NIH Single IRB Policy

The NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research will be effective January 25, 2018.

The policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after January 25, 2018. Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application.

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/offerors 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.

Costs associated with the sIRB review may be included as direct costs in the application budget. Work with your OSPA CGO/RA prior to submitting your proposal to NIH.

- NIH Policy on the Use of a Single IRB for Multi-Site Research (NOT-OD-16-094)
- Guidance on Exceptions to the Single IRB Policy (NOT-OD-18-003)
- Guidance on Implementation of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-18-004)
- Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-Site Research (<u>NOT-OD-16-109</u>)