Northwestern University
Institutional Review Board (IRB)

NIH Single IRB (A Year In Review)

Marcella Oliver, MS
IRB Reliance and Education Lead

Alec Henderson, BS, CIP
IRB Compliance Analyst
NIH Single IRB Policy

The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.

This policy, which is consistent with 45 CFR Part 46.114, is intended to:

- Enhance/streamline IRB review process in multi-site research
- Eliminate duplicative IRB review
- Reduce administrative burdens/inefficiencies
- Maintain human subject protections
- All IRB’s to concentrate on single site protocols
NIH Single IRB Policy cont.

Effective date: January 25, 2018

Applies to: Domestic sites of NIH funded studies where each site will conduct the same protocol involving non-exempt human subjects 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.
NIH Single IRB Policy cont.

- 5 Site Proposal
- 3 Sites Conducting the Full Protocol
- 2 Sites assisting with other parts of the Protocol
- 3 Sites are required to establish a Single IRB
Roles and Responsibilities

- Applicant/Offeror: Submit a plan describing the use of a Single IRB that will be the IRB of Record for all study sites. NIH acceptance will incorporate the plan into the terms and conditions of the award.

- Awardees: Ensure authorization agreements are in place and ensure communication between the Single and participating sites.

- Funding Institute or Center: Manage and oversee awards, communicate with awardee about the Single IRB compliance plan.
Roles and Responsibilities cont.

- **Overall PI and Lead Study Team**
  - **Overall Study PI**
    - Assumes leadership and responsible for conduct of the research
    - Designates the Lead Study Team
  - **Lead Study Team**
    - Submits materials to the Reviewing IRB for all sites, including study-wide and site-changes of protocol, continuing reviews, and reportable events
    - Provides draft study materials to all site study teams, including proposed consent form template
    - Provides IRB-approved study documents to all sites
    - Communication Plan
The selected sIRB is responsible for:

- Review of study and each site including any local context specific to the conduct of research.
- Mechanism for notifying each site of IRB review outcomes (i.e. initial review, modifications, continuing review, etc.).
- Maintaining Reliance Agreements for each site.
Relying Site Responsibilities

The selected relying site is responsible for:

- Providing local context information to the reviewing IRB
- Not initiating any study procedures without External IRB approval specific to their site
- Providing their local IRB with information regarding External IRB review
- Ensuring the lead site PI is notified immediately of any reportable events that occur
- Establishing a point of contact for their site
Evolution of sIRB Processing

- **Phase I**
  - Pre-consultation intake form
  - (January 25, 2018 – March 2018)

- **Phase II**
  - Pre-consultation intake form
  - Multi-site Evaluation Form
  - (April 2018 – November 2018)

- **Phase III**
  - Blended intake and evaluation form
  - (November 2018 – Present)
IRB Review of Requests

Pre-Consultation Request to IRB Determination

Phase I: 14 Business Days
Phase II: 7 Business Days
Phase III: 5 Business Days
Pre-Consultation Requests by Month

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108 Pre-Consultation Requests

- Biomedical: 59
- Social-Behavioral: 49
65 Letters of Support

Northwestern IRB LEAD - 37
Northwestern IRB CEDE - 28
Proposal Funding
(As of March 1, 2019)

- 55 projects with Northwestern as the proposed Prime award recipient submitted between (January 25, 2018 – January 24, 2019) for which an InfoEd number was provided
- 6-9 Months from grant submission to agency notification of funding status
- 7 Funded
- 6 in JIT/Revision
- 9 Not Funded
- 6 Withdrawn
- 27 Pending status
Tips

- When submitting a funded project in eIRB+, upload the Letter of Support in the application.
The InfoEd ID Number is used by the IRB to track the submission and will be required before the IRB will provide a letter of support.
Tips

- IRB of Record: If you are requesting the Northwestern IRB be the IRB of record for the proposed project, submit early.

- You should submit 5 weeks before your proposal is due...
Wait...but why?

- Why 5 weeks?
  - If the Northwestern IRB determines that it is unlikely that we will serve as the IRB for your project, there needs to be sufficient time to identify another IRB.
  - That IRB can be from one of the proposed sites or a commercial partner.

- We do not want you to submit a grant proposal that doesn’t include IRB fees if they may be required.
Looking Forward

- Additional IRB Office Reviewers
- IRB Fee Schedule
- Resubmissions and Revisions
- NIH Guidance
- January 2020 – Requirement to use sIRB for all federally funded projects
Does NIH sIRB Mandate Apply?

- Northwestern Submitted R01
- Sites
  - Northwestern – Enrolling site and Data Coordinating Center
  - University of Chicago – Enrolling site
  - Sorbonne Université – Enrolling site
  - Vanderbilt University – Data Analysis
  - Lund University – Enrolling site
  - Harvard University – Enrolling site

YES
Resources

OFFICE FOR RESEARCH
IRB Institutional Review Board

NEW STUDIES
RELIANCE AGREEMENTS AND SINGLE IRB
MODIFICATIONS
CONTINUING REVIEW / CLOSURE
REPORTABLE NEW INFORMATION
COMPLIANCE AND AUDITS

News & Announcements
Updated Biomedical Protocol and Consent Templates Available
The following templates have been updated:
• HRP-593 Biomedical Protocol Template • HRP-508
• Local Protocol Addendum Template • HRP-592
• Biomedical Consent Document Read More »

Updated Human Research Determination Form

Events
Chicago
Single IRB (A Year In Review) - Chicago Campus
More information

Mar 20

Evanston
Single IRB (A Year In Review) - Evanston Campus
More information

Mar 21

Information
Need to Report A Concern?
eIRB+ FAQs
Research Participants
IRB Members
CRC Resources

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Resources cont.

Single IRB

The single IRB (sIRB) mandate is a set of complementary federal policies that require certain types of federally-funded studies that involve multiple institutions to use a single IRB to accomplish IRB review and approval for all of the institutions. The basis for the Single IRB Model is to allow multiple institutions that are conducting the same protocol to use a single IRB for review. The NU IRB has allowed the use of a Single IRB for over 5 years and is well versed to assist researchers in preparing for the new phase of required use.

There are two policies that require the use of a Single IRB (NIH Single IRB Policy and Common Rule Update).

Single IRB Policies

The NIH Policy, effective January 25, 2018
General Contact Information

For additional information on IRB submission templates, regulatory guidance, upcoming education/training opportunities, and staff contacts, please visit our website:

https://eirbplus.northwestern.edu

- Main number (Bio-medical): 312-503-9338
- General IRB Questions: irb@northwestern.edu
- Social and Behavioral Questions: sbsirb@northwestern.edu
- Reliance Agreements: irbreliance@northwestern.edu
- eIRB assistance/queries: eirb@northwestern.edu
- Compliance queries/issues: irbcompliance@northwestern.edu
- Training queries/issues: irbtraining@northwestern.edu
- Social and Behavioral IRB: 847-467-1723
Contact Information

Marcella Oliver, MS
IRB Reliance and Education Lead
312-503-6071
m-oliver2@northwestern.edu

Alec Henderson, BS, CIP
IRB Compliance Analyst
312-503-5417
alec.Henderson@northwestern.edu
QUESTIONS?