OSR Monthly Meeting

October 15, 2019 (Evanston)
&
October 17, 2019 (Chicago)
AGENDA

• Announcements
• Single IRB Policy Updates
• Federal Policy News & Guidance
• Proposal Review Refresher
OSR Announcements

• New Executive Director Shandra White
  – Started on October 1
  – Will speak at the next monthly meeting

• Upcoming website changes
  – Transferring platforms: URL will stay the same, but you’ll notice subtle changes in look and feel
  – Sub/sponsor request form will be transferred to InfoEd as part of the Change Request module
  – Expected soon (late 2019); exact dates TBD
  – More info to come via listserv and at next OSR Monthly Meetings
OSR Monthly Meeting Scheduling

• End-of-2019 monthly meetings
  – Originally scheduled November meetings pushed to first week of December
  – Evanston: Tuesday, December 3
  – Chicago: Thursday, December 5

• Winter/Spring 2020 meetings
  – Generally 3rd Tuesday/Thursday of the month
  – Starting in January: 14th (Ev) / 16th (Chi)
  – Dates will be up on OSR website soon
Northwestern University Institutional Review Board (IRB)

Single IRB Policy Updates

Evanston
Marcella Oliver, MS, CIP
IRB Reliance and Education Lead

Chicago
Alec Henderson, BS, CIP
IRB Compliance Analyst
Single IRB

- How and When to request the Northwestern IRB cede review to an External IRB or serve as the Single IRB
- What is required when making the request
- What are your obligations
- Key tips to streamline the process
- Q & A
NIH Single IRB

Effective date: January 25, 2018

Applies to: Domestic sites of NIH funded studies for those sites that 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.
2018* Revised Common Rule
Single IRB Provision

Effective Date: January 19, *2020

Applies to cooperative research projects where the funding or oversight agency is subject to the Revised Common Rule.

Cooperative research: those projects covered by this policy that involve more than one institution.
2018* Revised Common Rule Continued

- NIH sIRB Mandate: Only applied to the sites conducting the same protocol
- Revised Common Rule: All sites located in the United State that are engaged in cooperative research.
- NIH is subject to the Revised Common Rule, thus the Revised Common Rule supersedes the NIH sIRB mandate.
The Single IRB of record for the cooperative research covers sites whose involvement is limited to research that is considered:

- Exempt
- Not Human Research
Northwestern as sIRB

The Northwestern IRB Office reviews requests to serve as the sIRB or cede review to an external IRB at the proposal stage through the Single IRB Pre-Consultation Request Form.
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.

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

Review Timeline: 5 weeks prior to proposal due date

Outcomes:
• Northwestern IRB may serve as the sIRB
• Northwestern IRB not a good fit, determine whether another participating site will serve
• Northwestern IRB not a good fit, if no participating site will serve, find an external IRB
Northwestern sIRB Review

Northwestern IRB not a good fit, based on:

- Number of sites
- State law in one or more of the proposed sites
- Complexity
- Risk
- Investigator qualification
- Institutional Resources
- Northwestern IRB Expertise
- Other
Northwestern sIRB Review

If the Northwestern IRB Office determines that the proposal is not a good candidate for Northwestern to serve as the sIRB:

**We will work with you to find a qualified IRB**

- Other participating sites have the first opportunity to determine whether their IRBs are good fits for the proposal.

- If no IRB from any participating site is willing to serve, we have options:
  - Trial Innovation Network (TIN) IRBs
    - Vanderbilt, Johns Hopkins, and the University of Utah
  - Commercial IRBs
Northwestern sIRB Review

If the Northwestern IRB Office determines that the proposal is a good candidate for Northwestern to serve as the sIRB:

We will schedule a meeting with you to discuss:

- Your responsibilities (IRB submission coordinating center.)
- IRB Fees
Evolution of sIRB Research
Community Resources

- **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 RedCap intake and evaluation form
  - (November 2018 – Present)

- **Phase IV**
  - Single IRB Fee Schedule (September 1, 2019)
In compliance with the NIH policy:

- “the applicant/offeror may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study by the sIRB.”

- “Recipient institutions have the flexibility to develop their own fee structures for single IRB costs in the manner that is most appropriate for their institutional systems and procedures, including a service center, fixed fee, or other appropriate methods. NIH will not dictate how recipients implement these structures, except to apply cost principles and administrative requirements.”
Northwestern University Site (Primary Awardee)

Proposal Development

- Northwestern University IRB Letter of Support for sIRB
- Letter of Support for sIRB from participating site institutions
- Personnel: include an IRB liaison
- Budget: IRB fees (Direct Costs)
- Budget: IRB liaison

Post-Award

- sIRB Confirmation
- IRB Liaison: Identify/Hire
- eIRB+: Develop study materials and submit new study application
- Reliance agreement between sIRB & sites
- Each site: IRB review
- IRB fees billed when services are completed
Relevant Factors that Impact sIRB Fees

The following factors are generally known during the grant preparation or study design phase and are relevant to the cost of sIRB review:

Number of years the study will be open
More years = more sIRB review effort needed over time = higher cost

Number of participating research sites needing sIRB review
More sites = more sIRB review effort needed = higher cost
Key Tips

1. All studies must undergo institutional reviews (COI, OSR, NMHC, NMH Device Committee, etc.)

2. External IRB approved consent forms must include required language from the Northwestern template consents

3. All approved study documents listed on the External IRB approval letter should be uploaded into the submission

4. All study team members must have Human Subject Protections training completed within the last 3 years
Resources cont.

Resources

IRB Authorization Agreement - Where NU IRB WILL be the IRB of record

IRB Authorization Agreement – Where NU IRB will NOT be the IRB of record

Individual Investigator Agreement (contact irbreliance@northwestern.edu to request the form)

Ceding Review: Independent IRB Workflow

Ceding Review: Other Academic Institutional IRB Workflow

NU IRB_Reviewing IRB Workflow

HRP-092 – SOP External IRBs

HRP-093 – SOP Northwestern University Serving as the IRB of Record

HRP-801 – SOP Establishing Authorization Agreements


HRP-1812 – Local Context Form

Submitting a New Project Submission (External IRB) Tutorial

Submitting a Modification and/or Continuing Review Submission (External IRB) Tutorial
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

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QUESTIONS?
Federal Policy News & Guidance
NIH Other Support

• General Guidance
  – Do NOT include gifts, prizes, or donors in “Pending support” or “Other agreements, resources, and significant collaborations”
  – Do NOT include the application being considered in “Pending support”

• Template Other Support Document
  – Prepared by NUCOI’s Kate Booth to help provide guidance to the research community on the preparation of the Other Support for proposals
  – Will be available soon on the OSR website
F&A Rates Guidance

• F&A rates finalized
• Rate use will go into effect 11/1/2019
  – 58% for the next two years, then increasing to 60%
  – Proposals already in route do not have to be updated, mandatory use by 11/1
  – Proposals should use the approved rates in all years of the budget, awards will be set up with the F&A rate in effect for that budget period. We will not “grandfather” in the rate in effect in year one of the award.
Other Policy/Guidance Items

- NSF PAPPG FY20 release delayed
  - Will NOT be released in January as per usual
  - Date is still TBD

- OSR has updated the NSF and NIH checklists
  - Finishing some final editing/formatting
  - Will be available on the OSR website soon
Proposal Review Refresher
Workflow and Process

• Pre-Route-action item is with department
• Under OSR Admin Review-action item has been assigned by RA to relevant GO
• OSR Admin Rev Complete-GO review is complete and action item is assigned to relevant RA for updates
• OSR Final Rev-RA assigns action item to GO for submission
Proposal Review

• Administrative review minimum required documentation
  – Solicitation (Please ensure it is the correct solicitation!)
  – Detailed budget: This can be in internal or sponsor format (or both if you wish)
  – Justification
  – Statement of work/abstract/narrative
Proposal Review Tips

• The department has edit access to the proposal in Infoed at any stage during workflow - you are never locked out
• OSR provides one admin review - we will do a final review as needed
• “Final Route” means the proposal is ready to submit
• Process is meant to minimize multiple reviews / routes and to submit proposals more efficiently
• Proposal notes are in the InfoEd record and viewable in the action item - either typed directly in the comments box or in a document will be uploaded in the action item.
• Questions outside the review may still be managed via email
Helpful Links

- Visit the Administrative Proposal Review page on the OSR website for more info
Thank you for joining us!

Find monthly meeting presentations on the OSR website at: https://osr.northwestern.edu/training/presentations