

In June 2016, the National Institutes of Health issued a formal policy regarding use of a single institutional review board (or sIRB) for multi-site research. This policy—effective May 25, 2017—promotes NIH’s expectation that a single IRB of record will be used in the ethical review of nonexempt, NIH-funded human subjects research protocols that are carried out at more than one site within the United States. Through this policy, NIH hopes to enhance and streamline the IRB review process in multi-site research. Eliminating duplicative IRB review is expected to reduce administrative burdens and inefficiencies without compromising human subjects protections, as well as to allow IRBs to concentrate on review of single-site protocols.

## Scope

The policy applies to the domestic sites of NIH-funded multisite studies, in which each site follows a single protocol involving nonexempt human subjects research. These studies may be supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. The policy does not apply to career development, research training, or fellowship awards. Foreign sites participating in NIH-funded, multisite studies are not expected to follow the policy. Definitions

NIH defines several relevant terms related to this policy.

An **authorization agreement** (also called a reliance agreement) documents respective authorities, roles, responsibilities, and communication between an institution providing ethical review and a participating site relying on the sIRB.

A **multisite study** is one that follows a single protocol in conducting nonexempt human subjects research at more than one site. (Note that the NIH definition is narrow, in that it includes only sites following a single protocol.)

## Responsibilities

In the application/proposal for NIH funding, the applicant/offeror is responsible for submitting a plan describing the use of an sIRB that will serve as the IRB of record for all sites. This plan should state that all participating sites will adhere to NIH’s sIRB Policy and describe how the sites and the sIRB will communicate. If, in delayed-onset research, an sIRB has not yet been identified, applications/proposals should indicate that awardees will follow the NIH sIRB Policy and inform the funding NIH Institute/Center prior to initiating a multi-site study that it intends to use a registered IRB of record. The applicant/offeror may request direct-cost funding for the additional costs associated with the establishment and review of the multisite study by the sIRB, with appropriate justification; all such costs must be reasonable and consistent with cost principles, as described in the NIH Grants Policy Statement

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and the Federal Acquisition Regulation.

Awardees are responsible for ensuring that authorization agreements are in place; copies of authorization agreements and other documentation should be maintained to document compliance with this policy, as needed. As appropriate, awardees must ensure that a mechanism for communication between the sIRB and participating sites is established. Awardees may delegate to others the tasks associated with these responsibilities.

The funding NIH institute or center is responsible for management and oversight of the award. This includes communicating with the awardee regarding implementation of its plan for complying with the sIRB Policy.

The sIRB is responsible for conducting the ethical review of NIH-funded multisite studies for all participating sites. In its review, the sIRB must meet the regulatory requirements delineated in the Common Rule. The sIRB may also serve as a Privacy Board, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes.

All participating sites are expected to rely on the sIRB to carry out the functions regulatorily required for IRB review. Participating sites are responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved protocol, and reporting unanticipated problems and study progress to the sIRB. Participating sites must also communicate information necessary for the sIRB to consider local context issues and state or local regulatory requirements.

### **Exceptions**

NIH will allow exceptions to this policy where sIRB review would be prohibited by a federal, tribal, or state law, regulation, or policy. NIH will consider requests for exceptions not based on such prohibitions, provided there is a compelling justification.

### **Effective date**

The NIH sIRB Policy applies to all competing grant applications (including new, renewal, revision, or resubmission applications) with receipt dates on or after May 25, 2017. Ongoing, noncompeting awards are not expected to comply with this policy until the grantee submits a competing renewal application.

Although NIH does not require designation of an sIRB for NIH-sponsored collaborative research when the site's involvement does not include subject interaction or intervention under a single protocol, an sIRB may still be utilized, if appropriate.

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Contact the IRB for more information about the NIH Policy on the Use of a Single Institutional Review Board for Multisite Research.

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