

NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

Purpose

The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46. This policy, which is consistent with 45 CFR Part 46.114, is intended to enhance and streamline the process of IRB review and reduce inefficiencies so that research can proceed as expeditiously as possible without compromising ethical principles and protections for human research participants.

Scope and Applicability

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 subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.

This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.

Consistent with the Roles and Responsibilities section, applicants/offers will be expected to include a plan for the use of an sIRB in the applications/proposals they submit to the NIH. The NIH's acceptance of the submitted plan will be incorporated as a term and condition in the Notice of Award or in the Contract Award. This policy also applies to the NIH Intramural Research Program.

Definitions

The **Authorization Agreement**, which is also called a reliance agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating site relying on the sIRB.

A **multi-site study** uses the same protocol to conduct non-exempt human subjects research at more than one site.

Participating site in a multi-site study is a domestic entity that will rely on the sIRB to carry out the site's initial and continuing IRB review of human subjects research for the multi-site study.

sIRB is the single IRB of record that has been selected to carry out the IRB review requirements at 45 CFR Part 46 for participating sites of the multi-site study.

Roles and Responsibilities

This policy establishes the following roles and responsibilities:

Applicant/Offeror. In the application/proposal for research funding, the applicant/offers is expected to submit a plan describing the use of an sIRB that will be selected to serve as the IRB of record for all study sites. The plan should include a statement confirming that participating sites will adhere to the sIRB Policy and describe how communications between sites and sIRB will be handled. If, in delayed-onset research, an sIRB has not yet been

identified, applications/proposals should include a statement that awardees will follow this Policy and communicate plans to use a registered IRB of record to the funding NIH Institute/Center prior to initiating a multi-site study. The applicant/offeror may request direct cost funding for the additional costs associated with the establishment and review of the multi-site 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 and the Federal Acquisition Regulation (FAR) 31.302 (Direct Costs) and FAR 31.203 (Indirect Costs).

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

Funding Institute or Center (IC). Funding ICs are responsible for management and oversight of the award, including communicating with the awardee regarding the implementation of its proposed plan to comply with the sIRB Policy. In the event that questions arise about the awardee's plan, including the IRB that has been selected to serve as the sIRB, the funding IC will work with the awardee to resolve them.

sIRB. The sIRB is responsible for conducting the ethical review of NIH-funded multi-site studies for participating sites. The sIRB will be expected to carry out the regulatory requirements as specified under the HHS regulations at 45 CFR Part 46. In reviewing multi-site research protocols, the sIRB may serve as a Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes. The sIRB will collaborate with the awardee to establish a mechanism for communication between the sIRB and the participating sites.

Participating Site. All sites participating in a multi-site study are expected to rely on an sIRB to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR 46. 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 communicate relevant information necessary for the sIRB to consider local context issues and state/local regulatory requirements during its deliberations. Participating sites are expected to rely on the sIRB to satisfy the regulatory requirements relevant to the ethical review. Although IRB ethical review at a participating site would be counter to the intent and goal of this policy, the policy does not prohibit any participating site from duplicating the sIRB. However, if this approach is taken, NIH funds may not be used to pay for the cost of the duplicate review.

Exceptions

Exceptions to this policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.

Effective Date

This policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017. Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application. For contracts, the policy applies to all solicitations issued on or after May 25, 2017. For the intramural program, the policy applies to intramural multi-site studies submitted for initial review after May 25, 2017.