# 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**

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# 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

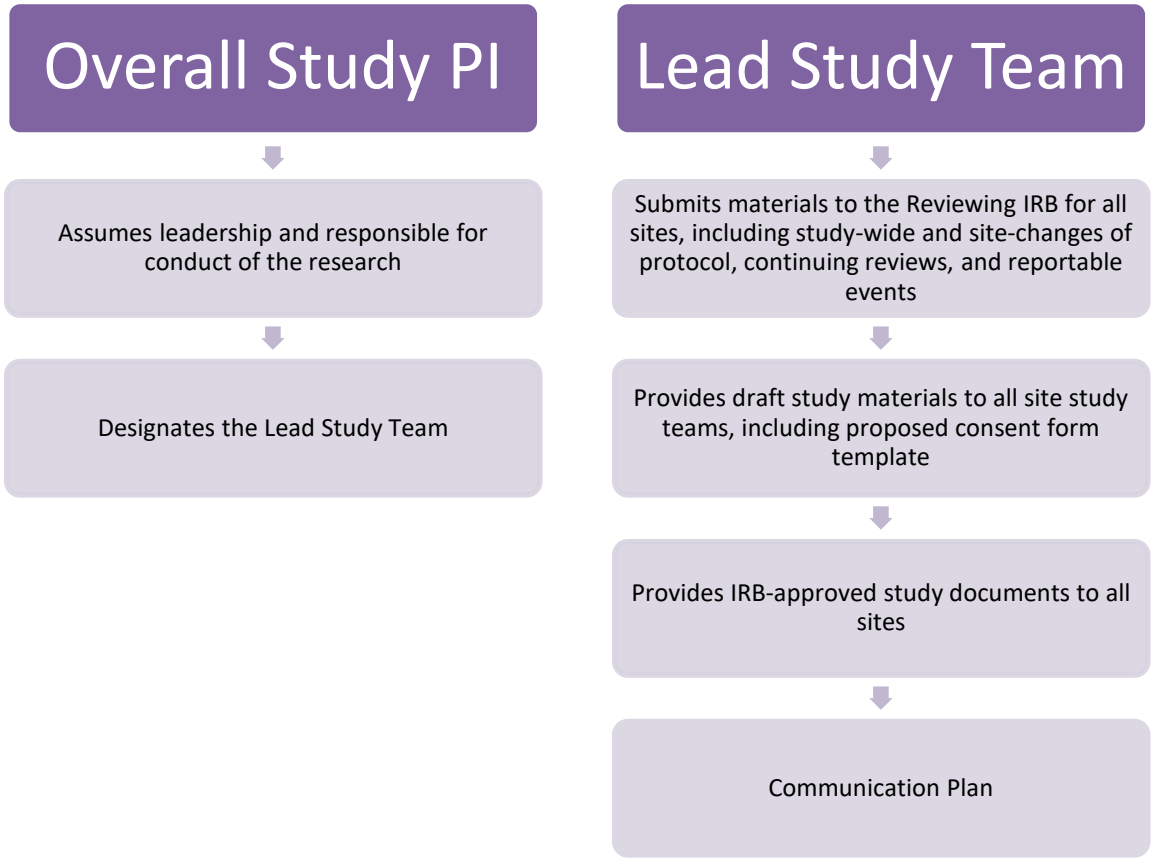
- Applicant/Offeror: Submit a plan describing the use of a Single IRB that will be the IRB of Record for all study sites. NIH acceptance will incorporate the plan into the terms and conditions of the award.

- 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



# Reviewing IRB Responsibilities

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

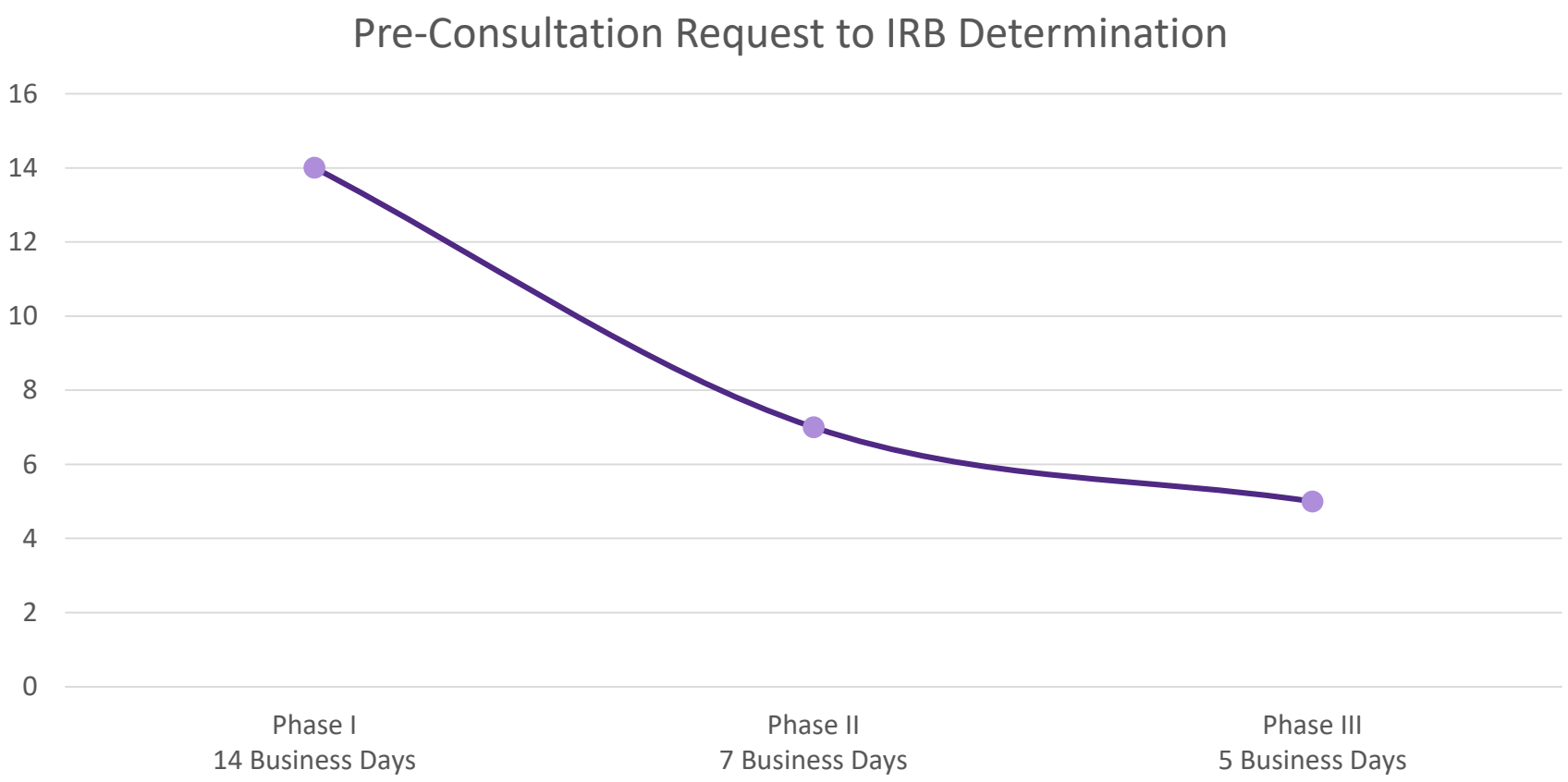
The selected relying site is responsible for:

- 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

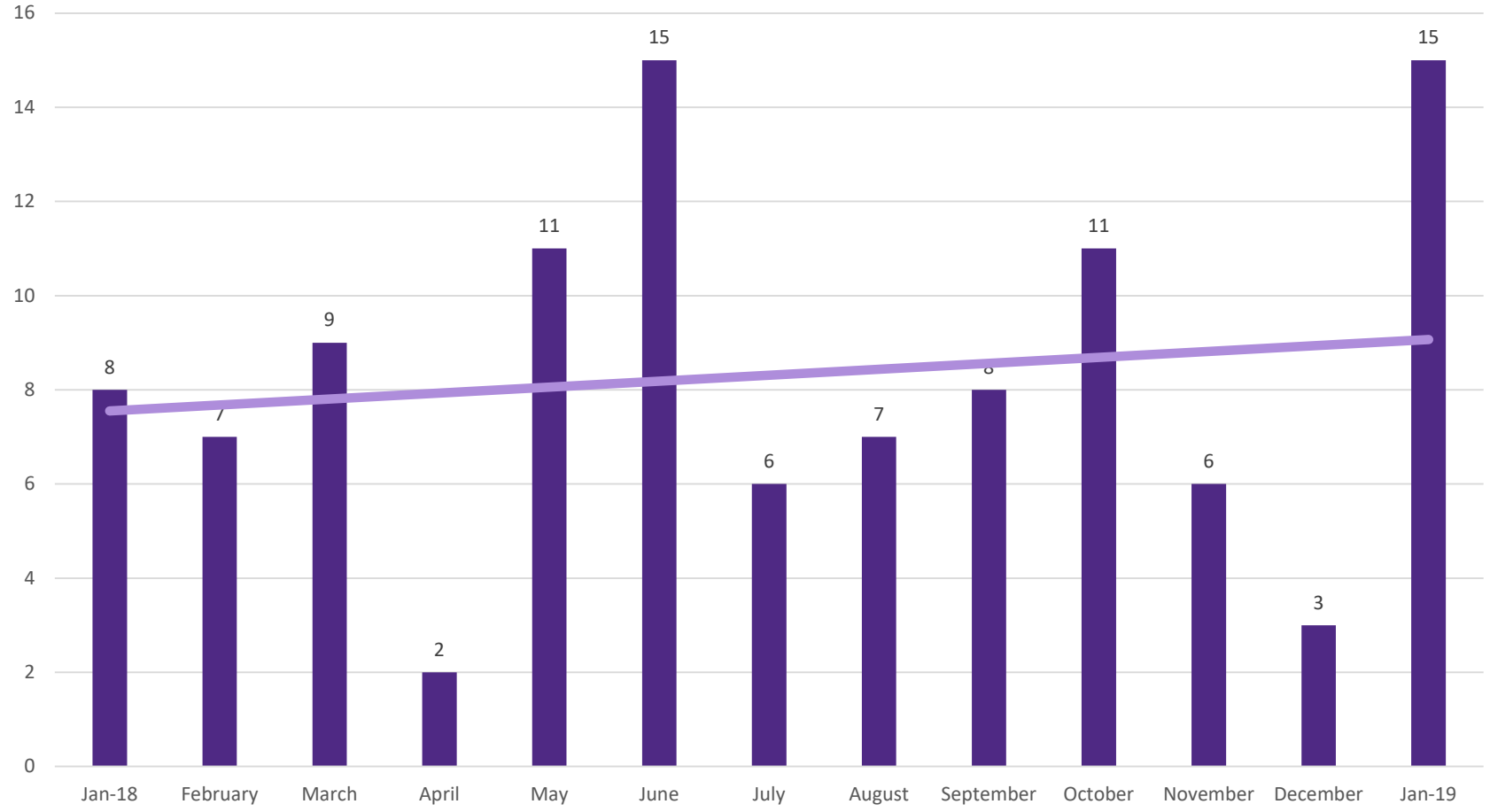
# Evolution of sIRB Processing

- 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)

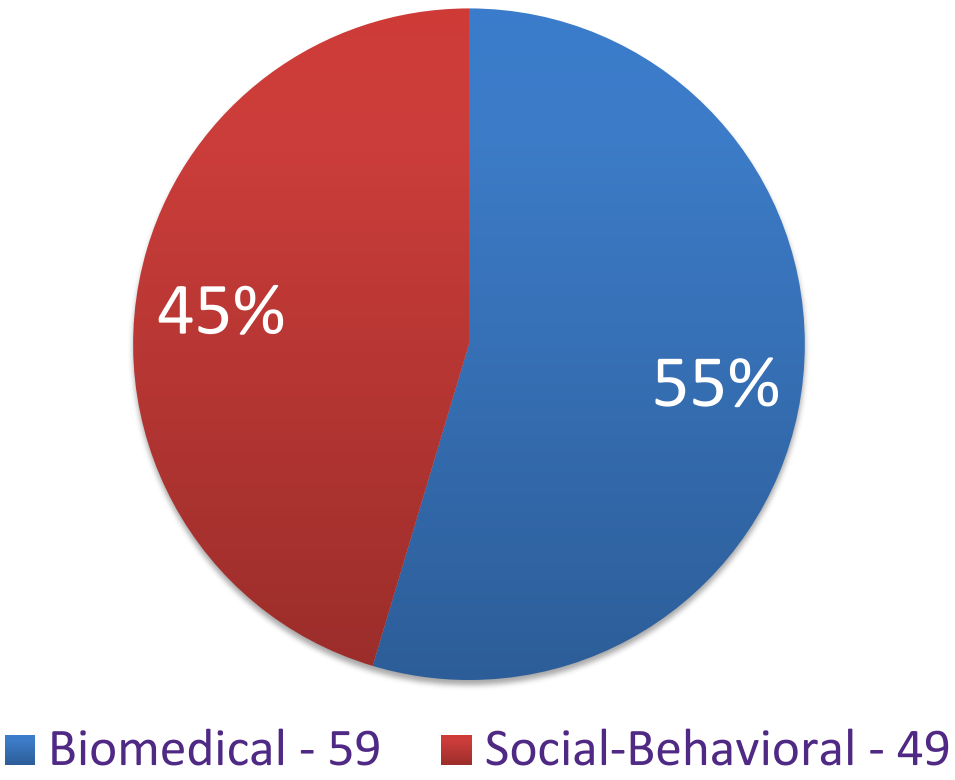
# IRB Review of Requests



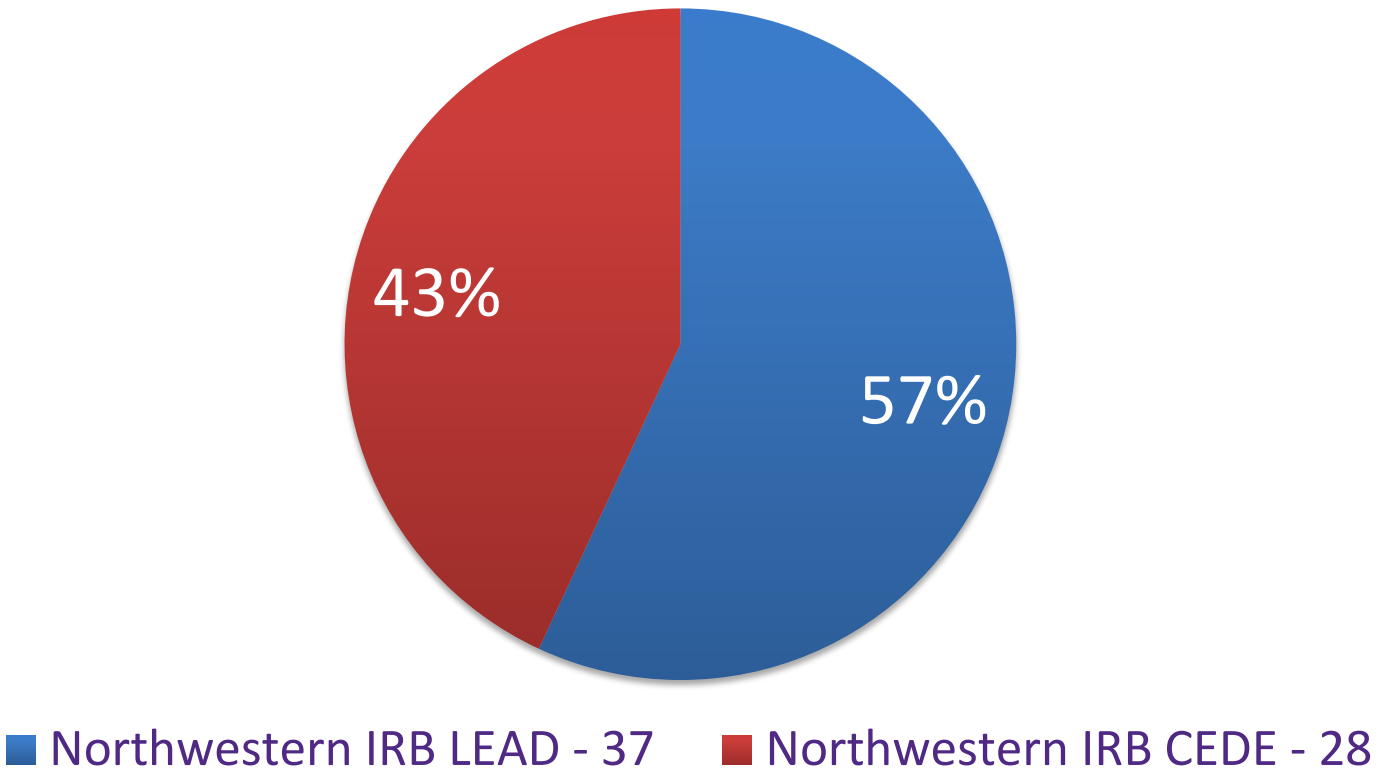
# Pre-Consultation Requests by Month



# 108 Pre-Consultation Requests



# 65 Letters of Support



# Proposal Funding

(As of March 1, 2019)

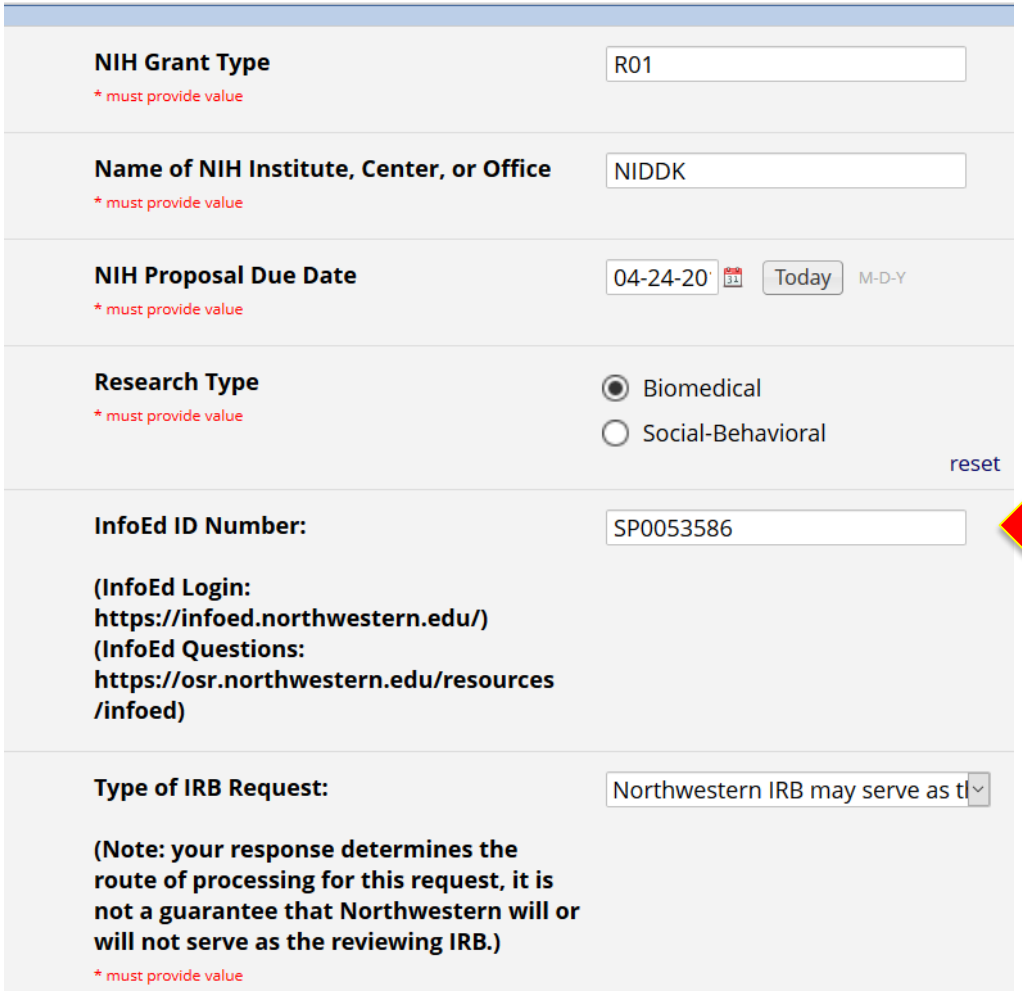
- 55 projects with Northwestern as the proposed Prime award recipient submitted between (January 25, 2018 – January 24, 2019) for which an InfoEd number was provided
- 6-9 Months from grant submission to agency notification of funding status

- 7 Funded
- 6 in JIT/Revision
- 9 Not Funded
- 6 Withdrawn
- 27 Pending status

# Tips

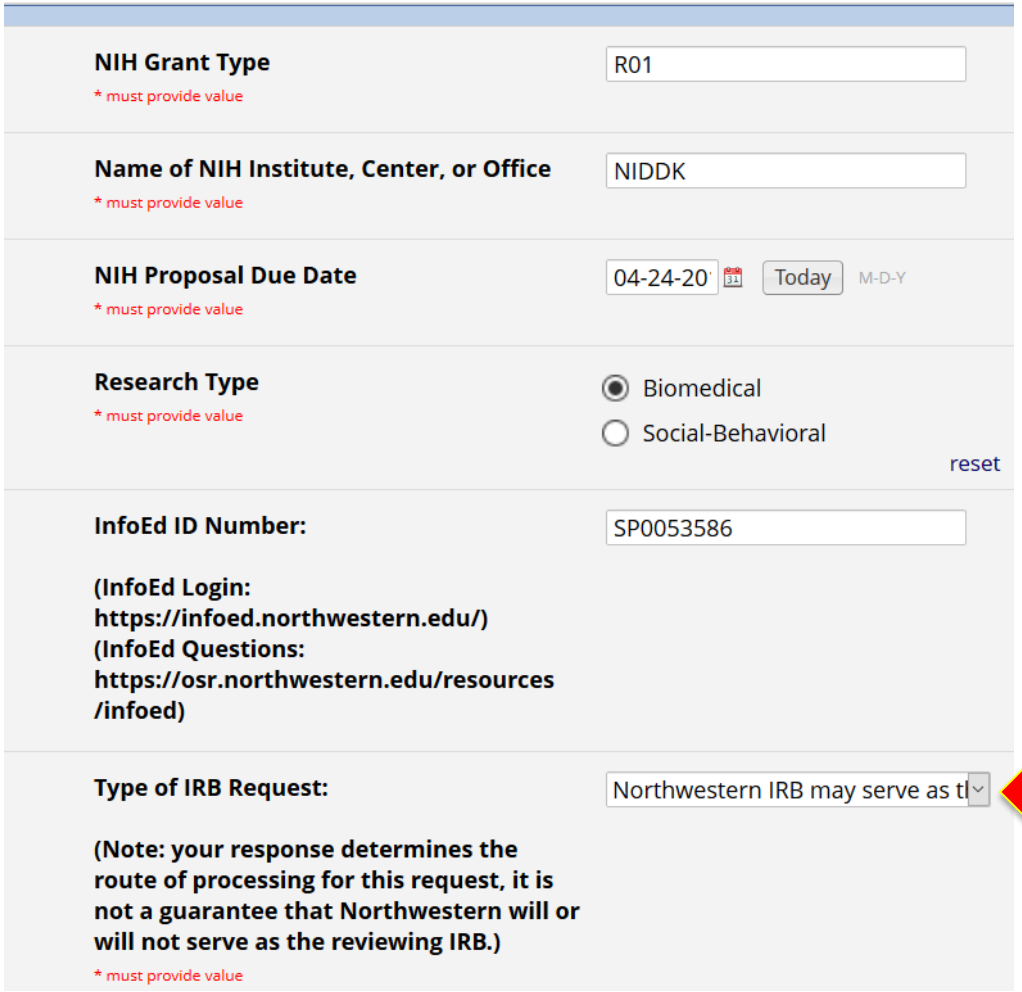
- When submitting a funded project in eIRB+, upload the Letter of Support in the application

# Tips




- 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.

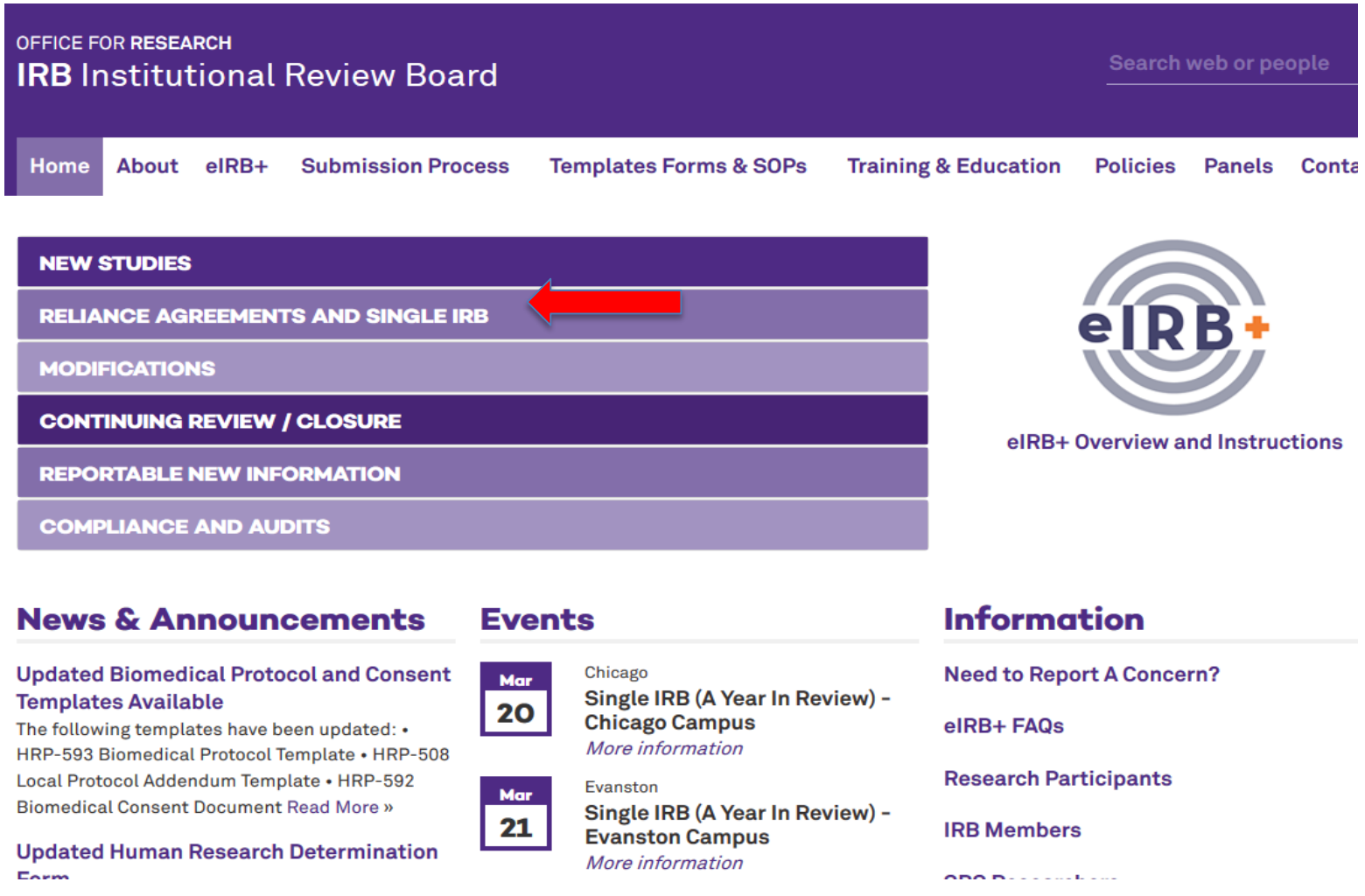
# Looking Forward

- 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

# Resources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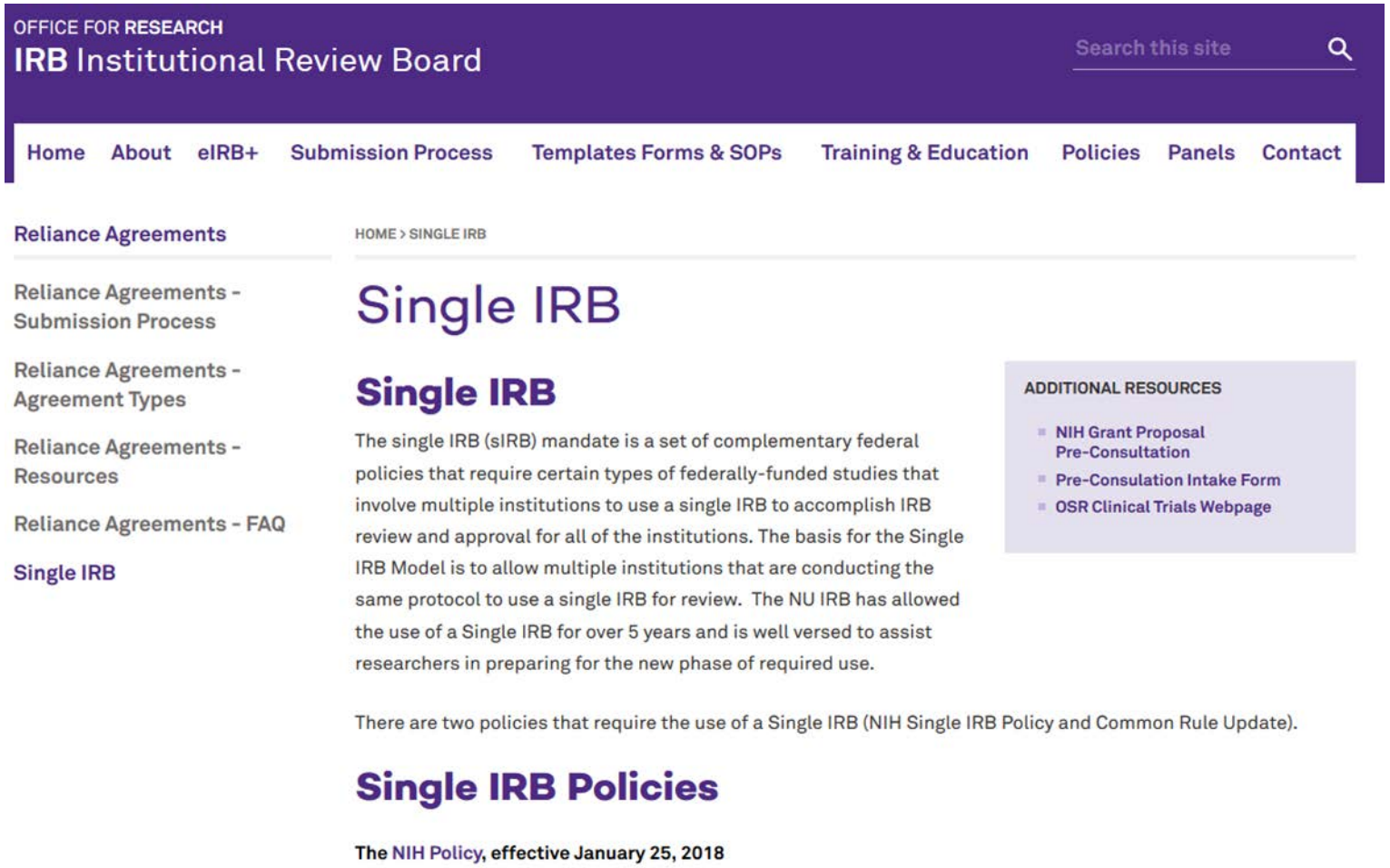
Submission Process
Templates Forms & SOPs
Training & Education
Policies
Panels
Conta
NEW STUDIES
RELIANCE AGREEMENTS AND SINGLE IRB
MODIFICATIONS
CONTINUING REVIEW / CLOSURE
REPORTABLE NEW INFORMATION
COMPLIANCE AND AUDITS
eIRB+
eIRB+ Overview and Instructions
News & Announcements
Updated Biomedical 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
Events
Mar 20
Chicago
Single IRB (A Year In Review) - Chicago Campus
More information
Mar 21
Evanston
Single IRB (A Year In Review) - Evanston Campus
More information
Information
Need to Report A Concern?
eIRB+ FAQs
Research Participants
IRB Members

# Resources cont.



# 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?