



Human Research Protection Program / Institutional Review Board
Standard Operating Procedure
2018 Common Rule

**For Studies Initially Approved on
or After January 21, 2019**

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1 NIH Single IRB (sIRB) for Multi-Site Research

The NIH sIRB policy applies to grant applications proposing non-exempt human research which are 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. The policy does not apply to career development, research training, or fellowship awards, nor to sites that are not conducting the same protocol as the other sites (e.g., sites providing statistical support or laboratory analysis only) or to foreign sites.

Exceptions to the policy are automatic when local IRB review is required by federal, tribal, or state law/regulation/policy. Such exceptions and the basis should be cited in the proposed sIRB plan (see below) and apply only to the site(s) to which the law/regulation/policy applies. Other exceptions will be considered when there is compelling justification. The site(s) and justification for why the site(s) cannot rely on the single IRB of record should be included in the proposed sIRB plan. NIH will consider the exception request and inform the applicant of the outcome.

1.1 Selection and Designation of a sIRB

MaineHealth investigators submitting applications for NIH-funded multi-site research must describe the sIRB plan in the funding proposal (grant application or contract proposal), and, if applicable, may request direct cost funding to cover additional costs related to the requirements of the NIH policy.

ORC **should be contacted as early in the grant writing process as possible** to either confirm that MaineHealth can provide IRB services for the study, or to assist the investigator in making alternative arrangements (e.g., use the IRB at one of the participating sites, SMART IRB, etc.). ORC will consult with others within the organization as needed and make a recommendation to the IO for consideration. If MaineHealth IRB can serve as the sIRB, ORC will assist the investigator in working with the Grants and Contracts Office to ensure accurate, direct cost, budgeting for the service.

1.2 Reliance Agreements for sIRB Studies

A Reliance Agreement (or "Authorization Agreement") between the sIRB and the participating sites is required. See Section 9.2 for details.

1.3 sIRB Responsibilities

1. Per the NIH Policy, the sIRB is responsible for conducting the ethical review of NIH-funded multi-site studies for participating sites and for carrying out the regulatory requirements as specified under the HHS regulations at 45 CFR Part 46.
2. The sIRB must have the necessary infrastructure to support the required activities (e.g., administrative or regulatory staff, policies, procedures, workflows and technology).
3. 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.

4. The sIRB can delegate to relying institutions the ability to monitor or observe the conduct of the research and/or the consent process.
5. The sIRB must review and approve proposed management plans for investigators determined to have a financial conflict of interest.

1.4 Participating Site Responsibilities

All sites participating in a multi-site study are expected to rely on a 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. Additionally, the participating site is responsible for:

1. Reporting incidents of protocol deviations or noncompliance to the sIRB;
2. Monitoring or observing the conduct of the research and/or the consent process, when specified in the Reliance Agreement;
3. Ensuring disclosure and management of conflicts of interest according to the participating sites' policies and procedures and submit for approval to the sIRB management plans related to investigator FCOI's in human subject research;
4. Reporting to the sIRB changes to research implemented to eliminate apparent immediate hazards to participants;
5. Ensuring ancillary reviews by Pharmacy, IBC, Radiation Safety Committee, Scientific Review Committee, etc. are conducted prior to commencement of the research (or IRB approval of the research, depending on local policy).

When an external IRB serves as the sIRB for a study in which MaineHealth is engaged, investigators must register the study with MaineHealth via IRBNet prior to submission to the external IRB following the procedures outlined in Section 8.3.4. Post-approval requirements for investigators are also detailed in Section 8.3.5. Research reviewed by external IRBs remains subject to review, approval, and oversight by MaineHealth HRPP and must adhere to all applicable policies, procedures, and requirements required for the safe and ethical conduct of the study.