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

Notice Number: NOT-OD-18-004

Key Dates
Release Date: October 11, 2017

Related Announcements
NOT-OD-16-094
NOT-OD-18-003
NOT-OD-17-076
NOT-OD-16-109
NOT-OD-17-062
NOT-OD-17-119

Issued by
National Institutes of Health (NIH)

Purpose

The purpose of this Notice is to provide additional guidance to the extramural research community for the implementation of the Final NIH Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research.

Background

On June 21, 2016, the NIH issued the Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. The goal of the sIRB policy is to reduce the burden of the IRB review process for multi-site research conducting the same protocol, allowing research to proceed effectively and expeditiously without compromising the protections of human subjects.

The sIRB policy applies to domestic sites of multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research funded wholly or in part by NIH, including grants, cooperative agreements, and Research and Development (R&D) contracts. The policy does not apply to:

- Foreign sites; or
- Career development (K), institutional training (T), and fellowship awards (F).

The policy allows for exceptions in the following instances:

- Sites for which federal, state, or tribal laws, regulations or policies require local IRB review.
- Other exceptions to allow for local IRB review may be considered by NIH based on compelling justification. These other exceptions must be reviewed and approved by NIH. Please see NOT-OD-18-003 for more information about exceptions to the policy.

As announced on June 16, 2017 (NOT-OD-17-076), the effective date of the policy has been extended to January 25, 2018. For grant applications, the sIRB policy will apply to all competing grant applications for due dates on or after January 25, 2018; and for R&D contracts, the policy will apply to all solicitations issued on or after January 25, 2018.

Implementation Guidelines

Single IRB Review Options for Meeting the Policy:
As required by the federal regulations at 45 CFR 46, any IRB serving as the sIRB of record for NIH funded research must be registered with the HHS Office for Human Research Protections (OHRP) and must have membership to adequately review the proposed study.

The following are examples of types of IRBs that could be used:

- An institutional IRB that is associated with either the awardee or a participating site;
- An independent, commercial or unaffiliated IRB; or
- A central IRB organized to review the proposed study.

Expectations for Applications/Proposals:
When possible, the sIRB should be identified by the applicant/offeror in the sIRB plan attachment within the application/proposal. Note that the Funding Opportunity Announcement (FOA) or Request for Proposal (RFP) may include specific requirements for IRB review, such as the intent to set up a central IRB for specific projects. The applicant/offeror is expected to follow the instructions in the specific FOA or RFP.

The following resources provide additional information about the sIRB plan:

- Instructions for writing a sIRB plan and providing the justification for exceptions to the sIRB policy within Section 3.2 of the Study Record in the grant application are provided in the PHS Human Subjects and Clinical Trials Information Form Application Guide.
- For studies considered delayed onset, instructions for documenting the applicant's intention to comply with the single IRB policy within the justification for delayed onset of multi-site human subjects research are provided in the PHS Human Subjects and Clinical Trials Information Form Application Guide.
- Instructions about sIRB costs are provided in the G.300 - R&R Budget Form.
- For R&D contracts, instructions for writing a sIRB plan and documenting exceptions to the sIRB policy within a proposal are provided in the solicitation.
- The approved sIRB plan will be a term and condition in the Notice of Award or in the Contract Award.

Note: Effective for due dates on or after January 25, 2018, applicants will be required to use the new PHS Human Subjects and Clinical Trials Information Form in the application package. To learn more about the implementation of the new PHS Human Subjects and Clinical Trials Information Form and the attachment upload for the sIRB plan, see NOT-OD-17-062 or NOT-OD-17-119.

Evaluation of sIRB Information

The adequacy of the sIRB plan will not factor into the review score or overall rating of the Protection of Human Subjects section, unless the FOA/RFP has specific requirements for the sIRB and associated review criteria. For grant applications, a note may be included in the Summary Statement if the sIRB plan appears to be missing or is incomplete, and this will need to be addressed before an award can be made. For contracts, the RFP will include requirements about what must be provided to NIH regarding the sIRB prior to the time of award and beyond.

Resources

- NIH sIRB Policy for Multi-Site Research (Policy WebPage)
- NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research(NIH Guide Notice)
- Clinical Research Policy – IRB Review
- FAQs on NIH Policy on the Use of a Single IRB for Multi-Site Research Costs
- FAQs on Implementation of the sIRB Policy
- NIH Office of Extramural (OER) Webinars

Inquiries

Please direct all inquiries to:

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