CLEAR Meeting December 12, 2023

Hosted by Sponsored Research

Today's Agenda

- Announcements
- A (Re-)Introduction to the COI Office
- CERES: Tips & Tricks
- SR Best Practices

Winter Recess: Office Closure & Deadlines

- **December 14, 2023 (Thursday): DUE to SR**
  - All transactions that require SR action before Winter Recess are due
  - Note: SR will be closed in the afternoon (after 12pm) for a staff holiday event
- **Dec. 22 (Friday) – Jan. 1 (Monday): CLOSED**
  - Regular SR office operations are suspended
- **January 2, 2024 (Tuesday): OPEN**
  - Sponsored Research reopens with normal business hours

Upcoming NIH Due Dates

NIH Due Date	SR (5-Day) Deadline	Description
January 25	January 18	All - new, renewal, resubmission, revision • Program Project Grants and Center Grants (P-series) • Research Demonstration Edu. Projects (R18, U18, R25) • *Institutional* National Research Service Awards (T-Series) • Multiple other activity codes (C, D, G, S, U)
February 5	January 29	• R01 (new) • U01 (new)
February 12	February 5	• Research Career Development (new) K-series
February 16	February 9	• Other Research Grants and Cooperative Agreements (new) R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3

CLEAR Meetings 2024

- Changing to a hybrid format
  - In-person meeting with networking time
  - Live online simulcast of the presentation and Q&A
- Planned schedule:
  - Quarterly alternating between campuses
  - Feb. (Chi), May (Ev), August (Chi), November (Ev)
  - Second week of the month - Exact dates TBD
- Ad hoc virtual brown bags (via Zoom webinar) for any notable issues that arise between quarterly meetings

Conflict of Interest

Emily Updegraff
Director, Conflict of Interest

What is a conflict of interest?

A situation where financial, professional or other outside activities or interests affect, or appear to affect, a person's judgment in carrying out University duties or responsibilities

The Big Picture

Translating ideas and intellectual property from the University to the marketplace is a critical component of Northwestern's research program.

Translation can create conflicts.

We must **balance** promoting innovation and entrepreneurship with preserving our commitment to Northwestern and safeguarding the integrity and objectivity of University research.

Balancing external interests and research integrity

Bias – even the *perception* of bias – can damage the **integrity of the science**, and the **trust of colleagues**, **sponsors, and the public**

External Interests	Research Integrity
Innovation	Objectivity
Entrepreneurship	Data integrity
$$$	Safety & welfare
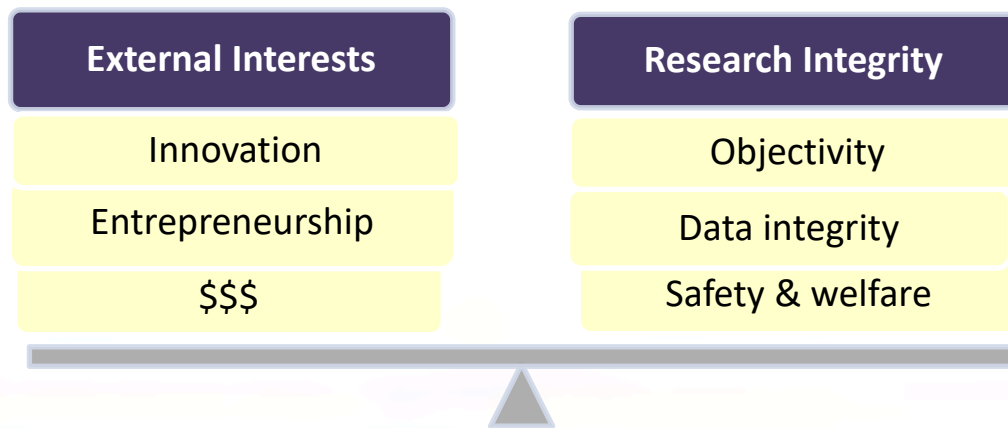
What Federal Sponsors Care About

Federal sponsors are responsible for being good stewards of funds – they want to make good decisions about allocation.

- Will the research results be trustworthy? (i.e. free of bias)
- Do you have the time and resources needed to do this work?
- Is this project already funded? (are you "double-dipping"?)
- Are there opportunities for diversion of intellectual property away from the U.S.?

Taxes

Budgets

Priorities

Funded Research

Translated Technology
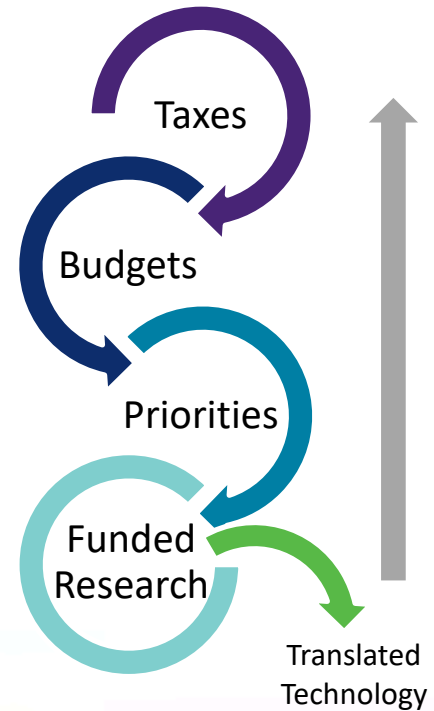
Northwestern's Process

Investigators disclose external interests and relationships

Northwestern reviews interests and research to identify COIs

Elimination, reduction, or management of COIs

Monitoring compliance with management strategies

Policy & Disclosure Requirements
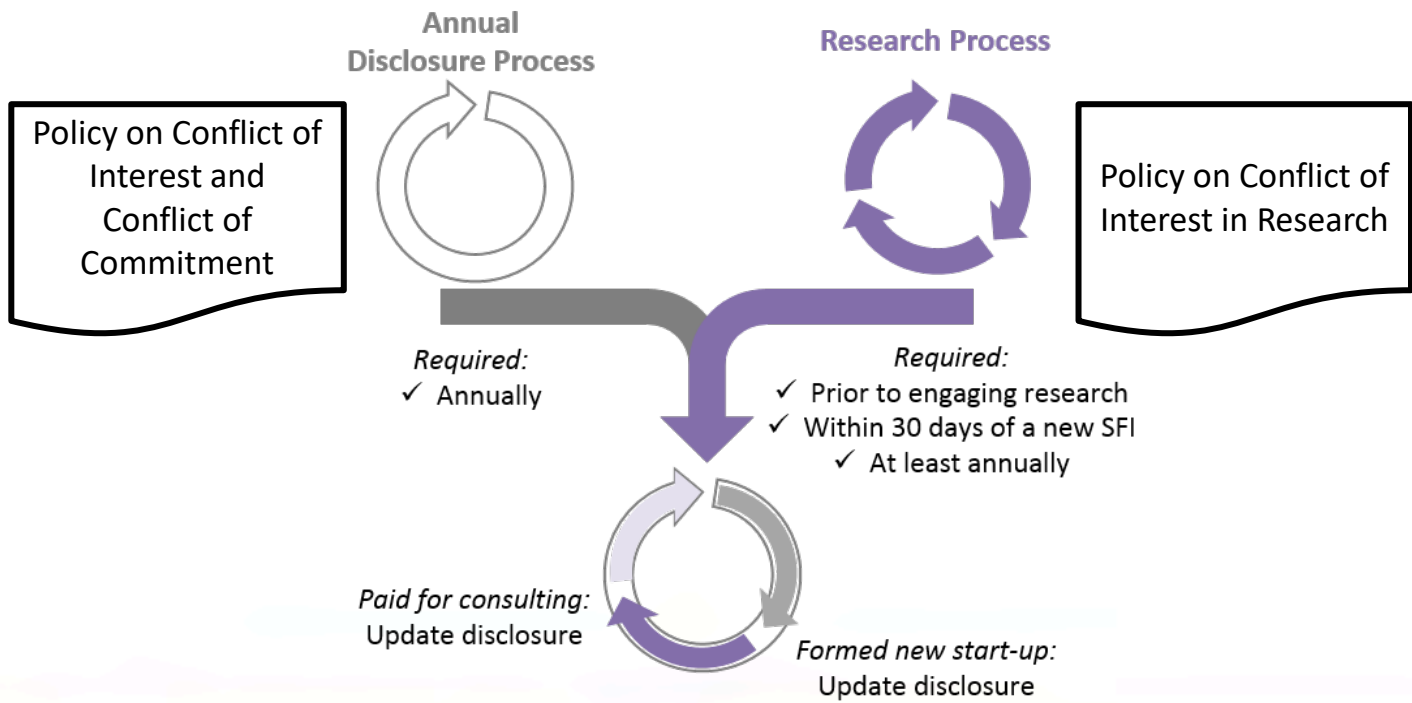
More on Process…
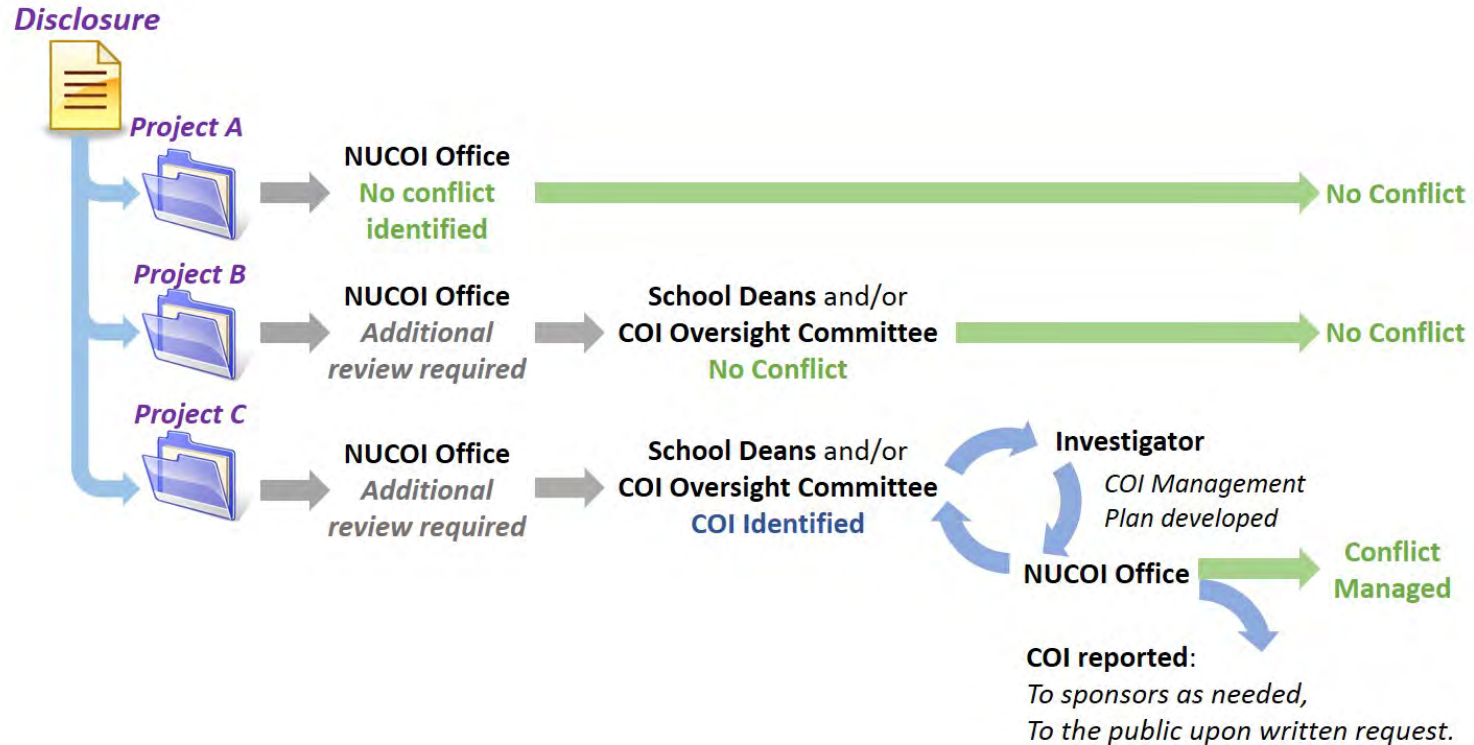
Factors considered in COI reviews

Nature of SFI

Level/Extent of SFI

Nature of Research

Role of Investigator

Nature, Extent, Relatedness

- External consulting

- Start-up companies

- Equity interests

- Option or licensing activity

- Intellectual property interests and stage

- Nature of research

- Role

What do we mean by "Management?"

Management strategies may include:

- **Disclosure / transparency**:
    - To research team & collaborators
    - In presentations & publications
- **Keep outside activities separate from Northwestern activities**. Unless there is an agreement in place, avoid:
    - Involving students & others in outside activities / personal financial interests
    - Using Northwestern resources (space, equipment) in outside work
- **Recusal** from negotiations between Northwestern & entity
- **Independent reviews** of research/other data/results
- **Reduced role in research**

Ancillary Reviews

- At the proposal stage
  - Usually because organizational COI review is needed
- As an agreement is being negotiated
  - When FCOI or OCI certification is required before agreement is signed
- When an award is made
  - To make sure all investigators are reviewed for COI
  - When FCOI is identified, to create management plan prior to award setup

Where to find us

<u>Northwestern Conflict of Interest Office (NUCOI)</u>
nucoi@northwestern.edu / *847.467.4515*

Emily Updegraff, Director

Garth Huskey, Senior Compliance Analyst

Honami Nelson, Compliance Analyst

Diana Sancen, Compliance Analyst

Paula Foster, Program Assistant 4

CERES Tips & Tricks

CERES Lifecycle
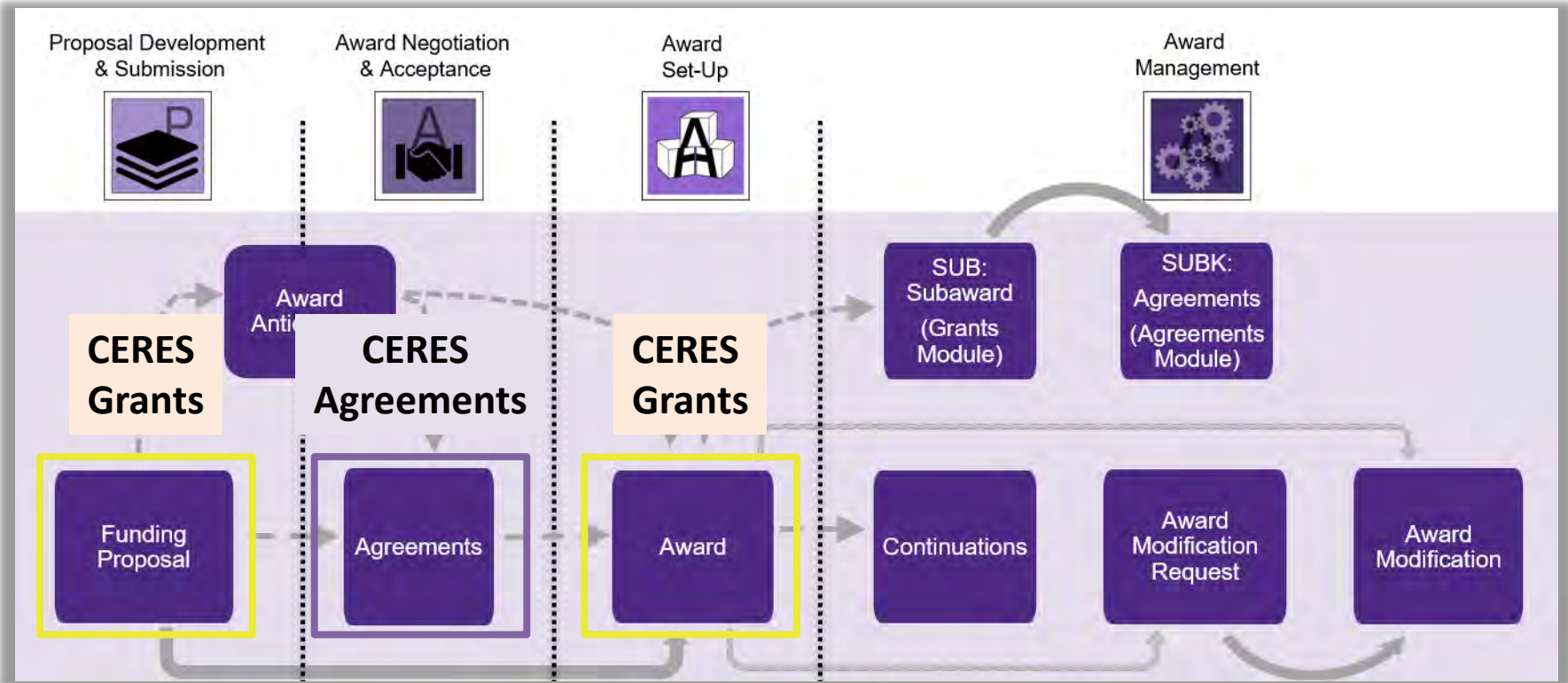
CERES Numbering

Grants Module

Records converted from InfoEd:
Shell Funding Proposals:
FP-SP0072470
Awards: **SP**0071137

Records created in CERES:
Funding Proposals: **FP**00002552
Awards: **AWD**00000522

Agreements Module

Records converted from InfoEd:

Most agreement types: **SP**0071137-x (multiple agreements on one award)

Outgoing subcontracts: **PROJ...**-x, **SUB**...-x

Records created in CERES:

Agreement-type specific prefixes:

SRA-, **DUA-**, **MTA-**, **SUBK-,** etc

Searching for Records

Dashboard	Agreements	Grants	Settings
Funding Proposal	Complex Projects	Awards	Reports	Help Center	Central Actions

Click on Funding Proposals or Awards in the sub-taskbar to access those modules.

Grants > Funding Proposal

Funding Proposal

Filter by Text
Type the first part of the text you want to find. Use % as a wild card.
Typing Gre finds "great," "Green," and "Greetings." Typing %ack finds "tack" and "Blackwall."

Filter by Dates
Type the date, such as 5/23/2015. Filter to the minute by including the time, such as 5-23-15 1:42 PM.

Use Comparison Operators to Make Your Filter More Efficient
Valid Operators. !=, >, >=, <, <=
Filter a date field with > 5/23/2015 to find all values after that date. Filter a numeric field with != 0 to find non-zero values.

Use Boolean Operators for Complex Searches
Valid Operators: -or, -and
Find any of several text values, such as filtering a name column with
Shaun -OR Shaun.
Find everything between two numbers, such as filtering a numeric column with
> 10000 -and <= 50,000.

Search for records using information you know by using **filters.** Add additional filters to narrow your search. The filters correspond to the column headers in the table.

Search 🔍 [   ] 🔍

Proposals	Draft	Internal Review	Sponsor Review	Awarded	Completed	Tableau

Filter by ❓ | PI ▼ | Enter text to search | 🔍 | ➕ Add Filter | ✖ Clear All
and by | Primary Sponsor ▼ | Enter text to search | ✖ Remove Filter
and by | Submitting Depa ▼ | Enter text to search | ✖ Remove Filter

ID
Name
State
PI
Primary Sponsor
Submission Type
Application Deadline
Specialist
Submitting Department

ID		SmartForm	State	PI	Primary Sponsor	Submission Type	Application Deadline	Specialist	Submitting Department
📁 FP00002553		[Edit] ▼	Department Review	Look	AAA New Jersey Automobile Club	Funding Submission	1/5/2024	Adamsel	Preventive Medicine
📁 FP00002552	...ility	[Edit] ▼	Pending Sponsor Review	Kozlowski	AAA New Jersey Automobile Club	Funding Submission	1/5/2024	Adamsel	Behavioral Medicine
📁 FP00002551	Test for Budget Editability	[Edit] ▼	Pending Sponsor Review	Kozlowski	University of Chicago	Funding Submission	12/1/2023	Adamsel	Behavioral Medicine
📁 FP00000440	T32 renewal	[Edit] ▼	Pending Sponsor Review	Markl	National Institute of Biomedical Imaging and Bioengineering	Funding Submission	5/25/2023	Godowic	General Radiology
📁 FP00000744	MURI white paper		...al Research Laboratory		Funding Submission	5/19/2023	Godowic	Physics & Astronomy
📁 FP00002528	Test 26	[Edit] ▼	...tion	...Evans	...som Corporation	Funding Submission	9/4/2023	Godowic	Neurology Basic Science
📁 FP00000020	Neighborhood perceptions and response to a technol...	[Edit] ▼	Awarded	Becker	National Institute on Drug Abuse	Funding Submission	5/8/2023	more	Ctr for Disem & Impl Science

Click on the **Name** of the funding proposal to access it.

How can I?

See more results without scrolling through so many pages...

24 items

◄ page 1 of 1 ►

100 / page

...Adjust the number of items appearing per page

See an Activity that isn't appearing on a workspace ...

Manage Access

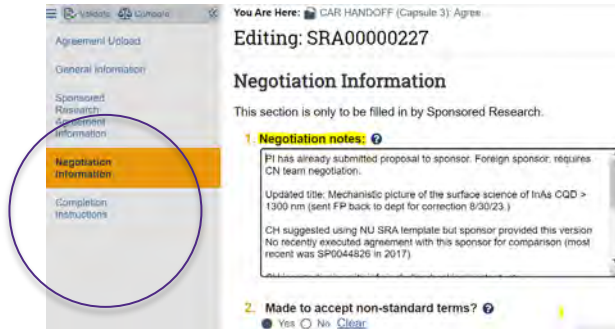1. **Select administrative contact:**

Trinita Coachman ···

...Double-check whether you are listed as the Admin Contact (Grants) or Primary Contact (Agreements); if you're not, make yourself the contact using Manage Access
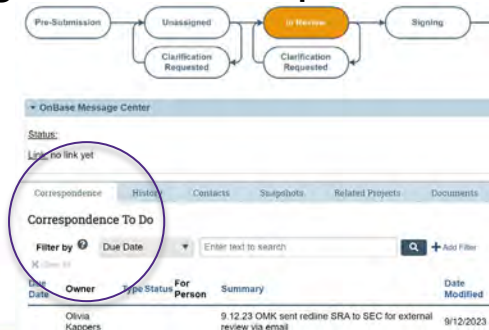
How can I?

See details regarding negotiations in process for Sponsored Research Agreements?

...Navigate to the SRA SmartForm **Negotiation Information** page

Get at-a-glance latest update on an agreement in negotiation...

...In the Agreement workspace:
- note the workflow bubble in orange
- see latest Correspondence on tab
- run **GA301 Agreement Detail** in Cognos

How can I?

Tell if I'm in the Grants or Agreements module...
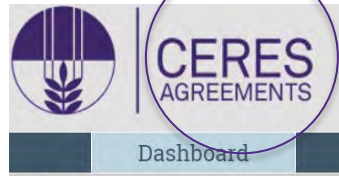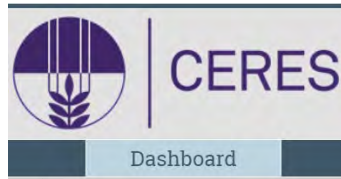
...Look for 'Agreements' in the logo

See all of the agreements in Pre-Submission that my department needs to complete and submit to SR?
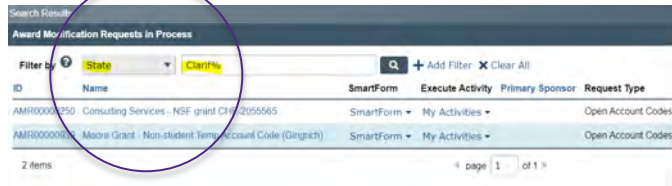
…Navigate to the Agreements Dashboard->In Process tab, scroll down to either My Agreements (to see items where you are RA) or All Agreements (whole dept), and click on the **Pre-Submission Agreements** tile

How can I?

See all **Award Mod Requests** that I/my department needs to provide clarifications and re-submit?
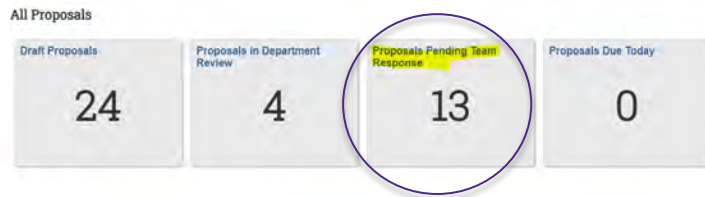
...Navigate to the Grants Dashboard->In Process tab, scroll to My Post-Award Items (to see items where you are RA) or All Post-Award Items (whole dept), and click on the **Award Mod Requests in Process** tile; add State filter for 'Clarif%'

See all **proposals** that I/my department needs to provide clarifications and re-submit?

…Navigate to the Grants Dashboard->In Process tab, scroll to My Proposals (to see items where you are RA) or All Proposals (whole dept), and click on the **Proposals Pending Team Response** tile

What's in my Inbox?

- Records from across both modules that are in a state that requires your action

- **Tip:**
  - You can see all records where you are listed as Admin Contact via the 'My Proposals' and 'My Post Award Items' tiles on the 'In Process' dashboard tab in the Grants Module; similar tab in the Agreements module
  - To see all records your security gives you access to, see the 'All Proposals' and 'All Post Award Items' sections on the same tab

What's in my Inbox?

What's in my Inbox?

Record Type	State	Likely Next Step
Funding Proposal	Draft	Submit for Department Review (once FP-Budget-SF424 ready)
	Department Review: Response Pending from PI	After RA makes changes, re-submit to resume Dept Review
	Specialist Review: Response Pending from PI	SR has requested changes; once complete, re-submit to return to Specialist Review in SR
	JIT Response Required	SR has responded to your proposal status confirmation JIT by opening the Funding Proposal record for updates. Upload your JIT documents, then execute the **Submit JIT Response** activity.

What's in my Inbox?

Record Type	State	Likely Next Step
Clinical Trial Agreement	Clarification Requested	SR has begun reviewing the CTA you submitted and has questions for you/the PI. Address questions and re-submit.
Outgoing Subcontract Agreement	Pre-Submission	SR has created a subcontract agreement record for you **to complete/update** and submit. (Note: don't make one of these yourself!)
Outgoing Subcontract Agreement	Clarification Requested	SR has begun reviewing the provided subcontract information and needs you to clarify some question(s)

Help! (Quick Reference)

Grants Module

Help! (Quick Reference)

Agreements Module

Agreements > Help Center

⚙ Properties

Help Center

Quick Reference	Videos

Export to CSV ⚙

Name	Description
Agreements Researcher's Guide	A guide for researchers and agreement submitters that includes steps for submitting a new agreement or amendment and responding to reviewer clarification requests.
Create and Submit a Clinical Trial Agreement (CTA)	Job Aid: This topic shows how to create and submit a Clinical Trial Agreement (CTA). After the related funding proposal is approved by the necessary department approvers and reviewed by Sponsored Research, the Research Administrator can create the CTA.
Create and Submit a Non-Funded Agreement	Job Aid: This topic shows how to create a non-funded agreement and submit it for review. Non-funded agreements may include MTAs, DUAs, NDAs, CAs, LOIs, or MOUs.
Create and Submit an Amendment to an Agreement	Job Aid: This topic shows how to create and submit amendments for agreements in the Active, Expired, and Evergreen state. Only one amendment can be in progress at a time, and multiple changes can be included in a single amendment.
Create and Submit an Outgoing Subaward Agreement	Job Aid: This topic shows how to complete an Outgoing Subaward Agreement and submit it for review. This agreement will be initiated by Sponsored Research, and the Research Administrator is responsible for completing and submitting the agreement.

Help! (Video Links)

SR Best Practices

General Guidance

- Reduce email/Teams traffic!

  - Be sure to include the related CERES ID in your subject line
  - Review the History tab, Correspondence BEFORE emailing SR
  - Consult [Capsule Roles](#) and [Find My Capsule](#) tool to find the appropriate staff member for your inquiry
  - **Note: No need to send an email/chat informing SR that you've sent something in CERES!**

Capsule Resources

Learn About Capsule Roles

Find My Capsule

Best Practice Tips

- F&A and PI eligibility waiver requests
  - Use the job aids provided to ensure the correct information is included so the ancillary review is actionable upon receipt
  - If returned for correction a new ancillary review must be completed and resubmitted.
- If you have a new org, submit request ASAP!

Best Practice Tips

- After the Fact Proposals
  - All proposals are required to be submitted to SR for institutional review and endorsement prior to submission
  - ATF (after the fact) proposals should include all required proposal materials and all forms should be completed prior to routing to SR
    - At minimum SR needs the submitted proposal, detailed budget and justification, solicitation and any other related materials (emails, etc.) that will aid in the timely review of the application. As applicable: any waivers or eligibility approvals must be routed via ancillary review
    - Awards resulting from ATF proposals will experience delay in negotiation and acceptance

Best Practice Tips

- When the PI or RA receives an award from a sponsor by email – use the **Send Grants Status Update** activity on the FP to convey it to SR, selecting Award Received.

  o Please don't create a Sponsored Research Agreement; SR will create one if it is needed to track negotiations

Send Grants Status Update

1. Grants status:
- ○ Award Anticipated
- ○ JIT Info Requested
- ○ Not Funded
- ○ Withdraw Submission (Proposal Not Reviewed)
- ● Award Received
- ○ other
- Clear

2. Comments:

3. Documents:
- ＋ Add
- Name
- AwardDoc.docx(0.01)

Best Practice Tips

- All documentation relevant to the review of the AMR should be uploaded IN the AMR, no documentation should be included in the pop up.

- Annual and final progress report / technical report deliverables are being added to records where the due dates are clearly indicated. Financial reports are not, nor are any special interim reports. PIs and departments must read the award document in full for any and all due dates.

Best Practice Tips

- New Award Setup + Award Modifications trigger SR to tee up subcontracts to RA
    - Wait for the agreement to appear in your inbox in Pre-Submission state; email notification is sent. **Please don't create an agreement yourself!**
- Use the Outgoing Subcontract Award Modification Request for other changes needed.

Resources

- SR's [CERES page](https://sponsoredresearch.northwestern.edu/resources/ceres/)
  - https://sponsoredresearch.northwestern.edu/resources/ceres/
- SR's [Help page](https://sponsoredresearch.northwestern.edu/resources/help.html)
  - https://sponsoredresearch.northwestern.edu/resources/help.html
- SR's [Training page](https://sponsoredresearch.northwestern.edu/resources/training/)
  - https://sponsoredresearch.northwestern.edu/resources/training/