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Reliance/Single IRB Guidance

What is IRB Reliance?

IRB Reliance is when one IRB agrees to rely on another IRB for the review and approval of a non-exempt 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 subject research when carrying out activities such as consenting subjects, collecting data, or analyzing identifiable data. **Please note that UT IRB will not enter into an authorization agreement for research determined to be exempt.**

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 currently signed the following master agreement(s).

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- **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.
- **National Cancer Institute Central Institutional Review Board (NCI CIRB)**, which is dedicated to protecting the rights and welfare of participants in cancer trials. More information about NCI CIRB can be found here: <https://www.ncicirb.org/>

UT is able to utilize the SMART IRB agreement to facilitate reliance with most institutions and major independent IRBs.

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

First, contact the ORSC at IRBreliance@austin.utexas.edu to determine if 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, discuss options with the ORSC IRB Reliance Specialist or the Assistant Director for the IRB Program.

When you are ready to submit your study for review, go to UT Research Management Suite – IRB Module (UTRMS-IRB) at <https://irb.research.utexas.edu/> and log in with UT EID and password to submit your application for IRB review. Once the main study is reviewed and approved, you can add participating sites under your study. Each relying site must complete the form “[HRP-UT931 – Template Site Specific Request to Rely on UT IRB Form](#).” This Form and any other supporting documentation should be uploaded in the system when you are completing the “Add Participating Site” activity.

If the study is a multicenter study where all sites have their own PI and will follow a standardized protocol, UT IRB will approve the protocol and template forms, such as informed consent first. After the initial submission is approved, you can add participating sites in the system. This ensures that UT IRB approves template forms prior to relying sites submit these approved forms slightly modified with their institution specific information. If the site submits the site documents prior to UT IRB approving the main study templates, sites would need to make changes to the documents they had previously submitted if UT IRB requires changes to any of the template forms.

How do I request a reliance arrangement if I want UT to rely on another IRB?

First, contact IRBreliance@austin.utexas.edu before you proceed with any submission to ensure that

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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 online application in UTRMS-IRB by going to <https://irb.research.utexas.edu/> and logging in with your UT EID. Once logged in, do the following:

- Create a new study online application.
- Complete this [HRP-UT930 Template Request to Rely on an External IRB Form](#) and upload it the system.
- Upload these documents:
 - a. Study protocol or IRB application approved or being reviewed by the external IRB
 - b. Informed consent(s) and HIPAA authorizations that will be used by UT PI
 - c. Approval letter for the study from the external IRB, if already approved
 - d. Any local context form(s) required by the external IRB
 - e. Verification of all applicable institutional approvals, such as IBC approval
 - f. PI's curriculum vitae (CV)

UT IRB will review the submission to assess compliance with institutional policies and procedures, and other external IRB regulatory requirements including:

- Determining if 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 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, if required

UT will correspond with UT 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?

UT needs to enter into a reliance agreement with the reviewing IRB if during the conduct of the study the PI including all research personnel are engaged in a non-exempt research and they represent themselves as UT affiliates.

Compliance Review Fee for Industry Sponsored Research

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UT charges a compliance review fee of \$1500 to conduct this internal review for industry sponsored studies. There is no charge for this review for non-industry sponsored research. Funds to pay this fee should be built into industry sponsored study budgets. Once the local IRB review is complete, ORSC will invoice the department for the funds.

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:

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

- Submitting the following as amendments or modifications 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
- Submitting 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 determines that an Unanticipated Problem occurred at the UT site
 - The reviewing IRB determines that Noncompliance occurred at the UT site
- Closing the study with the UT IRB when the reviewing IRB closes the UT Austin site

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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?

Effective January 25, 2018, the NIH has mandated that all domestic sites participating in a non-exempt, multi-site research study (where activities outlined in a single protocol are carried out at multiple institutions) use a single IRB (sIRB).

Effective January 20, 2020, the Common Rule requires a sIRB for all domestic sites participating in federally funded, non-exempt, cooperative research.

It is important to verify with the ORSC 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 IRBreliance@austin.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 IRBreliance@austin.utexas.edu in plenty of time to receive a response prior to the grant deadline.

Budget Considerations: 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. When another IRB will serve as the reviewing IRB, it will also be important to determine whether that IRB will charge a fee for initial and ongoing reviews for the UT site, and account for these charges in your budget.

When the UT IRB serves as the reviewing IRB for a federally funded multisite study for which single IRB review is required, the following charges will be assessed. The UT PI's department is responsible for paying the charges and recouping the costs from participating sites.

Activity	Cost per Site
Negotiate Reliance Agreement - Smart IRB or Master Agreement	\$120
Negotiate Agreement - Other	\$320
Initial Site Approval	\$300

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Site Modification or Closure	\$900 / academic year*
Unanticipated Problem – Site	\$445
Full Board Study	
Negotiate Reliance Agreement - Smart IRB or Master Agreement	\$120
Negotiate Agreement - Other	\$320
Initial Site Approval (reviewed as an expedited amendment)	\$300
Full Board Modification	\$370
Expedited Modification / Site Closure	\$900 / academic year*
Full Board Continuing Review	\$445
Unanticipated Problem	\$445

*The UT IRB will assess an annual charge of \$900 per site to cover costs associated with approving site amendments. The annual fee remains the same regardless of the number of amendments.

Fees will be assessed starting on September 1, 2020 for all federally funded multisite studies initially awarded after January 20, 2020.

Please note, we reserve the right to impose fees on funded, multi-site research involving reliance on UT IRB (where UT IRB acts as the reviewing IRB for other sites). Investigators are strongly encouraged to contact IRBreliance@austin.utexas.edu before submitting a proposal to ensure that the budget accounts for any IRB fees imposed.