Northwestern RESEARCH

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) <i>Institutional</i> 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
 - $\circ~$ In-person meeting with networking time
 - Live online simulcast of the presentation and Q&A
- Planned schedule:
 - Quarterly alternating between campuses
 - o Feb. (Chi), May (Ev), August (Chi), November (Ev)
 - $\circ~$ 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

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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**



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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



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More on Process...



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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

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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 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



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CERES Numbering

Grants Module



Records converted from InfoEd: Shell Funding Proposals: **FP-SP**0072470

Awards: SP0071137



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

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

Searching for Records

Dashboard	A	greement	ts		Grants	Set	ttings							
Funding Proposal	Complex Proje	cts /	Awards	Repo	orts Help Center	Centra	al Actions	CIICK	on Fu	nding				
Grants > Funding Proposal Funding Proposal								the s	ub-tas bs thos	skbar to se modules.				
Filter by Text Type the first part of the text you want to find. Use % as a wild card. Typing time finds "greet" "Green " and											Search 😮		Q	3
Greetings "Typing Back finds "tack" and "Blackwell"	Proposals	Draft	Internal	Review	Sponsor Review	Awarded	Completed	Tableau	Sea	rch for records usir	ig inform	ation you	u know	/
Type the date, such as 5/23/2015. Filter to the minute by including the time, such as 5-23-15. 1:42. PH.	Filter by 🔞	PI		Enter te	ext to search		A + Add Filter	X Clear All	vou	r search. The filters	corresp	ond to th	nanov ne	*
Use Comparison Operators to Make Your Filter More Efficient Valid Operators, I=, >, >=, <, <=	and by	Primary S	ponsoi 🔹	Enter te	ext to search	;	Remove Filter		colu	umn headers in the	table.		-	
Filter a date field with > 5/23/2015 to (find all values after that date. Filter a numenc field with 1= 0 to find non-zero values.	ID	ID Name	g Depa	Enter te	ALLO SEALCH	SmartF	orm State		PI	Primary Sponsor	Submission Type	Application Deadline	Specialis	t Submitting
Use Boolean Operators for Complex Searches Valid Operators -or, -and	FP0000255	PI Pi Primary Si	ponsor			[Edit] •	Department R	leview	Look	AAA New Jersey Automobile Club	Funding Submission	1/5/2024	Adamsel	Preventive Medicine
filtering a name column with Shawn -OR Shawn. Find everything between two numbers	FP0000255	Application	n Deadline	b lity		[Edit] •	Pending Spon	isor Review	Kozlowski	AAA New Jersey Automobile Club	Funding Submission	1/5/2024	Adamsel	Behavioral Medicine
such as filtering a numeric column with > 10000 -and <= 50,000.	FP0000255	Submitting Test for	Departmen	it Mobility		[Edit] ▼	Pending Spon	isor Review	Kozlowski	University of Chicago	Funding Submission	12/1/2023	Adamsel	Behavioral Medicine
	FP00000440) T32 rei	newal			(Edit) -	Pending Spon	sor Review	Markl	National Institute of Biomedical ling and Bioengineering	Funding Submission	5/25/2023	Godowic	General Radiology
	FP00000744	MURI	white paper			Click o	n the Nar	ne of t	he cocc it	al Research Laboratory	Funding Submission	5/19/2023	Godowic	Physics & Astronomy
	FP00002528	3 Test 26	5			Turium	R hi ohose			m Corporation	Funding Submission	9/4/2023	Godowic	Neurology Basic Science
	FP00000020) Neighb	orhood per	ceptions a	nd response to a technol	[Edit] +	Awarded		Becker	National Institute on Drug Abuse	Funding Submission	5/8/2023	more	Ctr for Disem & Impl Science

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

24 items

page 1 of 1



...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

See details regarding negotiations in process for Sponsored Research



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

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

(Pre-Satimission	Unassigned University Chertification	
- OnBase Message Center	Clarification Requested	
Status:		
Correspondence Histor Correspondence To Do Filter by O Due Date	Constacts Studgeholts. Related Projects 1	Add Filter
Date Owner Type State	Person Summary 9.12.23 OMK sent redine SRA to SEC for external	Date Modified

...In the Agreement workspace:

- note the workflow bubble in orange
- see latest Correspondence on tab
- run GA301 Agreement Detail in Cognos

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

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

Award Movific	ation Requests in Process		
Filter by @	State Clarifi	Add Filter X Clear All	
ID	Name	SmartForm Execute Activity Primary Sponsor	Request Type
AMR0000 250	Consulting Services - NSF grant CH0-2055565	SmartForm • My Activities •	Open Account Codes
AMERCODODO	Moore Grant - Non-student Temp Account Code (Gingnich)	SmartForm + My Activities +	Open Account Codes

...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

- 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

Dashboard Adm	in Agreemen	ts Grants	Settings				
e for Kimberly Griffin							😯 Hel
Create 🔫	My Inbox Assig	nments In Proces	s Capsule Activity				
ecently Viewed	My Inbox Filter by 🚱 ID	▼ Enter	text to search		Q + A	dd Filter	•
Recent Pinned FP000000621 PROT- Cl2021 REVENT ↔	Clear All	Name		Date Created	→ Date Modified	State	Coordinate
FP-SP0054023: CNS	SUBK00000466	60066516-A00_Universi Champaign_(AWD00000	iy of Illinois at Urbana- 1655) [Fan]	10/9/2023 1:36 PM	12/12/2023 8:25 AM	Unassigned	· · · · ·
SP0062800-MOD005:	SUB0000943- 1AM1	60060337-A0X_UKMC_	(SP0067995) [Meister]	10/19/2023 11:15 AM	12/12/2023 8:17 AM	Unassigned	
end	PROJ0013575- 1AM1	60052960-A04_Rehabili Chicago_(SP0047927) [/	ation Institute of Heinemann]	9/28/2023 4:18 PM	12/11/2023 7:54 PM	Unassigned	
SP0062800: Soy Isofiavosthma (SIRA) SP0068040: Northwesternr (NU- >>	SP0055121-1AM2	Amendment for Prot: PR Study to Evaluate the Sa with Parkinson's Disease Mutation 2	V-PD101- A Phase 1/2a fety of PR001A in Patients with at Least One GBA1	12/11/2023 2:09 PM	12/11/2023 3:27 PM	Unassigned	
CCNIC)	SRA00000257AM1	Amendment for Agreeme Support AONA 1	ent for: Spine Fellowship	12/7/2023 4:23 PM	12/7/2023 4:34 PM	Unassigned	

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.

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)

Dashboard	Admin	Agreements Grants Settings	
Funding Proposal	Complex Projects Awards I	Reports Help Center Central Actions	P Grants
oot > Grants > Help Center		a construction of the second se	Ulante
ala Contor			
erp Center			
[Guides Videos		
	Name	Description	
	Research Community Grants Reference Guide	Instructions for the NU Research Community for key tasks in preparing applications for sponsored funding using the Grants solution.	
	Create and Submit a Funding Proposal	Job Ald: This topic shows how to create a funding proposal and check it for errors and omissions.	
	Complete a Budget	Job Aid: This topic shows how to complete a primary sponsor budget.	
	Create a Cost Share Budget	Job Aid: This topic shows how to create a cost share budget if the project effort exceeds the salary requested on a primary sponsor budget or if the funding proposal has mandatory or voluntary committed cost sharing.	
	Create a Subaward Budget	Job Aid: This lopic shows how to create a subaward budget when an external collaborator will be contracted to perform work as part of a larger sponsored project. A subaward budget is created from and linked to a primary sponsor budget.	
	Create and Update SF424 Forms	Job Aki. This topic shows how to create SF424 forms once the funding proposal and budget are complete, but before they are submitted for review. Information from the funding proposal and budget auto-populate the SF424 pages.	
	Request a New Organization	Job Aid: This topic shows how to submit a request for a new organization (sponsor or subaward entity) to be added to the NU Organizations list.	
	Certify a Funding Proposal	Job Aid: This topic shows how the PI should review and certify that their proposal is complete and accurate. If PI certification is outstanding when the proposal moves to Department Review, the PI will receive a reminder email to complete IL	
	Add an Ancillary Review and Check the Review Status	Job Aid: 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.	
	Submit an Ancillary Review	Job Aki: This topic shows how to submit an ancillary review in either the Grants or Agreements modules.	
	F&A Waiver Ancillary Review	Job Aid: This topic shows how to add an ancillary review specifically for requesting an F&A Waiver. An ancillary review for F&A Waiver is required on a funding proposal or award.	
	PI Eligibility Ancillary Review	Job Aid: This topic shows how to add an ancillary review specifically for PI Eligibility. An ancillary review for PI Eligibility is required on a funding proposal or award. Requests should be made at least 3 weeks prior to the proposal deadline.	
	Department Reviewer Activities	Job Aki: This topic shows department reviewers how to review a funding proposal, add reviewer notes, request changes from the RA, review clarification responses, and submit a department review.	
	Respond to a Clarification Request	Job Aid: This topic shows how to respond to a clarification request if a reviewer requests changes. The proposal learn must make the approrpate changes and submit the revised proposal for review again.	
	Request an Advance Account	Job Aid: This topic shows how to submit a request for an advance account to Sponsored Research.	
	Respond to a Just-In-Time (JIT) or Similar Request	Job Aid: This topic shows how to respond to a Just-In-Time (JIT) or similar request from a sponsor. Both the Research Administrator and Sponsored Research will perform steps in CERES.	
	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 Administrator concreted the CTA.	
	Reconcile an Award Budget	Job Aki: This topic shows how to reconcile an award budget. Sponsored Research may contact the Research Administrator to reconcile the budget in certain circumstances.	
	Manage Deliverables	Job Ald: This topic shows how to add, edit, and complete deliverables on an award. Deliverables created in CERES a provide a way to track sponsor and Northwestern requirements for the award, such as deadlines, special reports, and progress reports.	
	Request an Award Modification	Job Aid: This topic shows how to create an Award Modification Request and submit it for review. During the life cycle of a research project, active awards often require changes, for example, budget adjustments, no cost extensions, or personnel changes.	
	Create a Continuation Proposal	Joh Aid: This tonic shows how to create a Continuation Pronosal and submit if for review & continuation pronosal is a type of follow on submission in CEDES used primarily for submittion progress reports for review and approval	

Help! (Quick Reference)

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

Agreements Module



Help! (Video Links)

Dashboard		Admin	Agreements	Grants	Settings	
Agreements	Reports	s Help Cente	er Central Actions			
Agreements > Help Center						Properties
Help Center						
		Quick Reference	Vīdeos			
						Export to CSV
		Name	Description			
		CERES 101	CERES 101 is a Computer-E CERES system, including an	Based Learning cours noverview of what the	e that covers CERES basic system is and how it is use	terminology and navigation. Learners will become familiar with the ed.
		Submit an Ancillary Review	This topic shows how to sub	mit an ancillary reviev	v in either the Grants or Agr	reements modules.
		Add Ancillary Reviews	This topic shows how to add workflows and can be added	ancillary reviews and to funding proposals	check the review status. A , awards, award modificatio	ncillary reviews take place concurrently with the normal review ns, and agreements.

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 <u>Capsule Roles</u> and <u>Find My Capsule</u> 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



• 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!

- 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

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

Send Gra	Send Grants Status Update						
1. Gra	nts status:						
0	Award Anticipated						
0	JIT Info Requested						
0	Not Funded						
0	Withdraw Submission (Proposal Not Reviewed)						
	Award Received						
0	other						
	Clear						
2. Con	nments:						
3. Doo	uments:						
-	H Add						
	Name						
	AwardDoc.docx(0.01)						

- 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.

- 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 <u>CERES page</u>

o https://sponsoredresearch.northwestern.edu/resources/ceres/

• SR's <u>Help page</u>

o <u>https://sponsoredresearch.northwestern.edu/resources/help.html</u>

• SR's Training page

o https://sponsoredresearch.northwestern.edu/resources/training/