Single IRB

Overview

The single IRB (sIRB) mandate is a set of complementary federal policies that require certain types of federally-funded studies that involve multiple institutions to use a single IRB to accomplish IRB review and approval for all of the institutions. This information may also be useful for multi-site studies that are not federally-funded but that wish to use a single IRB.

The basis for the single IRB model is to allow multiple sites that are conducting the same protocol to use a single IRB for review, instead of using multiple IRBs to review the research at the sites individually. The single IRB model has been in use for many years, across a wide variety of studies and circumstances.

The National Institutes of Health (NIH) policy requiring single IRB review for multi-site studies goes into effect on January 25, 2018. This policy applies to "the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subject's research. It does not apply to career development, research training, or fellowship awards.

	USA is Prime **(USA responsible for arranging Single IRB review)**
Sponsor Requires Single IRB	- USA will not serve as the single IRB, but rely on one of the selected independent IRBs or University IRB. - SMART IRB reliance agreement to be used, whenever possible - PI will work with appropriate grant office to develop budget to include in the proposal
	USA is a Participating Site **(main site is responsible for arranging single IRB review)**
	- The main site is responsible for selecting the single IRB, reliance mechanism, and costs. USA will cede review and serve as the Relying IRB.
Additional Information	
Reliance Agreement	- USA has signed the SMART IRB agreement - Investigators may use WIRB. USA already has an agreement with WIRB. Other sites would have to enter into agreement with WIRB unless they already have one.

Single IRB Review When USA is Prime

Considerations During Grant Preparation:

Determining who will be the Single IRB -

The single IRB and the Relying Sites are responsible for working together to come to a decision about relying on the single IRB for any given study. This decision must be documented in writing via an IRB Authorization Agreement, also called a Reliance Agreement. The Reliance Agreement outlines the obligations and responsibilities of both parties. It is preferable to utilize the SMART IRB agreement with all participating sites to avoid negotiating the terms of the agreement for each study with every participating site.

Costs of Single IRB Review -

The costs for IRB review at a single institution by that institution's IRB have typically been considered an indirect cost covered under an institution's Facilities and Administration (F&A) rate (except for industry-initiated-and-sponsored studies).

However, NIH expects that many single IRBs will charge fees to review other sites and these can be part of the direct costs. The fees are the responsibility of the prime site and should be included in the grant budget.

Fees for Independent IRB as Single IRB

It is the responsibility of the Principal Investigator (PI) to contact the independent IRB and get an estimate of fees to include in the budget.