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

<table>
<thead>
<tr>
<th>NIH Due Date</th>
<th>SR (5-Day) Deadline</th>
<th>Description</th>
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</table>
| 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
  o In-person meeting with networking time
  o Live online simulcast of the presentation and Q&A

• Planned schedule:
  o Quarterly alternating between campuses
  o Feb. (Chi), May (Ev), August (Chi), November (Ev)
  o 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**

<table>
<thead>
<tr>
<th>External Interests</th>
<th>Research Integrity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation</td>
<td>Objectivity</td>
</tr>
<tr>
<td>Entrepreneurship</td>
<td>Data integrity</td>
</tr>
<tr>
<td>$$$</td>
<td>Safety &amp; welfare</td>
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</table>
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.?
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

Policy on Conflict of Interest and Conflict of Commitment

Annual Disclosure Process
- Required:
  - Annually

Policy on Conflict of Interest in Research

Research Process
- Required:
  - Prior to engaging research
  - Within 30 days of a new SFI
  - At least annually

Paid for consulting:
- Update disclosure

Formed new start-up:
- Update disclosure
More on Process...

Disclosure

Project A
NUCOI Office
No conflict identified
No Conflict

Project B
NUCOI Office
Additional review required
School Deans and/or COI Oversight Committee
No Conflict
No Conflict

Project C
NUCOI Office
Additional review required
School Deans and/or COI Oversight Committee
COI Identified

Investigator
COI Management Plan developed
Conflicted Managed

NUCOI Office

COI reported:
To sponsors as needed,
To the public upon written request.
Factors considered in COI reviews

- 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

Northwestern Conflict of Interest Office (NUCOI)
nucoi@northwestern.edu  /  847.467.4515

Emily Updegraaff, Director

Garth Huskey, Senior Compliance Analyst

Honami Nelson, Compliance Analyst

Diana Sancen, Compliance Analyst

Paula Foster, Program Assistant 4
CERES Lifecycle

- Proposal Development & Submission
- Award Negotiation & Acceptance
- Award Set-Up
- Award Management

**CERES Grants**
- Funding Proposal
- Agreements
- Award
- Continuations
- Award Modification Request
- Award Modification

**CERES Agreements**
- SUB: Subaward (Grants Module)
- SUBK: Agreements (Agreements Module)

Northwestern | RESEARCH
CERES Numbering

Grants Module
Records converted from InfoEd:
Shell Funding Proposals: 
FP-SP0072470
Awards: SP0071137

Records created in CERES:
Funding Proposals: FP00002552
Awards: AWD00000522

Agreements Module
Records converted from InfoEd:
Most agreement types: SP0071137-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

CERES Grants is the landing page when you first log into the system.

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

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

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

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.
How can I?

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

...Adjust the number of items appearing per page

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

...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:
  o 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
  o 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?

<table>
<thead>
<tr>
<th>Record Type</th>
<th>State</th>
<th>Likely Next Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Proposal</td>
<td>Draft</td>
<td>Submit for Department Review (once FP-Budget-SF424 ready)</td>
</tr>
<tr>
<td></td>
<td>Department Review: Response Pending from PI</td>
<td>After RA makes changes, re-submit to resume Dept Review</td>
</tr>
<tr>
<td></td>
<td>Specialist Review: Response Pending from PI</td>
<td>SR has requested changes; once complete, re-submit to return to Specialist Review in SR</td>
</tr>
<tr>
<td></td>
<td>JIT Response Required</td>
<td>SR has responded to your proposal status confirmation JIT by opening the Funding Proposal record for updates. Upload your JIT documents, then execute the <strong>Submit JIT Response</strong> activity.</td>
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## What's in my Inbox?

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<td>Clinical Trial Agreement</td>
<td>Clarification Requested</td>
<td>SR has begun reviewing the CTA you submitted and has questions for you/the PI. Address questions and re-submit.</td>
</tr>
<tr>
<td>Outgoing Subcontract Agreement</td>
<td>Pre-Submission</td>
<td>SR has created a subcontract agreement record for you <strong>to complete/update</strong> and submit. (Note: don't make one of these yourself!)</td>
</tr>
<tr>
<td>Outgoing Subcontract Agreement</td>
<td>Clarification Requested</td>
<td>SR has begun reviewing the provided subcontract information and needs you to clarify some question(s)</td>
</tr>
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Help! (Quick Reference)

Grants Module
## Help! (Quick Reference)

### Agreements Module

#### Agreements > Help Center

### Quick Reference

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<tr>
<td>Agreements Researcher’s Guide</td>
<td>A guide for researchers and agreement submitters that includes steps for submitting a new agreement or amendment and responding to reviewer clarification requests.</td>
</tr>
<tr>
<td>Create and Submit a Clinical Trial Agreement (CTA)</td>
<td>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.</td>
</tr>
<tr>
<td>Create and Submit a Non-Funded Agreement</td>
<td>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.</td>
</tr>
<tr>
<td>Create and Submit an Amendment to an Agreement</td>
<td>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.</td>
</tr>
<tr>
<td>Create and Submit an Outgoing Subaward Agreement</td>
<td>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.</td>
</tr>
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*Export to CSV*
Help! (Video Links)

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<tr>
<td>CERES 101</td>
<td>CERES 101 is a Computer-Based Learning course that covers CERES basic terminology and navigation. Learners will become familiar with the CERES system, including an overview of what the system is and how it is used.</td>
</tr>
<tr>
<td>Submit an Ancillary Review</td>
<td>This topic shows how to submit an ancillary review in either the Grants or Agreements modules.</td>
</tr>
<tr>
<td>Add Ancillary Reviews</td>
<td>This topic shows how to add ancillary reviews and check the review status. Ancillary reviews take place concurrently with the normal review workflows and can be added to funding proposals, awards, award modifications, and agreements.</td>
</tr>
</tbody>
</table>
SR Best Practices
General Guidance

• Reduce email/Teams traffic!
  
  o Be sure to include the related CERES ID in your subject line
  o Review the History tab, Correspondence BEFORE emailing SR
  o Consult Capsule Roles and Find My Capsule tool to find the appropriate staff member for your inquiry
  o 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

View my Capsule Team

Download List

Display Capsule for a Dept

Contracts & Negotiation Teams

Learn More about Capsules
Best Practice Tips

• F&A and PI eligibility waiver requests
  o Use the job aids provided to ensure the correct information is included so the ancillary review is actionable upon receipt
  o 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
  o All proposals are required to be submitted to SR for institutional review and endorsement prior to submission
  o 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.
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
  o 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
  o https://sponsoredresearch.northwestern.edu/resources/ceres/

• SR's Help page
  o https://sponsoredresearch.northwestern.edu/resources/help.html

• SR's Training page
  o https://sponsoredresearch.northwestern.edu/resources/training/