistent with their policies and procedures and copy the Relying IRB on any such correspondence. The Reviewing IRB will serve as the IRB of record. The IRB may refuse, on a case-by-case basis, to serve as the IRB of record for another location.

Relying IRB

The IRB of the institution where the research will take place and which will rely on an external IRB which will serve as the IRB for a multi-center study. The IRB may refuse, on a case-by-case basis, to rely on the review of another IRB.

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