Northwestern University IRB Guidance for Single IRB and Cooperative Research Regulatory Requirements

Purpose

This guidance details the:

1. Federal regulations mandating the use of a Single IRB,
2. Northwestern University IRB Office Single IRB Pre-Consultation process in response to the federal regulations, and
3. Northwestern University workflow for investigators to ensure compliance with the Single IRB requirement.

Definitions

Collaborative Study: Human research involving more than one institution and/or site participating in the same research protocol, where each site completes a portion or portions of procedures.

Cooperative Research: Human research covered by (45 CFR 46) involving more than one institution and/or site. When conducting cooperative research, each institution and/or site is responsible for safeguarding the rights and welfare of human participants and for complying with this provision. Any institution and/or site located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.

IRB of Record: The IRB that is responsible for the ethical review of human research on behalf of an institution and/or site or individual investigator.

Lead Site: The primary awardee of a federally funded grant who is responsible for identifying the selected sIRB for cooperative research. For non-federally funded research this role is identified as the primary institution and/or site whom develops a research protocol.

Multi-Site Study: Human research involving more than one institution and/or site participating in the same research protocol.

Participating Site: An institution or site engaged in multi-site research, where a local investigator is responsible for the conduct of human research at their institution or site.

Relying IRB: An IRB that has designated through an agreement to cede review to an external IRB for a particular study.

Single Institutional Review Board (sIRB): An sIRB is the selected IRB of Record that conducts the ethical review for each site participating in cooperative research.

Background

The single IRB (sIRB) mandate is a set of complementary federal policies that require certain types of federally-funded research that involve multiple institutions, to use one IRB to accomplish IRB review and approval for all of the institutions conducting the study/trial. The Single IRB Model allows multiple institutions that conduct the same protocol to cede to a single IRB for review.

The NIH Single IRB Policy and Common Rule Cooperative Research Requirement are the two policies that require the use of a Single IRB .

The NIH Policy, effective January 25, 2018

- Applies to: Domestic sites of NIH funded studies where each site will conduct the same protocol involving non-exempt human research, whether supported by grants, cooperative agreements contracts or the NIH Intramural Research Program. It does not apply to Foreign Sites, career development (K), research training (T) or fellowship awards (F) and current awards.
- Exceptions: VA sites; international sites; sites involving tribal nations.

The revised Common Rule, effective January 20, 2020

- Applies to: All sites in the United States participating in a federally funded cooperative research study (involves more than one site).
- Exceptions: 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 of agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate.

All federal departments that have signed on to the revised Common Rule are subject to the cooperative research requirement. The following chart lists the agencies that are required to mandate the use of a single IRB for multi-site research.

Common Rule Departments and Agencies

	Department or Agency	CFR Citation (2018 Requirements)
1	**Department of Homeland Security**	**6 CFR Part 46**
2	**Department of Agriculture**	**7 CFR Part 1c**
3	**Department of Energy**	**10 CFR Part 745**
4	**National Aeronautics and Space Administration**	**14 CFR Part 1230**
5	**Department of Commerce**	**15 CFR Part 27**
6	**Social Security Administration**	**20 CFR Part 431**
7	**Agency for International Development**	**22 CFR Part 225**
8	**Department of Housing and Urban Development**	**24 CFR Part 60**
9	**Department of Justice**	**28 CFR Part 46**
10	**Department of Labor**	**29 CFR Part 21**
11	**Department of Defense**	**32 CFR Part 219**
12	**Department of Education**	**34 CFR Part 97**
13	**Department of Veterans Affairs**	**38 CFR Part 16**
14	**Environmental Protection Agency**	**40 CFR Part 26**
15	**Department of Health and Human Services**	**45 CFR Part 46**
16	**National Science Foundation**	**45 CFR Part 690**
17	**Department of Transportation**	**49 CFR Part 11**
18	**Office of the Director of National Intelligence**	**Follows CR because of EO 12333, as amended**
19	**Central Intelligence Agency**	**Follows CR because of EO 12333, as amended**
20	**Consumer Product Safety Commission**	**16 CFR Part 1028**

Current Regulatory Requirements

The revised Common Rule's Cooperative Research provision expanded and superseded the NIH's Single IRB policy. According to the Cooperative Research provision,

> Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

The provision provides for the following exceptions:

- Not Human Research
- Exempt Research
- 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)
- 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.

The Single IRB Process at Northwestern

In response to the single IRB regulatory agency mandate, the Northwestern University IRB Office instituted a process to assist the research community in determining whether the policy applied to their human research proposals. If applicable, the office will also provide letters of support that indicate Northwestern University is willing to either serve as the Single IRB of record or cede IRB review to an external IRB.

The Single IRB Pre-Consultation process must begin during the proposal development phase. The consultation must be completed prior to submitting the final documents to the Office for Sponsored Research in preparation for submission to the funding agency. As of September 1, 2019, the Northwestern University IRB Office began providing investigators fee quotes for studies that rely on Northwestern to serve as the IRB of record for external sites. The IRB fees take into account the number of sites, the complexity of the research (minimal risk vs. greater than minimal risk), and the number of years the study will require IRB review.

Guidance

Northwestern investigators who plan to submit proposals for federal funding opportunities that involve human research performed at more than one site, or who plan to be a sub-contracted site on a proposal submitted by an investigator outside of Northwestern, must undergo Single IRB Pre-Consultation.

- Single IRB Pre-Consultation is required for both requests for the Northwestern University IRB to either serve as the IRB of record for all sites cede IRB review to an external IRB.
- Requests for Single IRB Pre-Consultation should be made 5 weeks in advance of the proposal submission deadline or earlier if possible.
- Investigators should provide the Office for Sponsored Research (OSR) InfoEd Number associated with their submission during the Single IRB Pre-Consultation to align IRB and OSR review.
- The Northwestern University IRB Office will review the request and provide one of the following:
    1. Documentation that Single IRB requirement does not apply
    2. Letter of Support indicating our willingness to cede IRB review

3. Letter of Support indicating our willingness to serve as the IRB of record. The PI will also be provided with an invoice for the fees associated with the review of the external site(s)

- If the Northwestern University IRB Office determines it is not a good candidate to serve as the IRB of record for a proposal, the reliance team will provide a Letter of Support indicating our willingness to cede IRB review and assist the investigator with identifying a willing IRB in the following order:
    1. External IRB at one of the proposed participating sites
    2. Trial Innovation Network IRBs
    3. Preferred Commercial IRB partner
- The Northwestern investigator will then upload the Single IRB Letter of Support into their OSR InfoEd submission, and when applicable, include IRB review fees in their proposed budget.

The pre-consultation process was developed to engage with the research community during proposal time to ensure relevant information in alignment with Single IRB requirements are included in the final submission. Failure to go through Single IRB Pre-Consultation may result in:

- Delay in OSR proposal review and submission to the federal funding agency,
- Delay in IRB review if subsequently funded, and
- In situations where the proposal states Northwestern will serve as the IRB of record, the investigator is responsible for locating funds for IRB review and the Northwestern IRB may not be able to serve as the IRB for the proposed research.

For more information, please reference the Northwestern IRB's dedicated Single IRB webpage. All questions regarding the process should be directed to irbreliance@northwestern.edu.