CLEAR Meeting: October 15, 2025

Hosted by Sponsored Research

Today's Agenda

- Announcements
- Director of Research Education, Chris Kelly
- Proposal Updates
- Continuations vs. Revisions
- MTA & DUA Smart Form Guidance

Announcements

- Interim funding extended to 12/31/25
- Changes to SR structure & processes coming soon!
- Available for faculty & staff presentations/outreach
- Please plan carefully for upcoming proposal deadlines, noting:
    - NIH deadlines
    - Holidays

Upcoming NIH Due Dates

NIH Due Date	SR (5-Day) Deadline	Description
November 5	October 29	• R01, U01 - *renewal, resubmission, revision*
December 8	December 1	• F series (Individual NRSA) *All - new, renewal, resubmission, revision*
December 12	December 5	• R13, U13 Conference Grants & Cooperative Agreements *All - new, renewal, resubmission, revision*
January 25* (Sunday)	January 19	*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)

**Due date to NIH moves to next business day as standard due date falls on weekend or holiday.*

Winter Recess: Office Closure & Deadlines

- **Monday, December 15, 2025: DUE to SR**
  - All transactions that have a sponsor deadline before Winter Recess are due
  - RPPRs (due Jan. 1) should be complete and routed to SR
- **Wednesday, December 24 – Thursday, January 1: CLOSED**
  - Northwestern University administrative offices are closed
  - Regular Sponsored Research office operations are suspended
- **Friday, January 2, 2026: OPEN**
  - Sponsored Research reopens with normal business hours
- **Proposals due January 5 - 9 must follow 5-day deadline policy**
  - Example: Proposal due Jan. 5, 2026, is due to SR on Dec. 18, 2025

Office of Research Education

Christopher Kelly, Director

My Background

10+ years of experience working in research administration in various roles

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

Weill Cornell Medicine

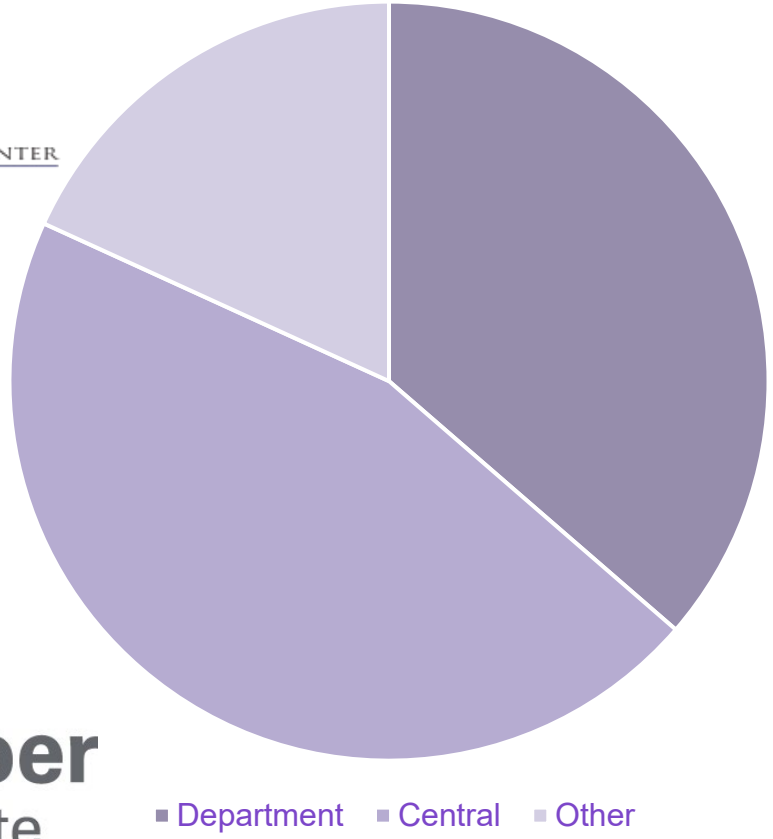
Boston College

The George Washington University Washington DC

Northwestern McCormick School of Engineering

Schepens Eye Research Institute Massachusetts Eye and Ear

Dana-Farber Cancer Institute



Needs from Stakeholders

- Can you walk me through what training currently exists in your department or team?
- Who typically provides the training, and how is it delivered (in-person, online, peer-led, etc.)?
- What is working well with existing trainings?
- What are some of the key knowledge gaps you encounter regularly?
- What are some of the business processes you find to be inefficient?
- Where do you currently go to find information on processes/procedure?
- How can my role help make your job easier?

Questions? Comments? Suggestions?

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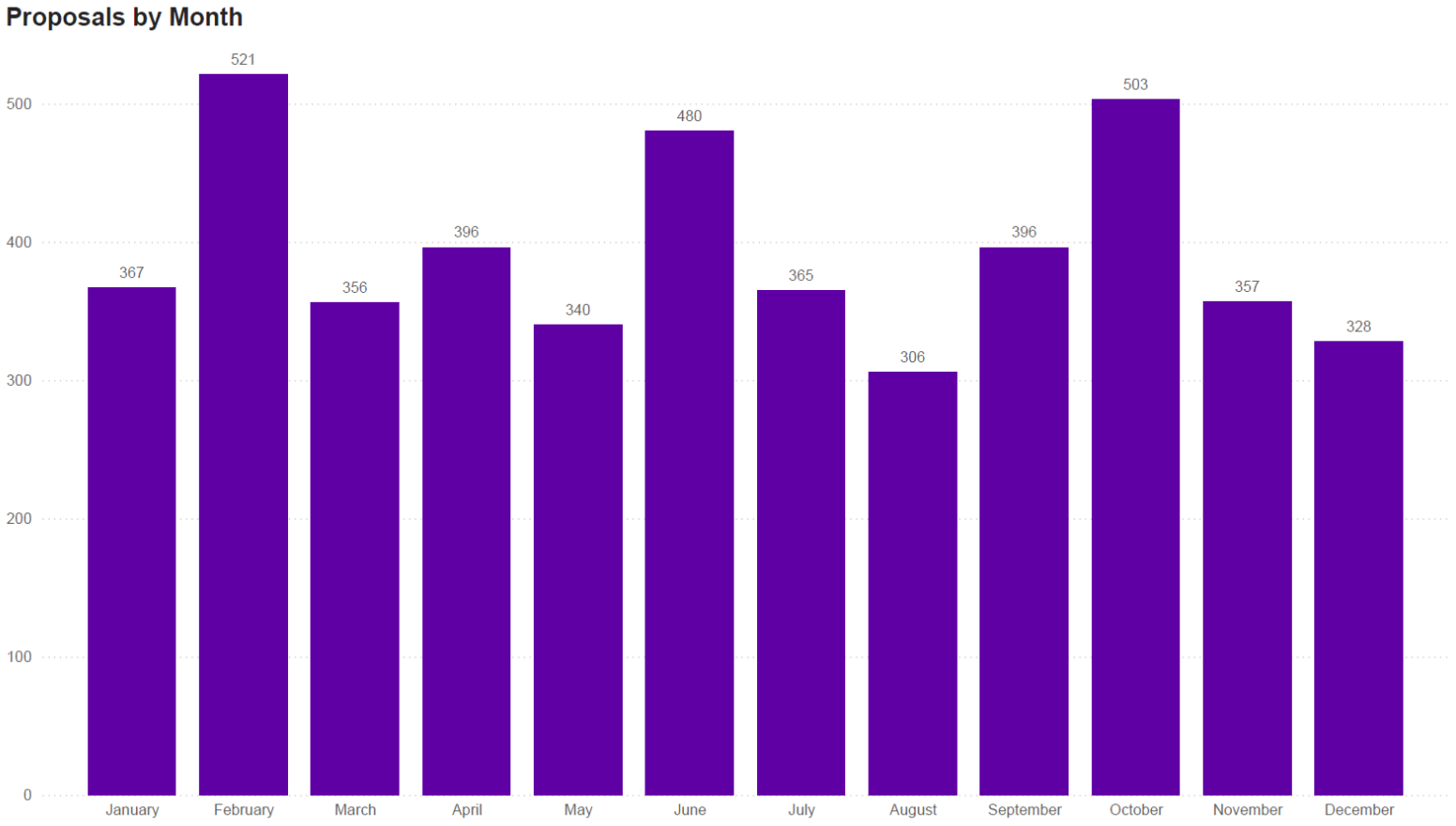
researchtraining@northwestern.edu

PROPOSAL UPDATES

Carrie Holbo, Assistant Director Pre-Award

THANK YOU!



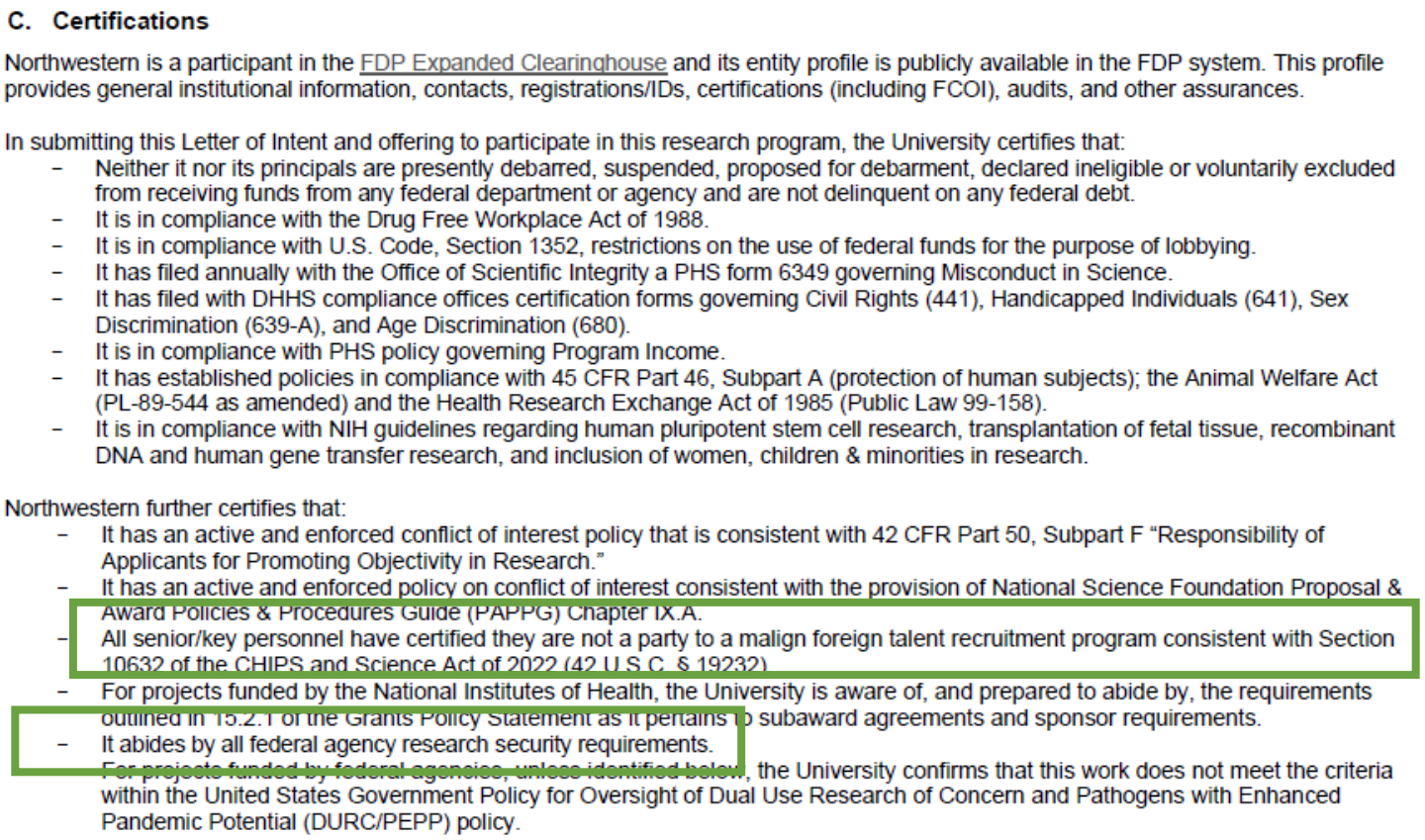
- Northwestern submitted more than ***4,700 proposals*** in FY2025.
- Each proposal team member reviewed and submitted an average of ***500 proposals each***.
- The busiest months are ***October, February and June.***

LOI Templates / Institutional Certifications

Use Northwestern's template whenever possible to streamline review and signature.

Our form aligns with the FDP format and includes all currently required certifications, including research security training.

Alert SR to any concerns or push back from other FDP entities.



C. Certifications

Northwestern is a participant in the FDP Expanded Clearinghouse and its entity profile is publicly available in the FDP system. This profile provides general institutional information, contacts, registrations/IDs, certifications (including FCOI), audits, and other assurances.

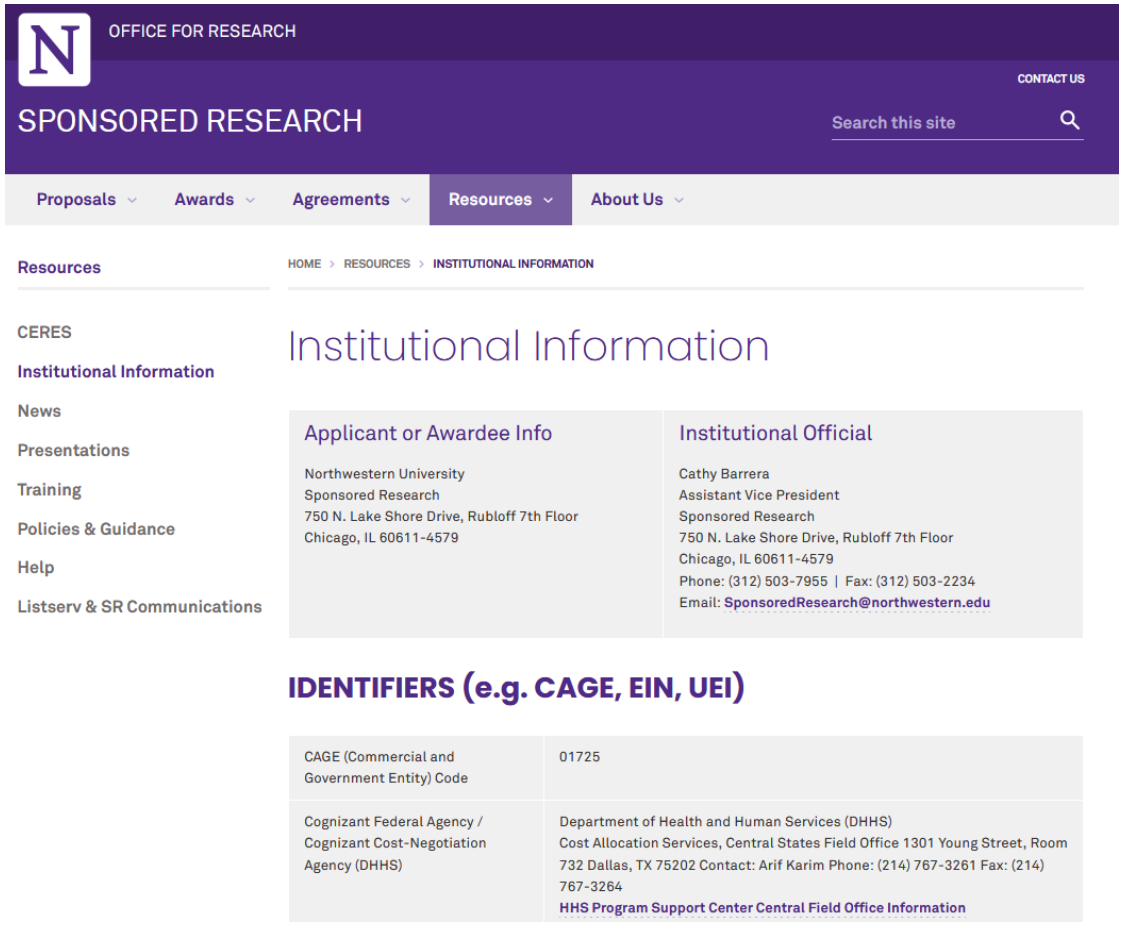
In submitting this Letter of Intent and offering to participate in this research program, the University certifies that:

- Neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from receiving funds from any federal department or agency and are not delinquent on any federal debt.
- It is in compliance with the Drug Free Workplace Act of 1988.
- It is in compliance with U.S. Code, Section 1352, restrictions on the use of federal funds for the purpose of lobbying.
- It has filed annually with the Office of Scientific Integrity a PHS form 6349 governing Misconduct in Science.
- It has filed with DHHS compliance offices certification forms governing Civil Rights (441), Handicapped Individuals (641), Sex Discrimination (639-A), and Age Discrimination (680).
- It is in compliance with PHS policy governing Program Income.
- It has established policies in compliance with 45 CFR Part 46, Subpart A (protection of human subjects); the Animal Welfare Act (PL-89-544 as amended) and the Health Research Exchange Act of 1985 (Public Law 99-158).
- It is in compliance with NIH guidelines regarding human pluripotent stem cell research, transplantation of fetal tissue, recombinant DNA and human gene transfer research, and inclusion of women, children & minorities in research.

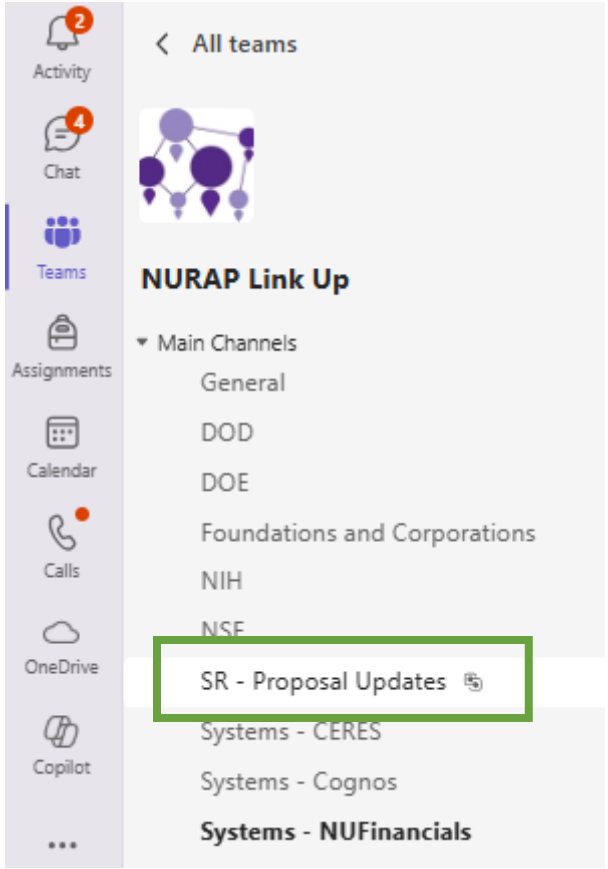
Northwestern further certifies that:

- It has an active and enforced conflict of interest policy that is consistent with 42 CFR Part 50, Subpart F "Responsibility of Applicants for Promoting Objectivity in Research."
- It has an active and enforced policy on conflict of interest consistent with the provision of National Science Foundation Proposal & Award Policies & Procedures Guide (PAPPG) Chapter IX.A.
- All senior/key personnel have certified they are not a party to a malign foreign talent recruitment program consistent with Section 10632 of the CHIPS and Science Act of 2022 (42 U.S.C. § 19232).
- For projects funded by the National Institutes of Health, the University is aware of, and prepared to abide by, the requirements outlined in 15.2.1 of the Grants Policy Statement as it pertains to subaward agreements and sponsor requirements.
- It abides by all federal agency research security requirements.
- For projects funded by federal agencies, unless identified below, the University confirms that this work does not meet the criteria within the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (DURC/PEPP) policy.

Resources



NEW!!
Teams Channel



In Progress / Planned

- **Other Support – Expanded Resources**
- **Proposal Development and Submission SPOT Course**
- **Proposal Review Criteria / Required Documents**
- **RPPR Resources / Unobligated Balance Calculator**
- **Presentations to new faculty**

Have suggestions or requests for proposal-related resources? E-mail carrie.holbo@northwestern.edu.

Proposals Submitted Without SR Review

Sponsored Research, acting on behalf of the Board of Trustees of Northwestern University, as delegated in the University Bylaws, is responsible for the review and approval of all proposals and proposal updates for research and other sponsored activities that are to be funded by external parties.

Only SR is authorized to submit proposals for the University.

PIs are not considered authorized organizational representatives. ***They should not submit proposals independently, particularly to Federal sponsors.***

Proposals Submitted Without SR Review

- A “proposal” is considered to be ***any document or package outlining a request for funds***, whether submitted by e-mail or via a sponsor portal, etc.
- Limited exceptions exist for ***preliminary proposals***, so long as no detailed budget information is being provided and no authorized signature is needed.
- Proposals should not be submitted without SR review just to ***circumvent the deadline policy***.
- Sponsored Research reserves the right to ***withdraw*** proposals submitted without review, or to ***require changes*** in order to bring them into compliance.

Terms & Conditions at Proposal Stage

Given the volume of proposals reviewed, and the limited amount of time before a deadline, it is not always possible to fully vet a sponsor's terms and conditions at proposal stage.

In instances where a sponsor indicates their terms are being accepted by virtue of the proposal submission, or that they are non-negotiable, SR will do a ***preliminary review*** only.

- ***Approval to submit a proposal does not guarantee acceptance of terms.***

- All ***award documents will be reviewed in full***, including escalation to other offices as needed (INVO, ECIC, NUCOI, IT Security, etc.) at award stage.

CERES Tips for Award Management

Maura Cleffi, Assistant Director Award Management
and Members of the Award Management Team

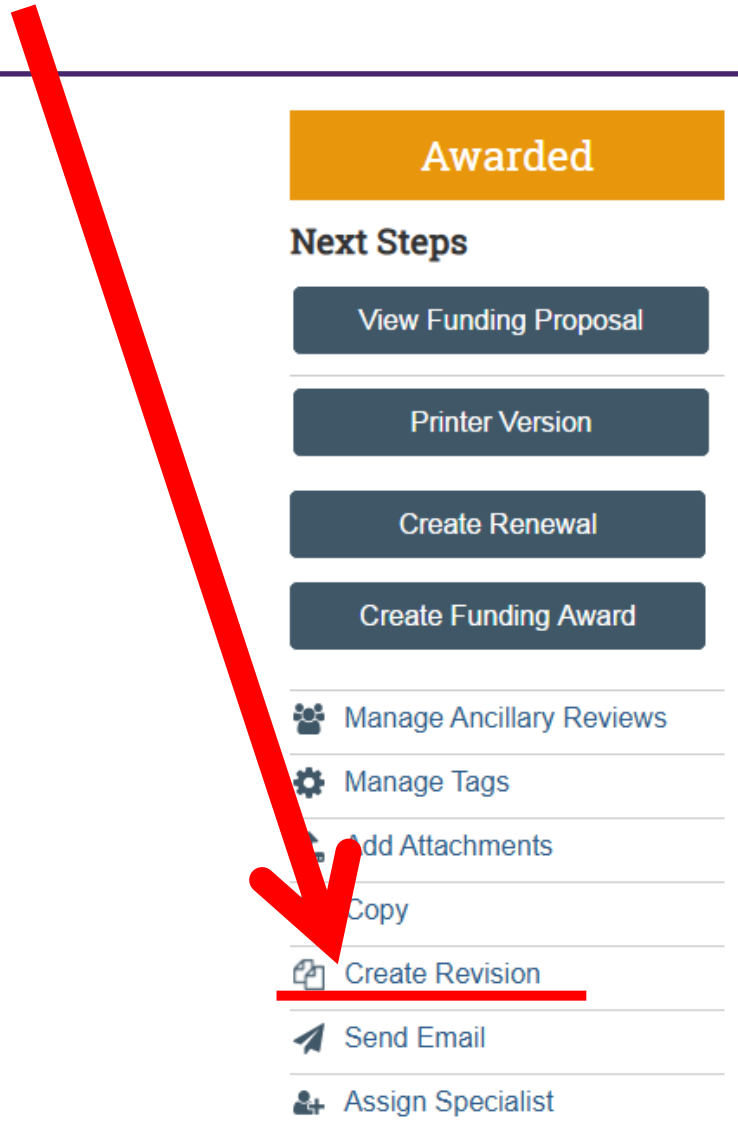
When/why to use:

- Revision proposal (Rev. record)
- Continuation proposal (Con. Record)
- Award modification request for rebudget (AMR)

*Please note clinical trials may have different processes in CERES

When do I need a Revision FP (funding proposal) record???

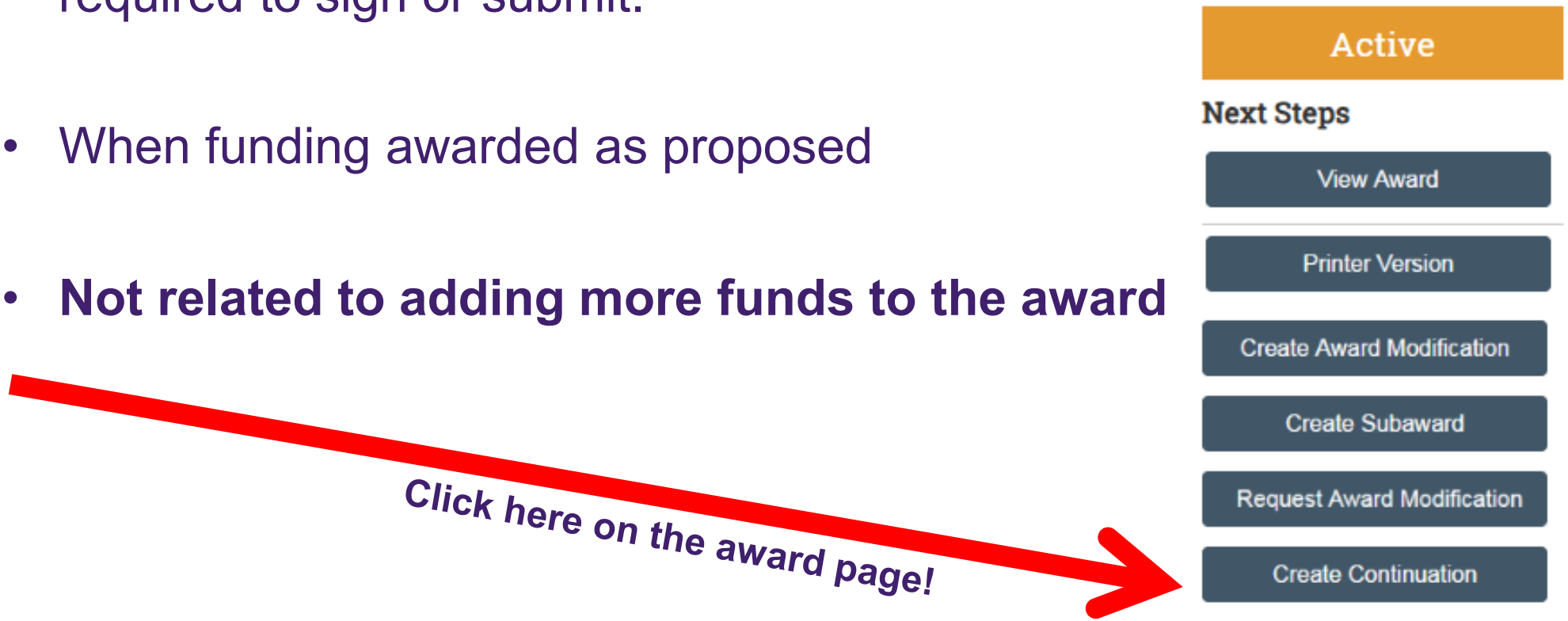
- For **new funds that were not originally planned for at proposal or acceptance stage**, a revision FP record needs to be created from the original funding proposal of an award.
- **Department REQUIRED to make one** upon receipt of an amendment used to add **additional funds** to the budget
- Best practice is to include the budget for the entire project period at original proposal stage



(Psst, is located on the FP page, NOT the AWD or SP Page!)

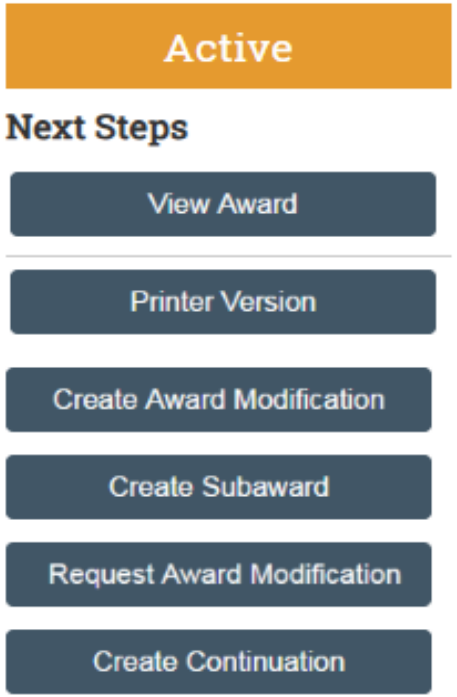
When do I need a Continuation record???

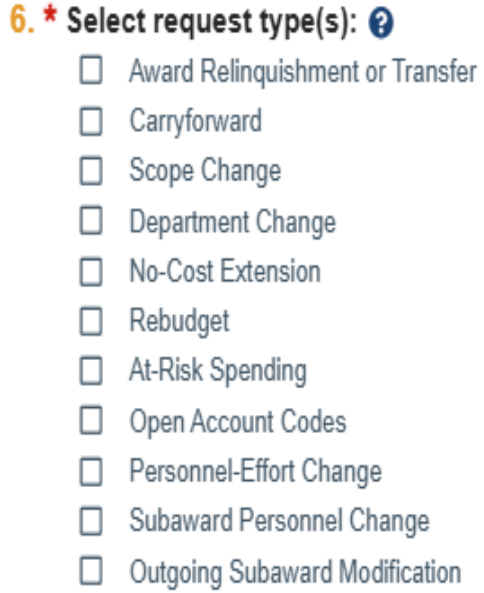
- Used for progress reports (including but not limited to RPPRs) when SR is required to sign or submit.
- When funding awarded as proposed
- **Not related to adding more funds to the award**



Rebudget AMR

- When moving funds from one account code to another or between separate chart strings
- Not when adding new funds to project
- When budget reduction/reallocation exceeds sponsor threshold
- Award modification is created from Award record in CERES





Best practice: include a spreadsheet outlining the changes

MTA and DUA SMARTFORM Guidance

Clay Arnett, Senior Director, Contracts & Negotiations
Adrienne Lundquist, Associate Director, Contracts & Negotiations

MTA Smart Form

Question 2 Material Transfer Information Page: Describe the Material Being Transferred

Please provide as much detail as possible when describing the material. Ideally give us more information than just "cells" or "stuff in a freezer."

❌ **Don’t say:**

"Blood"

"Cell lines"

"A freezer full of stuff"

✅ **Do say:**

Be specific. Like this:

“The HEK293T cell line expressing a recombinant GFP-tagged protein”

If you are transferring a freezer full of materials attach a spreadsheet of all the materials.

Question 3 Material Transfer Information Page:

Brief Description of the Research Involving the Material

This section helps us understand what you're doing and why. The more detail you provide, the faster we can move your agreement forward.

We're looking for:

- What you're doing
- Why you're doing it
- How the material helps you do it

🛑 **Avoid:**

"To study cancer."

✅ **Instead, say something like:**

"We will use the [specific cell line] to evaluate the efficacy of a new compound targeting the [specific pathway] involved in triple-negative breast cancer. This will include in vitro assays, protein quantification via western blot, and live cell imaging."

Examples: The Good, the Bad, and the Vague

Biological Materials (cell lines, plasmids, antibodies)

❌ *Bad*: “We’ll use the cell line to study disease.”

🤷 *Vague*: “We’ll use the HeLa cell line to understand cellular responses.”

(Which responses? What kind of analysis?)

✅ *Good*: “We’ll use the HeLa-GFP cell line to examine apoptosis pathways in response to Compound X via live-cell imaging and protein analysis.”

Examples: The Good, the Bad, and the Vague

Chemical Compounds

❌ *Bad*: “We will test the chemical.”

🤷 *Vague*: “The compound will be used in antimicrobial screening.”

(Screening how? Against what? In what system?)

✅ *Good*: “Compound 23B will be tested for antimicrobial properties against drug-resistant *E. coli* using standard MIC assays.”

Examples: The Good, the Bad, and the Vague

Animals (e.g., transgenic mice)

❌ *Bad*: “We’re using mice for research.”

🤷 *Vague*: “We’ll use genetically modified mice to investigate neurological outcomes.”

(What outcomes? Which gene? What kind of study?)

✅ *Good*: “The [transgenic mouse strain] will be used to generate a knockout model to study [specific gene] in neurodevelopment. Work will be conducted under IACUC protocol #1234.”

Examples: The Good, the Bad, and the Vague

Human Tissues or Specimens

❌ *Bad*: “We need human tissue for our project.”

🤷 *Vague*: “We’ll analyze donated human tissues for protein expression.”

(Which tissues? Which protein? Is this IRB-approved?)

✅ *Good*: “Frozen liver tissue from consented donors will be analyzed via immunohistochemistry to validate expression of [target protein]. Covered under IRB #4567.”

Final Tips: Material Descriptions

Be clear, concise, and complete.

Match your description with what's in your IRB, IACUC, or grant.

❌ *Bad*: "To study cancer."

🤷 *Vague*: "To test a new compound on cancer cells."

✅ *Good*: "To test Compound X on triple-negative breast cancer cells using XYZ assays."

Question 10 Material Transfer Information Page

Was any part of the material created by or received from a third party not named in this agreement?

This helps ensure that all necessary permissions are in place. If someone else created or contributed any part of the material — whether it's a cell line, plasmid, compound, or anything else — we need to know.

Question 10 Continued

✅ **If YES, include:**

Who created or provided the material (e.g., another PI, an external collaborator, a vendor, or repository)

Documentation, such as:

- The original MTA or license agreement
- Terms of use
- Northwestern record ID(s) for relevant MTAs

📌 **Example:**

“Yes — the parent cell line was originally obtained from ATCC under their standard MTA. Our lab subsequently introduced a GFP-tagged construct. The incoming material is covered under Northwestern MTA Record ID #MTA-2021-0045.”

Question 10 Continued

❌ **Avoid:**

“Yes.” (…and nothing else.)

“We got it from another lab.” (Please be more specific.)

🛑 **Reminder:** If any portion of the material came from outside your lab, we need documentation to confirm you're authorized to use or share it.

Question 11 Material Transfer Information Page

Will the material be shared with any third party not named in this agreement?

We need to know if the material will be passed on to any third party — either internal (e.g., a core facility) or external (e.g., a collaborator at another institution).

Question 11 Continued

✅ **If YES, provide:**

Who will receive the material

Why you're sharing it (e.g., collaboration, subcontract, analysis)

Documentation that allows for this distribution (MTA, agreement, or Record ID)

📌 **Example:**

"Yes — a portion of the purified antibody will be sent to BioCore Analytics, an external vendor performing mass spectrometry analysis under our sponsored research agreement. Transfer is authorized under MTA Record ID #MTA-2023-0091."

Question 11 Continued

❌ **Don’t just say:**

“Possibly.”

“Maybe with a collaborator.”

🛑 **Reminder:** Sharing materials without the proper agreements can violate transfer terms, compromise IP rights, or create compliance issues. Be proactive — tell us who, why, and under what authority.

DUA Smart Form

Question 1: Data Use Information Page

What is the direction of transfer?

Let us know whether you're receiving data, sending data, or both. Be clear and specific, especially if the data will be moving between multiple institutions or collaborators.

✅ **Do say:**

"We will be receiving a limited data set from [Institution] for use in a machine learning project."

"We are sending de-identified clinical trial data to a collaborator at [University X] for secondary analysis."

❌ **Don't say:**

"Transfer."

"Data will be exchanged."

Why it matters: Knowing the direction helps determine which party is responsible for protections, compliance, and reporting.

Question 2: Data Use Information Page

Describe the Data Set

Please describe what data is being transferred. The more detailed and specific, the smoother the review process.

❌ *Bad*:

- "Health data"
- "De-identified data"
- "Survey results"

🤷 *Vague*: "We're sharing de-identified patient data."
(What kind? From where? How many participants? What time frame?)

✅ *Good*:

"The data set includes de-identified EHR data from 1,200 patients treated for Type 2 diabetes at Northwestern between 2015–2020, including demographics, lab values (HbA1c, LDL), medication history, and encounter notes."

"Survey responses from 350 adolescents collected as part of the 'Teen Mental Health and Social Media Use' study. Variables include age, gender, screen time, PHQ-9 depression scores, and qualitative responses to open-ended questions."

Question 7: Data Use Information Page

Was any of the data generated by a third party not named in this agreement?

This helps ensure that all necessary permissions are in place. If someone else generated part of the data, we need to know.

✅ **If YES, include:**

- Who created the data (e.g., another Northwestern PI, another institution, a data repository)
- Documentation (original DUA, permissions, terms of use, or reference ID)

Example: “Yes — the dataset includes the All of Us Research Program data accessed under project ID #AU1234. We are using variables permitted for secondary analysis under their Data Use Agreement.”

❌ **Avoid:**

- “Yes.” (…and nothing else.)
- “We got it from a colleague.” (Please be more specific.)

Question 8: Data Use Information Page

Will any of the data be shared with third parties who are not a party to this agreement?

We need to know if the data will be passed on to anyone else—internal or external.

✅ **If YES, provide:**

- Who will receive it
- Why you're sharing it
- Documentation that allows you to do so (DUA ID, IRB protocol, etc.)

Example: "Yes — de-identified transcript data will be shared with Dr. Jane Smith at the University of Example for NLP model training under a subcontract governed by DUA #5678."

❌ **Don't just say:**

- "Possibly."
- "Maybe with a collaborator."

🛑 **Reminder:** Sharing data without appropriate agreements can violate IRB protocols, data use terms, or federal regulations. When in doubt, spell it out.

Final Tips: Data Descriptions

- **Be specific**. “Survey data” isn’t enough. Tell us what’s in it, where it’s from, and how it’s structured.
- **Align your descriptions** with what’s in your IRB protocol, grant, or repository access agreement.
- **Attach supporting documents** where relevant (data dictionaries, DUA copies, IRB letters, etc.).

❌ *Bad*: “De-identified data.”

🤷 *Vague*: “De-identified clinical data from cancer patients.”

✅ *Good*: “De-identified EHR data from 500 breast cancer patients at NMH, including demographics, pathology reports, and treatment timelines, collected from 2010–2020”

Question 18: Data Use Information Page

Is any of the data GDPR or PIPL controlled?

This question helps us understand whether international data privacy laws apply to your project. If you're receiving personal or identifiable data from the European Union or China, these laws may apply.

What’s GDPR and PIPL?

GDPR (General Data Protection Regulation) is the EU’s data privacy law. It applies to personal data of individuals located in the EU, even if you're based elsewhere.

PIPL (Personal Information Protection Law) is China’s version of GDPR and applies to personal information of individuals in China or from Chinese citizens residing outside of China.

These laws typically cover:

Names, contact info, ID numbers

IP addresses, genetic/biometric data

Anything that can directly or indirectly identify a person

Thank you for joining us!