

SINGLE IRB FAQs

Common Terms

Multi-Site Study: A multi-site study uses the same protocol to conduct non-exempt human research at more than one site.

Participating Site: In a multi-site study a participating site is a domestic entity that will rely on the sIRB to carry out the site's IRB review of human research for the study. In eIRB+ this is called a "pSite", in which a separate submission will be required for each external site relying upon the NU IRB.

sIRB: An sIRB (Single Institutional Review Board) is the selected IRB of record that conducts the ethical review for participating sites of the multi-site study. Also known as the Reviewing IRB.

Relying IRB: An IRB designating an agreement to cede review to an external IRB for a particular study

What is the difference between a central IRB and a single IRB?

Both are designed to help streamline IRB review, and the terms are sometimes used interchangeably. In general: A Central IRB is the IRB of record that provides the ethical review for all sites participating in more than one multi-site study. The sites are usually in a network, consortium or particular program. A Single IRB (sIRB) is the IRB of record, selected on a study-by-

study basis, which provides the ethical review for all sites participating in a multi-site study. A Central IRB may serve as the Single IRB in some cases.

If a single IRB review is required, how is the decision made as to which IRB will be the reviewing IRB and which institution(s) will be the relying institution(s)?

There are a number of different ways that the decision as to which entity will be the Reviewing IRB and which will be the Relying IRBs can be made: (1) The sponsor or funder may identify the Reviewing IRB; (2) the applicant for funding may propose the Reviewing IRB or; (3) the group of researchers involved in the research may collectively decide which IRB they would prefer to serve as the Reviewing IRB.

In all cases, consideration should be given to issues such as expertise in a particular area of research or familiarity with the participant population, or one IRB's capabilities for serving as the Reviewing IRB. The Secretary's Advisory Committee on Human Research Protections (SACHRP) has previously provided guidance on this topic in its document entitled: ["Recommendations on Consideration of Local Context with Respect to Increasing Use of Single IRB Review."](#)

What types of studies are expected to use a single IRB under the new NIH policy? Are other sponsors requiring the use of the single IRB?

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.

Yes, all federal sponsors, as of January 19, 2020, require all sites in the United States participating in a federally funded cooperative research study involving more than one site to use single IRB review.

Exceptions: Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or Research for which any Federal department of agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate.

As a UMMC investigator, what is my first step when a single IRB is required? Will UMMC serve as the Reviewing IRB for some studies?

It is recommended that you contact the Human Research Office **at least 5 weeks** prior to the grant application due date to discuss options for IRB review of a multi-site or collaborative study where UMMC will either be the lead or participating site. The UMMC IRB will determine if it is appropriate for us to serve as the Reviewing IRB or if the study should be ceded to an External IRB. If it is determined that an External IRB will serve as the Reviewing IRB for all sites, the IRB Reliance Manager will provide the Investigator/Research Team with the appropriate letter of support to include with the grant proposal.

What are the responsibilities of the Reviewing IRB and the Relying IRB(s) with respect to information pertaining to the local context?

The Reviewing IRB must have access to information on local context and must ensure that the review of the research adequately considers local context issues and concerns. Local context generally refers to local circumstances, preferences, and variability and could include such issues as variation in language, economic issues, and the like. In general, the relying institution should provide information on local context to the Reviewing IRB with updates as appropriate.

What are the responsibilities of the Reviewing IRB and the Relying IRB(s) pertaining to applicable state and local laws?

Both HHS and FDA regulations require that “the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.” Information relating to state or local laws that would have implications for the research conducted at the relying institution(s) must be considered by the Reviewing IRB. Some states have laws that impact research such as age of majority, additional informed consent requirements, and/or additional privacy notification requirements. The Reviewing IRB needs to be aware of the relevant state laws that impact proposed research at participating sites. There are multiple approaches that IRBs can use to facilitate this. A Reviewing IRB can develop and maintain a state law database, and put in place mechanisms to identify when research will be conducted in a location with applicable local laws. The Reviewing IRB can also obtain the information from the Relying IRB(s).

What are some of the key responsibilities of the Reviewing IRB and the relying IRB(s) with respect to the oversight of research?

Monitoring and Auditing

The Authorization Agreement should identify what information needs to be relayed to the Reviewing IRB

relating to its oversight of research. The IRB Authorization Agreement should identify which IRBs/institution will have responsibility for monitoring and auditing or otherwise supervising, as appropriate, the activities at sites relying on a Reviewing IRB, including both routine activities as well as for-cause investigations. Relying IRBs should consider what role the local research institution will play in review and oversight of a study, given that the local research institution is a site where the research will be conducted and has the best knowledge of (1) the conditions under which the research is implemented and (2) the qualifications of the investigators and study teams. The Reviewing IRB may rely on the relying institutions for these functions, but this division of responsibilities should be explicit in the authorization agreement.

Complaints from Research Participants

The Authorization Agreement should address the management of participant complaints that includes mechanisms for notifying the relying sites, as well as the Reviewing IRB, including institutional officials, of any issues identified at a site. Resolution of complaints will ordinarily require cooperation between the Reviewing IRB and the relying IRB(s)

Investigator Qualifications and Education

The IRB Authorization Agreement should specify the process to ensure that investigators participating in the research have adequate qualifications and have

undergone required training and that this information is communicated to the Reviewing IRB.

Responsibility for Conducting Investigations

The Reviewing IRB and the relying IRB(s) both have the authority to conduct fact-finding and investigations regarding protocol deviations, noncompliance or unanticipated problems. However, the Reviewing IRB will necessarily need to rely on obtaining information from the relying IRB, and the relying IRB typically will have the greater need and capacity to manage the fact-finding or investigation and greater access to relevant information.

Reporting Responsibilities

IRBs have a reporting responsibility to organizational officials, regulatory agencies like OHRP and the FDA, and sponsors for serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and suspensions or terminations of IRB approval.

Who is responsible for conducting IRB review of the grant?

The Authorization Agreement should state that the Reviewing IRB is responsible for assessing consistency between the grant and the protocol.

How does ceding IRB review affect other aspects of the human research protection program?

The Relying IRB(s) must consider the impact of ceding IRB review on other functions integral to the safe conduct of research and the protection of human subjects in research. These include, but are not limited to: management of conflict of interest issues and clinical trial agreements, as well as radiation safety and institutional biosafety review. These reviews may be integrated with the local IRB review and can affect participant safety and IRB review generally. When IRB review is ceded to another IRB, there exists a responsibility to ensure the continued integration of these reviews and communication to the Reviewing IRB as necessary and appropriate. It is suggested that relying institutions assess how ceding IRB review will affect existing processes, and what changes are required, in preparation for reliance on a single IRB.

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