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

Effective on January 25, 2018

Scope

The NIH 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.

The final policy is intended to apply only to studies where the same research protocol is being conducted at more than one site; it does not apply to studies that involve more than one site but the sites have different roles in carrying out the research. Applicants/offerors will be expected to submit a plan identifying the sIRB that will serve as the IRB of record for all study sites in the applications/proposals they submit to the NIH. It will be the responsibility of the applicant/offeror to assure that the sIRB is qualified to serve; the applicant’s plan will not be evaluated in peer review.

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.

For the complete final policy and additional information: grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html