HUMAN RESEARCH PROTECTION

Single IRB review for federally funded research

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Visit the Hennepin Healthcare HRPO webpage for current forms and information:
https://www.hhrinstitute.org/researcher-resources/ohsr/

1) Is my research subject to the single IRB requirement?

Most federally-funded research conducted by more than one U.S. based institution must use a single IRB (sIRB). As of January 20, 2020, the revised Common Rule established that research involving human subjects conducted by more than one U.S. institution must use a single IRB (sIRB) unless the research meets exemption criteria. The National Institutes of Health (NIH) implemented a variation of the sIRB policy that went into effect on January 25, 2018.

Revised Common Rule

- Effective Date: January 20, 2020
- Applies to "Cooperative Research" defined as those research projects that involve more than one institution (U.S. institution)
- Any institution located in the U.S. that is engaged in non-exempt cooperative research must rely upon the approval by a single IRB for that portion of the research conducted in the U.S.

NIH Single IRB Policy

- Effective Date: January 25, 2018
- Applies to the domestic sites of NIH-funded (wholly or partially) multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research.
- Protocols that address the same research questions, involve the same methodolodoes, and evaluate the same outcomes are the "same protocol."

2) Are there exceptions to the single IRB requirement for federally funded research?

Revised Common Rule

- Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
- Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context; or
- Cooperative research conducted or supported by DHHS agencies other than NIH, if an IRB approved the research **before** January 20, 2020

NIH Single IRB Policy

- sIRB prohibited by a federal, state, or tribal law, regulation or policy (policy-based exceptions).
- Other exceptions not based on a legal, regulatory, or policy requirement, if there is a compelling justification for the exception. These other exceptions must be reviewed and approved by NIH.
- Cooperative research conducted or supported by NIH if either:
  - The NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or
  - NIH excepted the research from its single IRB policy before January 20, 2020

IMPORTANT: If you're unsure whether your project is subject to the single IRB requirement, you may contact your program officer/funding agency for clarification.
Any exception to the sIRB requirement must be obtained writing.

For more information or other questions, please contact the IRB office (IRBReliance@hhrinstitute.org) or your Grant Administrator (https://www.hhrinstitute.org/researcher-resources/sponsored-research-administration/grant-administration-portfolio-assignments/)

3) Where can I find more information about the Common Rule sIRB requirement and the NIH sIRB Policy?

For more information on the Common Rule sIRB requirement:

OHRP: Revised Common Rule Cooperative Research Provision (45 CFR 46.114): https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-requirement/index.html

For more information on the NIH sIRB policy:

Single IRB Policy for Multi-site Research
https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

Frequently Asked Questions – Single IRB Policy for Multi-site Research
https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm#5182

Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html

Guidance on Exceptions to the NIH Single IRB Policy
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-003.html

Additional Guidance on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-058.html

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
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html

4) What are my options for selecting an IRB to serve as the sIRB for my study?

The institution submitting the grant application or the federal awarding agency is responsible for selecting the sIRB. The sIRB may be an IRB of an institution that is participating site or an independent/commerical IRB. Hennepin Health Research Institute (HHRI) IRB is not currently agreeing to serve as the sIRB. Efforts are currently underway to evaluate and prepare for the HHRI IRB to serve in this capacity; more information will be provided as this process evolves.

5) Who can I contact at HHRI with questions about sIRB requirements?

IRB Office	Grant Administration
Erin Venegoni: IRBReliance@hhrinstitute.org or 612-873-6651	You may find your Grant Administrator contact information here: https://www.hhrinstitute.org/researcher-resources/sponsored-research-administration/grant-administration-portfolio-assignments/

Provide the following information, if known:

- Name of the Hennepin Healthcare PI
- Name of the lead site (if it is not Hennepin Healthcare)
- Name of the sIRB, if already selected
- Title of the grant
- Grant deadline
- A link to the NIH Request for Applications (RFA) or contract solicitation
- Brief description of the project
- Brief description of Hennepin Healthcare's role on project

6) How do I prepare a proposal that requires an sIRB?

Scenario 1: HHRI is NOT the prime institution for the application (i.e., another institution will be submitting the application to the funding agency):

Contact the HHRI Reliance Manager to obtain an **HHRI letter of commitment** for the sIRB selected by the prime institution	The HHRI Reliance Manager is the point of contact for obtaining an institutional letter of support for an sIRB when HHRI is a participating/subcontract site Unless otherwise required by the funding agency, no IRB/sIRB approval is required at the time of proposal submission NOTE: Hennepin Healthcare IRB is not currently available to serve as an sIRB for multi-site research

Scenario 2: HHRI is the prime institution for the application (i.e., HHRI will be submitting the application to the funding agency):

Contact the HHRI Reliance Manager to discuss the process/approval of **sIRB selection**	The HHRI Reliance Manager is the point of contact for guidance in identifying an sIRB when HHRI is the prime institution for a proposal You may select a commercial IRB (HHRI recommends Advarra) You may select a collaborating academic institution willing to serve as the sIRB for the study (HHRI recommends identifying a participating institution of SMART IRB to facilitate reliance – you may search the SMART IRB website for participating sites: https://smartirb.org/participating-institutions/) NOTE: Hennepin Healthcare IRB is not currently available to serve as an sIRB for multi-site research
Include the cost of the sIRB services in the **budget** – this is a direct cost	If using Advarra, complete the Advarra Budget Questionnaire to obtain a cost estimate for IRB fees for your study If a collaborating institution is serving as the sIRB, the IRB fees for sIRB services (if that IRB is charging) must be included in their subaward budget Also consider other costs such as funds for study monitoring or need for a designated staff position to serve as the IRB liaison for working with the sIRB and all participating sites
If submitting an NIH proposal, you must include an **sIRB plan**	**For NIH grant applications**: You must include an sIRB plan; refer to Section 3.2 of the NIH General Application Guide (G.500) for instructions on what information must be included
Obtain documentation of **commitment** from participating sites to confirm selection of the sIRB	Note: You are **NOT** required to include any letters or other documentation of commitment in the grant application
Complete application for submission to funding agency	Unless otherwise required by the funding agency, no IRB/sIRB approval is required at the time of proposal submission

7) How do I establish sIRB reliance for a funded study?

Contact the HHRI Reliance Manager to initiate the **request to rely** on the designated sIRB	**Scenario 1: If Hennepin Healthcare is the prime awardee (lead site):** Notify IRBReliance@hhrinstitute.org that the grant was funded Develop the protocol, consent(s), and other materials required for IRB submission Work with the designated sIRB to submit for overall study approval Once you receive overall study approval, follow the steps in the 112 Guidance *Relying on an external IRB/single IRB* available on the IRB website. **Scenario 2: If Hennepin Healthcare is NOT the prime awardee/lead site:** Follow the steps in the 112 Guidance *Relying on an external IRB/single IRB* available on the IRB website This step will usually occur AFTER the lead site obtains initial overall study approval so that you can provide the following materials with your request for reliance: ✓ Final IRB approved protocol ✓ IRB approval letter (overall study approval) ✓ IRB approved consent form localized for Hennepin Healthcare participants