IRB Reliance

What is IRB Reliance?

IRB Reliance is when an IRB agrees to rely on another IRB for the review and approval of a research project. IRB Reliance can be established between institutions or between an institution and an independent IRB, such as Western IRB or the NCI Central IRB. A reliance arrangement is particularly useful when multiple study sites are following the same study protocol or procedures. Reliance arrangements can also be useful when some of the study sites or partners do not have their own IRB.

Reliance agreements may be put in place when:

- UT Austin has agreed to be a reviewing IRB for one or more other institutions / organizations
- UT Austin has agreed to rely on the IRB of another institution or an independent IRB

Anytime a researcher affiliated with UT Austin is engaged in the conduct of human subject research and wishes to rely on an IRB other than the UT Austin IRB, the Office of Research Support and Compliance must agree to the arrangement, and UT Austin must sign a reliance agreement with the reviewing IRB. An individual is considered engaged in the conduct of human subjects research when carrying out activities such as consenting subjects, collecting data, or analyzing identifiable data.

How is IRB Reliance Documented?

In order to establish a reliance arrangement, the participating institutions or organizations must enter into a reliance agreement to document the arrangement. This agreement may be called a reliance agreement or an authorization agreement. These agreements are most often study specific; however, some master agreements exist to document the reliance arrangement between institutions for any study. Reliance agreements must be signed by an authorized institutional official since the agreement is between institutions and not between investigators.

Has UT Austin signed any master reliance agreements?

UT Austin has signed the following master agreement(s). We will be adding additional agreements with commercial IRBs for review of industry sponsored research.

- SMART IRB, which is an IRB reliance agreement signed by more than 400 institutions and independent IRBs. Check the [SMART IRB website](#) to determine if an entity has signed the SMART IRB agreement.
Until specific agreements are signed with the major independent IRBs, UT is able to utilize the SMART IRB agreement to facilitate reliance with these IRBs.

**How do I request a reliance arrangement if I want UT Austin to serve as the reviewing IRB (IRB of Record)?**

First, you should contact the Office of Research Support and Compliance at orsc@uts.cc.utexas.edu to determine that the UT IRB is willing to serve as the IRB of Record (reviewing IRB) for other participating sites. Until further notice, the UT Austin IRB will consider serving as the IRB of Record when the study involves no more than 4 sites. If a study will involve more than 4 sites, please discuss options with the RSC IRB Manager or Assistant Vice President for Research Support and Compliance.

When you are ready to submit your study for review, you should submit your study as usual. You will make the request in Section 4a of the IRB Proposal Template that asks for information about study locations. Each relying site must complete the form “Site Specific Application for Relying on the UT IRB.” This application and any supporting documentation should be submitted to the UT IRB by the UT PI.

**UT PI directed study with relying sites:** When study procedures will occur at multiple sites and all study procedures are being directed by the UT PI (i.e., no site PIs), requests for reliance from participating sites can be made at the time of the initial submission or via amendments.

**Multicenter study:** If the study is a multicenter study where all sites have their own PI and will follow a standardized protocol, your initial submission should not identify any relying sites. The UT IRB will approve the protocol and template forms, such as informed consent. After the initial submission is approved, you should submit an amendment to add non-UT Austin sites. The reason for adding sites via amendment after the initial protocol is approved is so that template forms can be approved before relying sites submit these forms with institution specific information for IRB review. Otherwise, if the UT IRB requires changes to any of the template forms, each site would need to make changes to the documents they had submitted for review.

**What information needs to be provided by a relying site when the UT Austin IRB is serving as the reviewing IRB?**

Relying sites must provide:

- Site specific application for relying on the UT IRB

- Any study documents that have been customized for the site (i.e., informed consent form)
**How do I request a reliance arrangement if I want UT to rely on another IRB?**

First, contact orsc@uts.cc.utexas.edu before you proceed with any submission to ensure that UT is amenable to relying on the other IRB. Taking this step can save you time in the long run.

Once you have determined that UT is willing to rely on the external IRB, you must submit an abbreviated submission in IRBaccess to formally request the reliance. Instead of submitting the standard Protocol Template, you should submit the following documents:

- Request to Rely on an External IRB form
- PI’s curriculum vitae
- Study protocol or IRB application approved by the reviewing IRB, if applicable
- Informed consent(s) and HIPAA authorizations that will be used at UT Austin
- Approval letter for the study from the external IRB, if already approved
- Any local context form(s) required by the external IRB
- Verification of all applicable institutional approvals, such as IBC approval

The submission will be reviewed for compliance with institutional requirements and other typical requirements of an external IRB including:

- Determining the PI is qualified and has appropriate credentials and privileges to conduct the research
- Verifying that all research personnel have completed CITI human subjects training and GCP training, if applicable
- Verifying that a COI review has been completed, and sharing any COI management plan with the external IRB
- Conducting HIPAA approvals for waiver of authorization, if applicable
- Confirming that IBC approval is in place, as needed

UT will correspond with the PI and/or the external IRB to finalize the reliance arrangement and document the agreement.
How do I know if UT needs to enter into a reliance agreement with the reviewing IRB?

Whenever the research personnel, including PI and all study staff, will be representing themselves as UT affiliated individuals during the conduct of the study, UT needs to enter into a reliance agreement with the reviewing IRB.

After my study is approved by an external IRB, what are my responsibilities?

- **Responsibilities with the Reviewing (External IRB)**

  When your study is approved by an external IRB, you are responsible for following all of the policies of the reviewing IRB. The study PI and all research personnel should be familiar with the policies of the Reviewing IRB. These responsibilities may be outlined in the reliance agreement or the approval letter, but typically will include:

  o Adhering to the study procedures approved by the reviewing IRB
  o Submitting any changes for approval prior to implementation (amendments) including changes in study personnel
  o Reporting all unanticipated problems and noncompliance within deadlines established by the reviewing IRB
  o Reporting any changes in financial relationships that may be perceived as a COI
  o Cooperating with any post approval monitoring requests

- **Responsibilities with the UT IRB**

  Even though your study is approved by an external IRB, you still have some responsibilities with the UT IRB. These include:

  o Submit the following as amendments to your UT submission:

    ▪ PI and personnel changes to UT for approval prior to submitting to the reviewing IRB (required because most reliance agreements require UT to verify personnel qualifications and training)
    
    ▪ Addition of drugs or devices
    
    ▪ Change in research funding
Submit a report on your UT submission when:

- An Unanticipated Problem occurs at the UT site (see the UT IRB Policies and Procedures Manual Section 9: Reporting Unanticipated Problems)
- The reviewing IRB determined that an Unanticipated Problem occurred at the UT site
- The reviewing IRB determined that Noncompliance occurred at the UT site

Close the study with the UT IRB when the reviewing IRB closes the UT Austin site

What should I do if my grant proposal requires a plan for Single IRB Review, or I am asked to collaborate on a grant that will propose Single IRB Review?

It is important to verify with the RSC any plans for use of a single IRB before a grant proposal is submitted. If you are preparing a grant proposing that the UT IRB serve as the reviewing IRB, it is particularly important to contact orsc@uts.cc.utexas.edu at least 2 weeks before your proposal is due to ensure the UT IRB is willing to serve. Similarly, if the grant will require that UT rely on an external IRB, it is important to contact orsc@uts.cc.utexas.edu in plenty of time to receive a response prior to the grant deadline.

IRBs may charge for the review of external site submissions, even on federally funded projects. Thus, it is important to consider potential IRB charges in grant budgets. At the present time, the UT IRB is not charging a fee for the review of external sites. When another IRB will serve as the reviewing IRB, it will also be important to determine whether that IRB will change a fee for initial and ongoing reviews for the UT site, and account for these charges in your budget.