

# CLEAR Meeting

## February 6, 2024

Hosted by Sponsored Research

# Today's Agenda

- Announcements
  - Progress Reports: NSF & RPPR Reports
  - Restricted codes through ASRSP
  - Budget Allocation/Reconciliation Do's and Don'ts
- FDP January Meeting Highlights
- IRB Reliance
- Roles & Responsibilities between SR and Departments

# Upcoming NIH Due Dates

NIH Due Date	SR (5-Day) Deadline	Description
March 5	February 27	<ul style="list-style-type: none"> <li><b>R01 Research Grants</b></li> <li><b>U01 Research Grants - Cooperative Agreements</b> <i>renewal, resubmission, revision</i></li> </ul>
March 12	March 5	<ul style="list-style-type: none"> <li><b>K Series Research Career Development</b> <i>renewal, resubmission, revision</i></li> </ul>
March 16* (Saturday)	March 11	<ul style="list-style-type: none"> <li><b>Other Research Grants and Cooperative Agreements</b> (R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3) <i>renewal, resubmission, revision</i></li> </ul>
April 8	April 1	<ul style="list-style-type: none"> <li><b>F Series Fellowships <i>Individual</i> NRSAs</b> (including F31 Diversity) <i>new, renewal, resubmission</i></li> </ul>
April 12	April 5	<ul style="list-style-type: none"> <li>R13, U13 Conference Grants &amp; Cooperative Agreements <i>All - new, renewal, resubmission, revision</i></li> </ul>

\*due date pushes to next business day – Monday, March 18

# NIH Salary Cap Update

- The Federal Executive Level II (i.e., NIH salary cap) has increased to \$221,900 effective January 1, 2024.
  - National Institutes of Health [Guidance on Salary Limitation for Grants and Cooperative Agreements FY 2024 \(NOT-OD-24-057\)](#).
- CERES was updated on January 31st with the new salary cap:
  - New cap will automatically populate new budgets going forward
  - Budgets created before the CERES update will need to be manually updated
- Reference the [Sponsored Research website](#) for guidance regarding:
  - Manually updating in-progress proposals in CERES
  - Rebudgeting guidance for submitted proposals and active awards

# Progress Reports

- NIH RPPR deadlines are real deadlines
- When submitting late, the university and PI are non-compliant with the terms and conditions of the Federal award.
- January 15<sup>th</sup> RPPR deadline:
  - On-time submission rate of only 50%.
  - Half of all RPPRs were late.
  - Some were still pending as of 2/5/24.

# Progress Reports cont.

- Carefully review your RPPR before sending to SR to eliminate easily avoidable administrative issues.
- Northwestern has seen a significant uptick in the number of post-RPPR submission queries by NIH, particularly in areas such as:
  - Other Support having more than 12 person months
  - Insufficient unobligated balance justifications.
- Northwestern has also seen an increase in notices from NSF for delinquent annual technical reports.

# Opening Restricted Account Codes

- Award Set-up: SR sets up accounts indicated by the budget and is also opening a wider array of account codes for awards where sponsors allow rebudgeting latitude.
- After award set-up: If there are *restricted* budget account codes needed –
  - DO: Follow [ASRSP's process to request opening of restricted account codes](#)
  - DON'T: Submit an AMR in CERES – it will be declined

# Budget Allocation & Reconciliation

- DO: Provide budget category specificity in allocations and when returning an Ancillary Review with a budget reconciliation.
- DON'T: Use "Other Expenses" for any allocations.



# FDP January Meeting Highlights

# What is FDP?

- [Federal Demonstration Partnership \(FDP\)](#): Association of federal agencies (e.g., NIH, NSF), research policy organizations, and academic research institutions with administrative, faculty, and technical representation.
- FDP's goal: Streamline the administration of federally sponsored research and foster collaboration to enhance the national research enterprise.
- FDP hosts three (3) membership meetings per year, which regularly feature presentations by NIH and NSF on notable policy-related topics.

# FDP Highlights: New (Free!) Resource

- [\*Demystifying the Research Enterprise\*](#) by Kelvin Droegemeier
- Available at MIT press, free and open to anyone
- Not a “how to” guide but an educational resource to faculty and staff to help navigate the research enterprise

# FDP Highlights: NSF

- Updated [NSF 24-1 Proposal & Award Policies & Procedures Guide](#) (PAPPG) effective May 20, 2024
  - Look for updated solicitations as a result
- NSF [webinar March 12<sup>th</sup>](#) on PAPPG changes
- NSF Spring Conference June 3-5
  - in person in Philadelphia
  - virtual attendance is an option
  - registration opens in March

# FDP Highlights: Common Forms

- Implementation of the Common Forms (biosketch and Current and Pending/Other Support)
  - NSF will implement with the new PAPPG May 2024
  - NIH is planning a phased implementation, starting January 2025 followed by SciENCv templates May 2025
- US Dept of Energy and Dept of Defense reviewing potential adoption of the use of the common forms

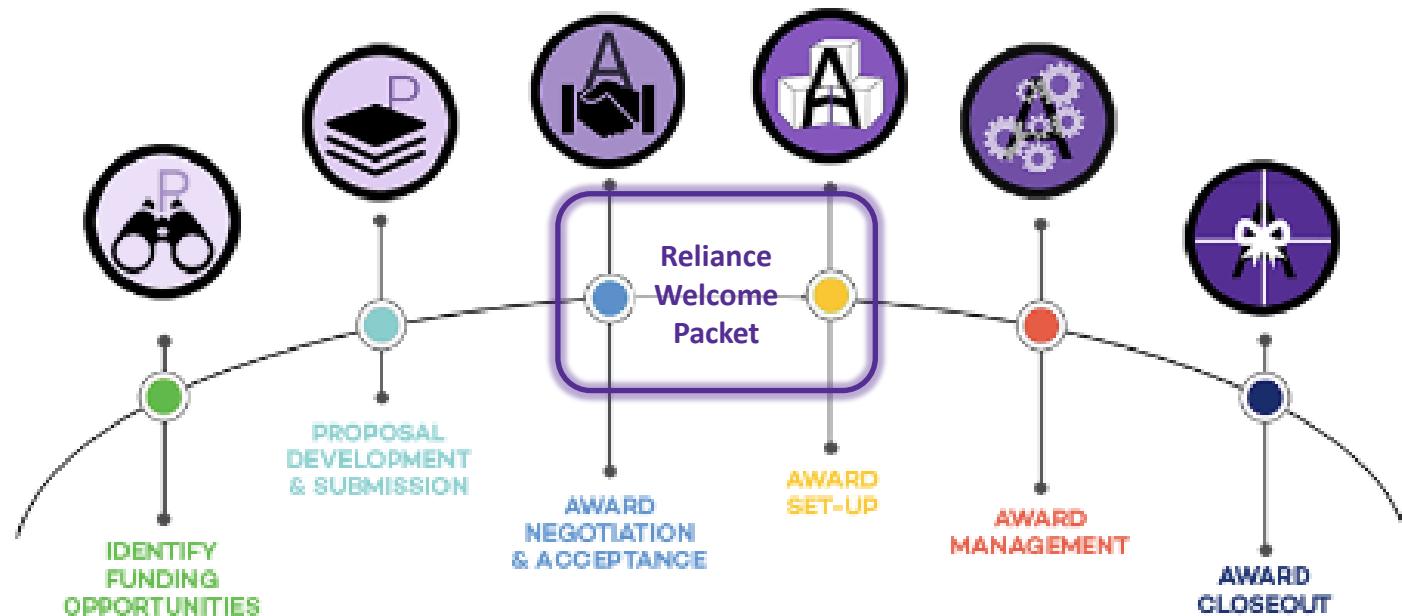
# FDP Highlights: Research Security

- NSF research security training modules are live
  - Training will be required in the new PAPPG
- [Updated disclosure matrix available](#) on the NSF website
- NSF updated definitions for Malign Foreign Talent Recruitment Programs (MFTRP)
  - New certifications for senior/key personnel, will be ineligible to serve as senior/key if they are a participant
  - Go live with new PAPPG
  - NSF is building capability for PI and Co-PI to provide certification on an annual basis, organization certification at proposal submission that all personnel aware of term and are not part of MFTRP

# Let's Talk about IRB Reliance!

Rita Knasel, IRB Reliance Analyst  
Institutional Review Board Office | Northwestern University

# SPONSORED PROJECT LIFECYCLE





- Single IRB Planning
- Northwestern Serving as the IRB of Record
- Northwestern Relying on an External IRB
- SMART IRB & IREx
- Northwestern Affiliates & Chicagoland Partners
- Research at Northwestern Qatar

# Northwestern Serving as the IRB of Record

Northwestern University IRB is willing serve as the IRB of Record for external sites when federally mandated, required by sponsors, or on a case-by-case basis. Serving as the IRB of Record for another site or institution is established by reliance agreements. A reliance agreement is an agreement between two or more institutions that allows an institution's IRB to rely on another institution's IRB for review of human subjects' research.

- Effective January 20, 2020, most federally funded research must utilize a single IRB (sIRB). Please see our webpage [Single IRB Planning](#) for more information.

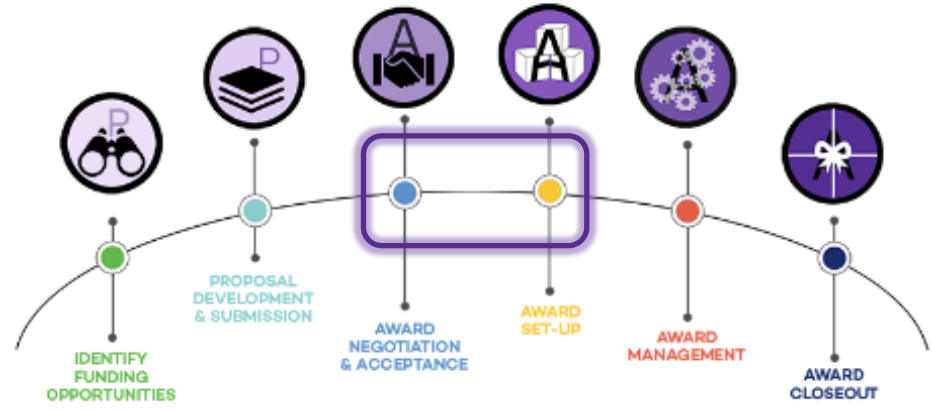
## IRB of Record Study Start-Up: Reliance Welcome Packet

The instructions and documents included in this packet have been designed to help study teams communicate with their collaborators and streamline the reliance process when Northwestern is serving as the IRB of Record. Depending on the details of your project, your assigned IRB analysts may ask for information or documents which are not included in this packet.

This table serves as your guide to the contents of the Welcome Packet. Please review the chart below for the list of documents included in the Welcome Packet and instructions on what to do with them.

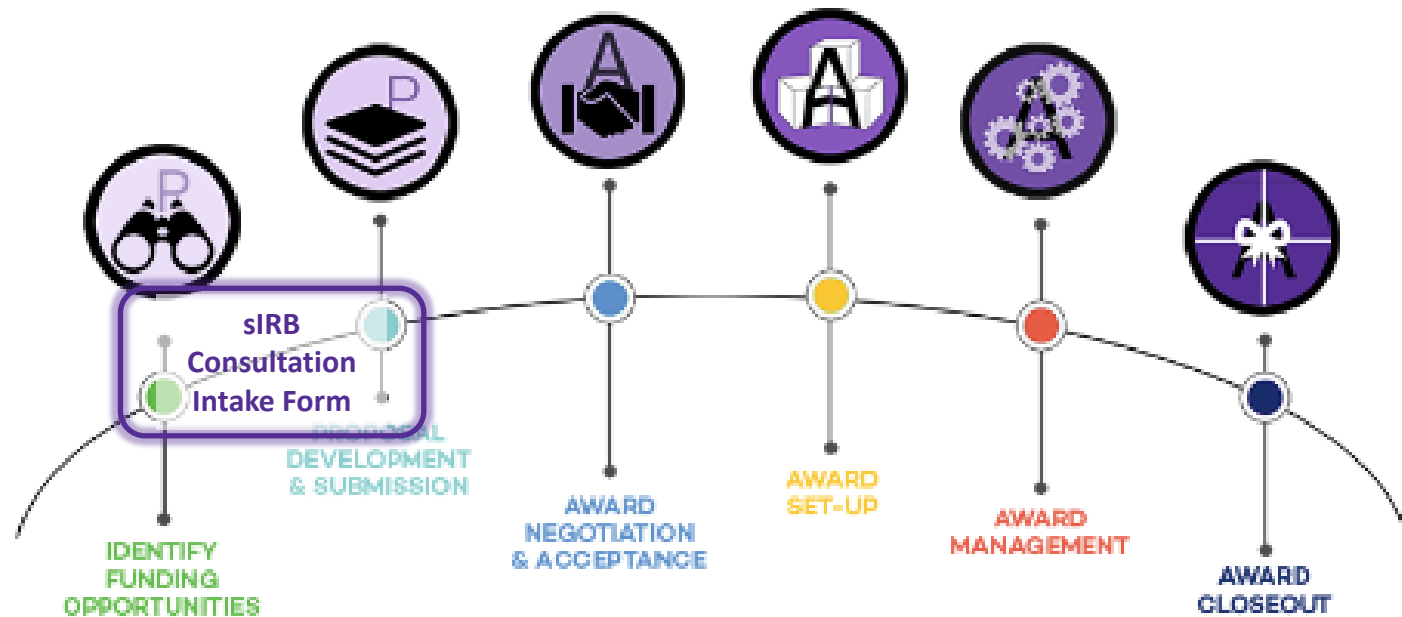
Document	Action
<a href="#">Reliance Process Overview</a>	Review.
<a href="#">Reliance Process Flowchart</a>	Review.
<a href="#">Email Template</a>	Review, fill in appropriate information, and send to collaborator(s).
<a href="#">Cover Letter</a>	Review, fill in appropriate information, and send to collaborator(s).
Reliance Mechanism	See "Reliance Process Overview" for instructions. Download from the "Reliance Agreement Templates" section below or <a href="#">SMART IRB &amp; IREx</a> webpage.
Local Context Form	(If applicable) Download from the "Resources" section below, review, send to collaborator(s), and upload to eIRB+ once received from collaborator(s).

# SPONSORED PROJECT LIFECYCLE



irb.northwestern.edu > Reliance > NU Serving as the IRB of Record  
 or  
<https://irb.northwestern.edu/reliance/nu-serving-as-the-irb-of-record.html>

# SPONSORED PROJECT LIFECYCLE



- Single IRB Planning
- Northwestern Serving as the IRB of Record
- Northwestern Relying on an External IRB
- SMART IRB & IREx
- Northwestern Affiliates & Chicagoland Partners
- Research at Northwestern Qatar

## Single IRB Planning

If your proposed research involves federal funding, human subjects, and multiple research locations, please fill out our [Single IRB Consultation Intake Form](#) prior to submitting your grant application. This applies to initial, resubmission, and renewal applications for federal funding opportunities. If you are at a different time point, or are seeking to add external investigators to a federally funded research study, the Single IRB Consultation Process is still necessary and the intake form should be filled out as soon as possible.

Contact [irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu) for any additional questions.

**Helpful Links**

- [Single IRB Consultation Intake Form](#)
- [OSR Clinical Trials Webpage](#)
- [Single IRB Guidance](#)

### Single IRB Policies and Background

There are two 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. For more information please see our [Single IRB Guidance Document](#) for more information.

### NIH Single IRB Mandate

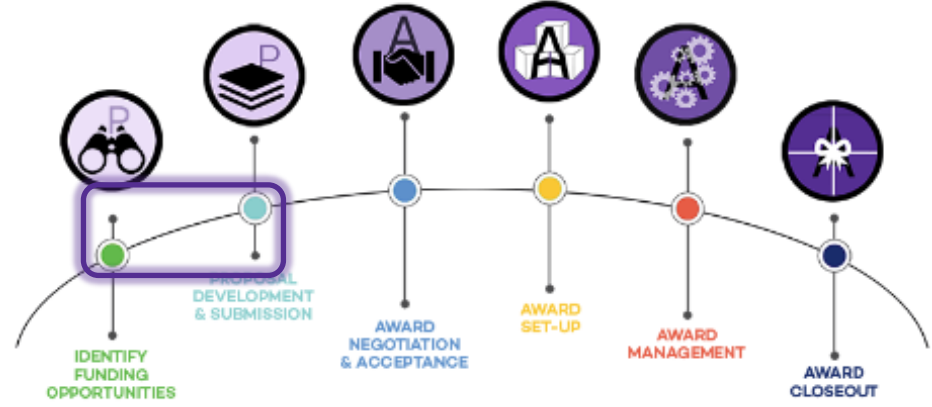
Effective January 25, 2018 the [NIH Single IRB Policy](#) states all competing NIH grant applications (new, renewal, revision or re-submission) for multi-site studies with [NIH receipt dates on or after January 25, 2018](#) must include a [plan describing the use of a sIRB](#) for the study.

- 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.

### Cooperative Research Requirement

Effective January 20, 2020 the [Common Rule Cooperative Research Requirement](#) states projects sponsored by [signatories of the revised Common Rule](#), involving multiple research locations conducting human subjects research, with [IRB approval dates on or after January 20, 2020](#), must use a sIRB. This is mandated by the

# SPONSORED PROJECT LIFECYCLE



[irb.northwestern.edu](http://irb.northwestern.edu) > Reliance > Single IRB Planning  
 or  
<https://irb.northwestern.edu/reliance/single-irb-planning.html>

Thank you!

Please email  
[irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu)  
with questions

# Roles & Responsibilities

# Why Focus on Roles & Responsibilities

- Clarify who is responsible for what functions.
  - Avoid duplicative work
  - Streamline processes
  - Better support our PI's

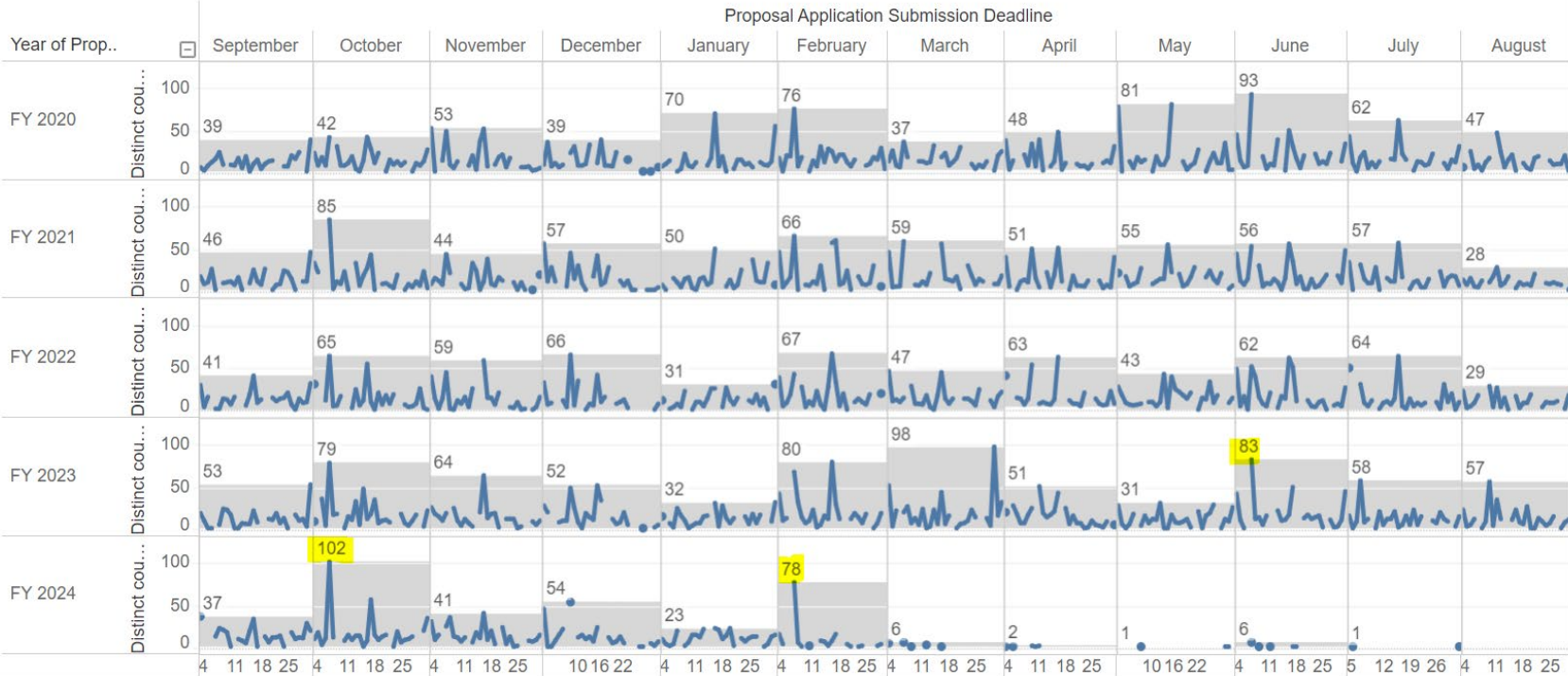
# Northwestern Metrics FY23

- Award Amount     ~\$1B
- # of Awards        3,888
- # of Proposals    3,575

# Volume of Proposals by Month

Year of Proposal Applic...

(All) ▾





# Proposal Deadline Policy Adherence

			2023							
School	Incoming Subaward	FP Count	Arrived 5+ Days			Arrived Less than 5 Days				
			% of Total	Median Days Arrived Ready to Submit vs Deadline	Avg. FP Clarifications Requested Total	FP Count	% of Total	Median Days Arrived Ready to Submit vs Deadline	Avg. FP Clarifications Requested Total	
Feinberg School of Medicine	False	465	52%	6	1	432	48%	3	1	
	True	188	54%	7	2	158	46%	3	1	
Weinberg CollegeArts&Sciences	False	76	38%	5	1	123	62%	3	1	
	True	26	45%	6	1	32	55%	2	1	
McCormick Sch Engg & App Sci	False	76	49%	5	1	78	51%	3	1	
	True	40	46%	6	1	47	54%	3	1	
Research Centers & Institutes	False	38	62%	5	1	23	38%	4	1	
	True	29	60%	5	1	19	40%	2	1	
School of Communication	False	25	71%	5	1	10	29%	4	1	
	True	10	71%	7	0	4	29%	4	1	
School of Educ & Social Policy	False	18	82%	5	1	4	18%	2	1	
	True	8	80%	6	1	2	20%	4	1	
Kellogg School of Management	False	3	27%	6	1	8	73%	3	1	
	True					1	100%	4	1	
Office of the Provost	False	2	33%	8	1	4	67%	3	1	
University Library	False	2	50%	11	1	2	50%	3	2	
Medill School of Journalism	False	2	100%	6	2					
Northwestern School of Law	True	2	100%	16	2					
Northwestern Univ in Qatar	False	2	100%	11	5					
Research Operations	False					1	100%	4	1	
Grand Total		1,012	52%	6	1	948	48%	3	1	

# Advisory Committee Members

- Cathy Barrera, McCormick School of Engineering
- Sheri Carsello, School of Communications
- Bethany Ekesa, Feinberg School of Medicine
- Jen Felten, Feinberg School of Medicine
- Melanie Mkrdichian, Feinberg School of Medicine
- Bryan Runkel, Feinberg School of Medicine
- Hillary Sparks, University Research Institutes and Centers Administration (URICA)
- Grant Upson, Feinberg School of Medicine
- Reid Wellensiek, Weinberg College of Arts & Sciences

# Roles & Responsibilities Documents

- Working to develop guidance documents that show who is responsible for which actions related to proposals and award management.

# Proposal Submission

- Department is responsible for working with PI's to create the proposal.
- Focus is on following the RFP/FOA and ensuring that all required documents are uploaded in the correct format.
- Ensuring that budget components are compliant with Northwestern and Sponsor guidelines.

# Proposal Review

- SR is responsible for ensuring that regulatory requirements are met and that Northwestern policies are followed.
  - IRB, IACUC, COI, F&A rates, Fringe Rates, Cost Share, PI Eligibility, and any restrictive terms and conditions (Controlled Unclassified Information, Publication Restrictions, Foreign National Exclusions, NIST compliance requirements)

# Proposal Package

- In order to achieve a competitive proposal package for the volume of proposals we have, it is important to avoid duplicative efforts.
- SR is not intended to be a "second set of eyes" for the proposal creation but rather to review the existing proposal for regulatory and institutional compliance.

# Award Management

- SR & ASRSP are responsible for regulatory & Northwestern compliance.
- Departments are responsible for "day to day" management of awards.

# Changes that impact responsibility

- Opening more account codes
  - Pro: eliminates need for AMR to request account code opening
  - Pro: eliminates need for cost transfers when "parking" expenses on other accounts
  - Con: removes a "control" where SR previously checked for sponsor allowability and/or preapproval.



# Changes that impact responsibility

- Issuing subawards for multiple years
  - Pro: reduces administrative burden related to requesting subsequent year funding.
  - Pro: allows sub sites to continue work instead of waiting for amendments.
  - Con: Removes a "control" where the current request for an amendment forces attention to the subaward to ascertain if the subsite is complying with terms & conditions and if funding should continue.

# Changes that impact responsibility

- Increasing length of Advance Accounts
  - Pro: Prevents requests for additional time
  - Pro: Allows research to continue when awards are still pending after 90 days
  - Con: Removes a control where SR checks for pre-award spending limitations

# Training & Escalation Process

- Most "research intensive" departments have infrastructure to support RA's. First line of questions should be directed internal to your department.
- SR has training available online at <https://sponsoredresearch.northwestern.edu/resources/training/spot.html>
- Look for a more robust training curriculum coming soon.

# Partners in Research

- Goal is to be collaborative and for departmental and central offices to each take a "piece" of the grant lifecycle.
- Reduce duplication of effort by ensuring that everyone understands that their work is unique and that we "build" on each other's work.

# Open communication

- Reach out to your Advisory Group representative to bring topics to our bi-weekly meeting.
- Contact me directly at [renee.gonzales@northwestern.edu](mailto:renee.gonzales@northwestern.edu)

Questions?