Single IRB Review

Overview:

In an effort to reduce duplicate submissions and oversight by multiple IRBs for the same protocol, the ETSU IRBs offer reliance agreement opportunities for multisite research. Reliance arrangements between multiple institutions allow the IRB of one site to perform the IRB review for participating sites conducting the same protocol. The ETSU IRBs may enter into reliance agreements for collaborative research when deemed appropriate on a study-by-study basis and in accordance with NIH policy and federal regulation.

NIH sIRB Mandate

Effective January 25, 2018, the NIH mandated the use of single IRBs as a contingency for funding of NIH multicenter studies. This mandate applies to:

- NIH funded or supported projects
- Competing grant, cooperative agreement, or contract applications
- Grant receipt date on or after 1/25/2018
- Non-exempt research
- Domestic awardees and conducted at U.S. domestic sites
- Involve multiple sites, all of which are conducting the same protocol

Common Rule sIRB Regulation

Effective January 20, 2020, the 2018 Common Rule regulations require the use of a single IRB for all cooperative research funded by any Common Rule agency. This applies to:

- All multisite research, supported by any federal department or agency
- Non-exempt research
- Domestic awardees and conducted at U.S. domestic sites

What research is excluded from sIRB?

The sIRB mandate does not apply to studies that are:

- Not funded or supported by any federal department or agency,
- Funded to foreign awardees,
- Conducted at international sites, **or**

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- Where review by the proposed sIRB would be prohibited by federal, tribal, or state law, regulation, or policy.

Cooperative research funded or supported by DHHS or NIH, but initially approved before 1/20/2020, are also excepted from the sIRB mandate.

For collaborative research not subject to the sIRB requirement, institutions participating in the research may enter into a reliance agreement to avoid duplication of effort as deemed appropriate by the institutions engaged in the research.

Who will serve as the Single IRB?

The federal department or agency supporting the research may identify the sIRB in the request for proposals or terms of the award. In most situations, the lead Principal Investigator (or primary awardee), in collaboration with the IRB office at the lead PI's institution, will select the sIRB. The selected IRB must be willing to serve as the sIRB, and all participating sites must agree to rely on the sIRB. It is important that the lead PI contact their IRB office as soon as possible to develop a sIRB plan. The proposal should include a letter of support from the selected sIRB. The proposal should also include the anticipated sIRB fees in the budget, which may vary depending on the sIRB fee schedule and size, scope, and complexity of the proposed study.

Who to contact for assistance with sIRB?

If an ETSU employee is the lead PI, the IRB Office and the Office for Research and Sponsored Programs must be consulted at least 60 days prior to the sponsor application submission date. The IRB and ORSPA will help facilitate the documentation needed to prepare the sIRB plan and budget.

IRB@etsu.edu
423-439-6054
www.etsu.edu/irb

research@etsu.edu
423-439-6052
www.etsu.edu/research