NIH Single IRB Review Policy
Effective January 25, 2018

Source: https://osp.od.nih.gov/clinical-research/implementation-of-the-sirb-policy/

Single IRB (sIRB) Policy: Requires that a single IRB handle ethical review of non-exempt human subjects research that uses the same protocol but is conducted at multiple sites. This differs from current practice, which *allows* but does not *require* single IRB review.

To carry this out, an IRB at one of the sites must agree to be responsible for IRB review of the research occurring at all sites, and all sites must agree to defer their oversight to the reviewing IRB.

Formal agreements (called "reliance agreements" or "institutional authorization agreements") must be established between institutions that outline responsibilities.

FAQ's

What types of studies are expected to use a single IRB under the new NIH policy?
The NIH single IRB policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program.

The NIH single IRB policy does not apply to studies conducted under career development, research training or fellowship awards. Under the policy, "multi-site" is defined as two or more sites. Foreign sites participating in NIH- funded, multi-site studies will not be expected to follow this policy. The policy recognizes that it may not always be possible to use a single IRB, and it provides for exceptions.

When does the single IRB policy take effect?
The single IRB policy is effective for grant applications received for due dates on or after January 25, 2018. For contracts, the policy applies to all solicitations issued on or after January 25, 2018. Please note that this date is eight months later than the effective date that appears in the published single IRB policy. NIH decided to extend the effective date to provide additional time for implementation.

The NIH single IRB policy states that it applies to domestic "NIH-funded multi-site studies." What does "NIH-funded multi-site studies" mean?
For the NIH single IRB policy, "NIH-funded multi-site studies" mean that the same protocol involving non-exempt human subjects research is being conducted at more than one site and is being wholly or partially funded by NIH.

What is meant by the "same research protocol" for the NIH single IRB policy?
Protocols that address the same research questions, involve the same methodologies, and evaluate the same outcomes are considered to be the "same research protocol." Additionally, sites that are accruing research participants for studies that are identical except for variations due to local context consideration would be considered to be conducting the "same research

protocol." If a study involves a separate site for study coordination or coordination of data and statistical analyses and thee site is conducting the same protocol as the other participating sites, then all sites would be expected to rely on the designated single IRB.

Investigators who have questions about whether specific research protocols fall under the policy should discuss them with the Program Official listed on the FOA.

Who is responsible for selecting the single IRB for an NIH award and when must this be done?

In the NIH application/proposal for research funding, the applicant/offeror is expected to submit a plan describing the use of a single IRB that would be selected to serve as the IRB of record for all study sites. Where possible, the plan would identify the IRB that will serve as the single IRB. For delayed-onset research, where the IRB cannot be identified, applications/proposals should include a statement indicating that award recipients will follow the NIH single IRB policy and will provide a single IRB plan to the funding NIH Institute or Center prior to initiating a multi-site protocol.

Potentially Challenging areas:

Must the participating sites proposed in the NIH application agree ahead of time to rely on the single IRB identified in the application?

Sites should agree to a single IRB arrangement prior to the submission of an application or proposal. The applicant should indicate the participating sites' willingness to rely on the selected single IRB in the single IRB plan.

Does the NIH single IRB policy apply in cases where the sites in a multi-site study are funded by multiple NIH awards?

Yes. The policy applies to NIH-funded collaborative research protocols where all sites for a particular study are conducting the same protocol, regardless of the number of NIH awards funding that study protocol.

If an NIH awardee has an ongoing multi-site trial that is still recruiting, must a single IRB be selected and take over the review for all participating sites?

The NIH single IRB policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after the policy effective date. Ongoing, non-competing awards will not be expected to follow the policy until the grantee submits a competing renewal application after the policy is in effect. For contracts, the policy applies to all solicitations issued on or after the effective date.

Will signed Reliance Agreements from participating sites need to be in place prior to NIH funding?

No. Signed reliance agreements from participating sites will not be required to be in place prior to funding a multi-site study but must be in place prior to starting the proposed multi-site human subjects research. A Reliance Agreement must be in place at a participating site before that site engages in human subjects research for the project.

In what timeframe is an NIH awardee expected to execute the Reliance Agreement with participating sites?

NIH requests certification of IRB approval as part of the Just-in-Time process. However, NIH recognizes that, for some studies, obtaining signed Reliance Agreements among sites may take longer to complete. In such cases, an acceptable timeframe for establishing the single IRB and obtaining IRB approval must be agreed upon by the NIH funding Institute or Center and the award recipient(s). Awards will not be made without certification of IRB approval; however, in extenuating circumstances the grant award will be made without certification of IRB approval but will include terms and conditions restricting all human subjects activities. Once the Reliance Agreements are signed and IRB approval is obtained, the NIH Institute or Center will lift the restrictions by revising the Notice of Award and the award recipient may then start the proposed multi-site human subjects research. A Reliance Agreement must be in place at a participating site before that site engages in human subjects research for the project.