

SIRB Fee Quote Supplement

Single IRB (SIRB) Review Services for Multisite Studies. Single IRB review fees apply to all funded multisite research projects that use the University of Utah IRB as the SIRB. The SIRB review fees are a flat rate so investigators can budget to cover the costs of IRB services. SIRB fees are not subject to the University indirect cost rate and should be budgeted as a direct cost.

How We Calculate SIRB Fees. The UU IRB does not charge an itemized per-submission fee based on the number of documents a study uses, the number of amendments submitted, or the number of continuing reviews. The IRB charges a flat rate based on the median amount of SIRB effort needed for such a project. If a project utilizes more than the median amount of effort, the IRB will not charge more. Additionally, the IRB will review all reportable problems and events free of charge. The SIRB fee for each project is calculated based on the following factors:

How We Calculate SIRB Fees	
Number of years the study will be open	The longer a study is open, the more SIRB review effort is needed. This results in a higher fee for service.
Number of participating research sites	The more sites involved, the more SIRB review effort is needed. This results in a higher fee for service.
Whether the U of U or its Affiliate Institutions are participating sites in the study	If the University of Utah or one of its Affiliate Institutions is a participating site in the study, we will waive a portion of the SIRB review fee for federally funded research. Because the University of Utah will cover a portion of the IRB review costs as part of the indirect rate if the UU is engaged in research, we reduce the amount billed as a direct cost to an award.
Site Buffer (Optional)	This component of the fee quote is optional. The purpose of the site buffer is to ensure that the budget for SIRB fees is sufficient to cover any changes in the expected sites over the course of the study. Specifically, sites may drop out and other sites may replace them or a study not meeting enrollment goals may need to add more sites. The standard buffer percentage is 20%.

Services Covered by SIRB Review Fees

Initial review fees will cover the following:

- Reliance consultation and confirmation
- Reliance agreement negotiation
- Initial reliance invitations to Human Research Protection Program (HRPPs) and relying institutions
- Reliance documentation procurement
- Site-specific community and institutional considerations requests
- Overall full protocol and supporting documents review
- Generic informed consent review

- Recruitment material review
- Site-specific informed consent review
- Recruitment material review

We will review an unlimited number of documents that are required for IRB review/approval. Annual review fees cover ongoing reviews including amendments, continuing reviews and progress updates, and all reportable problems and event reviews.

Services Not Covered by SIRB Review Fees

- SIRB Review Fees do not cover:
- Site assessments
- FDA Pre-IND/IDE Compliance Review for sponsor-investigators
- Regulatory audits
- Document preparation, copy editing, troubleshooting, and formatting
- Complex reliance agreement negotiations

If sites need assistance obtaining a Federalwide Assurance (FWA), joining an agreement, or learning to use an electronic system, the IRB may train the lead PI or designee; after that, the trained individual is responsible for training study team members and relying sites. The PI is responsible for staying informed of changes to policies or processes and training study team members. IRB staff are not responsible for technical support or electronic system troubleshooting.

The Principal Investigator (PI) retains responsibility for the design, conduct, reporting, and scientific integrity of the research. While the SIRB assists with initiating and negotiating reliance, the PI must obtain all required institutional and ancillary approvals and secure necessary agreements with outside entities. Although tasks may be delegated to qualified team members, the PI retains overall responsibility for ensuring compliance with all laws, regulations, and policies.

SIRB Fee Invoicing Schedule

Invoices are sent by the IRB's electronic system via email directly to the Responsible Principal Investigator (R-PI) and R-PI's contacts listed in the IRB application. Individual invoices are not sent to each Participating Site (pSite) Investigator. It is expected that the R-PI will coordinate payment of the fees, whether the fee is paid as a direct cost on the primary award or from a subcontract.

An initial payment is required before beginning SIRB review services. After an initial protocol is approved via a New Study Application, annual fees are charged to cover services provided in the previous year and for all sites that are included in the study at that point.

Fee	What it Covers	When Will This Invoice Be Sent?
Initial Protocol Review	Reliance consultation and confirmation, New Study Application review including	Before the New Study Application review begins



Institutional Review Board

THE UNIVERSITY OF UTAH

	overall full protocol and supporting documents review.	
Initial Site Review (per site)	Reliance confirmation, local context review, site-specific documents review and approval.	When the site is submitted for initial approval
Annual Protocol Review + Annual Site Review	Annual review fees cover ongoing reviews including amendments, continuing reviews and progress updates, and all reportable problem and event reviews for the previous year.	• Year 1: End of year 1 • Year 2: End of year 2, etc. • Final Year: With the Final Project Report

Next Steps After You Obtain Your Fee Quote

Fee quotes are only valid for the funding proposal listed on the quote and expire one year after they are issued. A new quote should be obtained if re-applying for a Request for Proposal even if the project is the same.