

Single IRB (SIRB) Review Services for Multi-Site Studies: Single IRB review fees apply to all funded multi-centered research projects that use the University of Utah IRB as the SIRB. This includes studies with federal funding, industry funding and for-profit funding, etc.

The SIRB review fees are a flat rate so investigators know what the cost of SIRB review services will be from the beginning and can budget accordingly. SIRB fees are not subject to the University indirect cost rate and should be budgeted as a direct cost.

SIRB Review Fee Calculation: 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 and 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:

Fee Quote Calculation	
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 continues to cover a portion of the IRB review costs as part of the indirect rate, we will reduce the amount billed as a direct cost to an award
Site Buffer	<i>This component of the fee quote is optional.</i> 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%

SIRB Review Fee Services:

Initial Review Fees	
Protocol Review	Reliance consultation & confirmation services, overall full protocol and supporting documents review, generic informed consent review, recruitment material review, and unlimited number of documents that are require IRB review/approval
Sites Review	Reliance negotiation, Human Research Programs (HRPs) communication, and reliance documentation procurement, site-specific community and institutional considerations, site-specific informed consent review, recruitment material review (unlimited number of documents that are require IRB review/approval)
Ongoing Review Fees	
Annual Protocol Review	Unlimited ongoing reviews: amendment reviews, Continuing reviews, all reportable problem and event reviews
Annual Site Review	Unlimited ongoing site reviews: amendment reviews, Continuing reviews, all reportable problem and event reviews

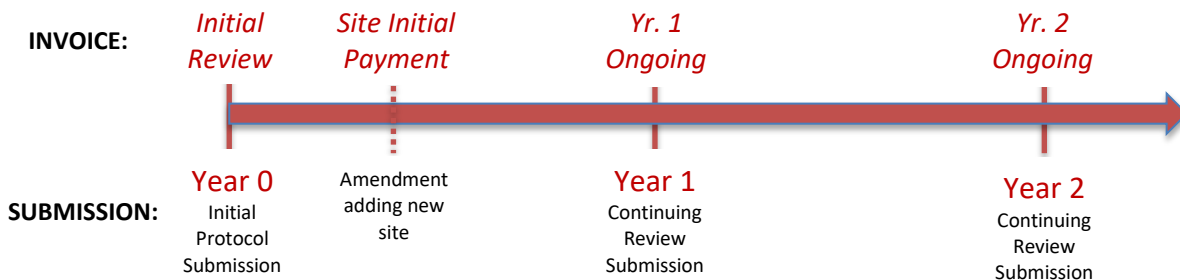
The SIRB Review Fees do not cover Pre-IND/IDE Compliance Review for Sponsor-Investigators, regulatory audits, or complex reliance agreement negotiation.



sIRB Fee Invoice Timeline

Invoices are sent by the ERICA system to email directly to the Responsible Investigator and Responsible Investigator's contacts listed in the ERICA application. Individual invoices are not sent to each participating site investigator. It is expected that the Responsible Investigator 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 for the new protocol. After a protocol is approved, an annual fee is invoiced to cover services provided in the previous year and for all sites that are included in the study at that time point. All payments can be processed upon receipt of the initial or annual ongoing invoices.



Next Steps Following Obtaining Fee Quote

Fee quotes are only valid for that particular funding proposal. A new quote should be obtained if re-applying for a Request for Proposal even if the project is the same. The IRB will ask for the status through email notification to PI and/or individual requesting the quote every three months.