CERES and Clinical Research

April 21, 2023

CERES

What is CERES?

The Centralized Electronic Research System, a more streamlined and modernized system to support the growing research enterprise

Overview of

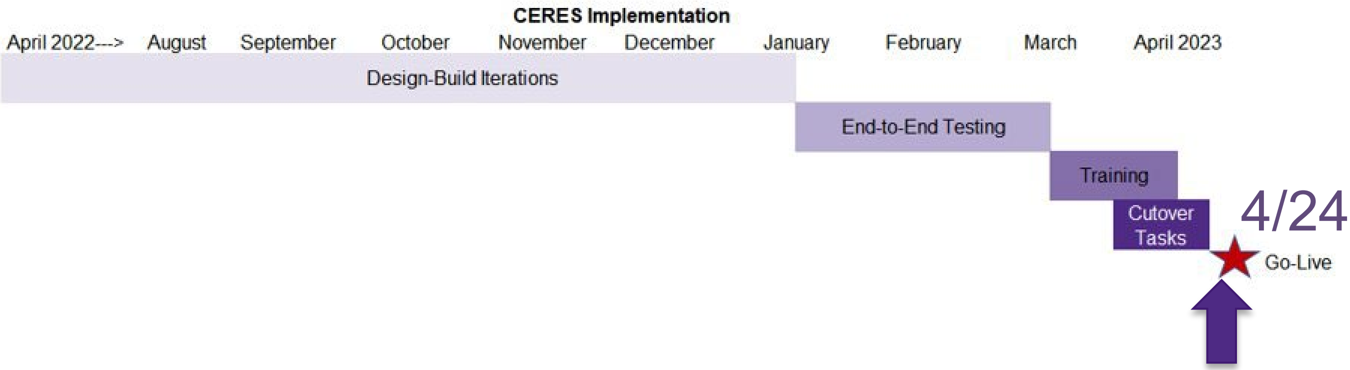
Sponsored Research Administration Transformation Program (SRATP)

Northwestern is enhancing the technology resources that support its research enterprise. The program's goals are twofold: to implement a new enterprise sponsored research administration management system and to deliver a revamped analytics environment required to support business functions. These aims include **replacing InfoEd** with Huron Grants and Agreements, a change intended to strengthen processes, maximize efficiency, and support continued growth of Northwestern research. This effort is a partnership between Northwestern Sponsored Research and Northwestern Information Technology.

https://sponsoredresearch.northwestern.edu/sra-transformation/index.html


SRATP
CERES
Implementation
-0:37

Program Timeline



CERES

Benefits of CERES

- ✓ One-stop shop for the overall sponsored project lifecycle
- ✓ More complete information enables smoother review processes
- ✓ PI certification can occur while funding proposal is in draft or department review
- ✓ Workflow progress will be easily visible, bringing transparency to processes

CERES

Basic Concepts & Navigation: Structure & Status

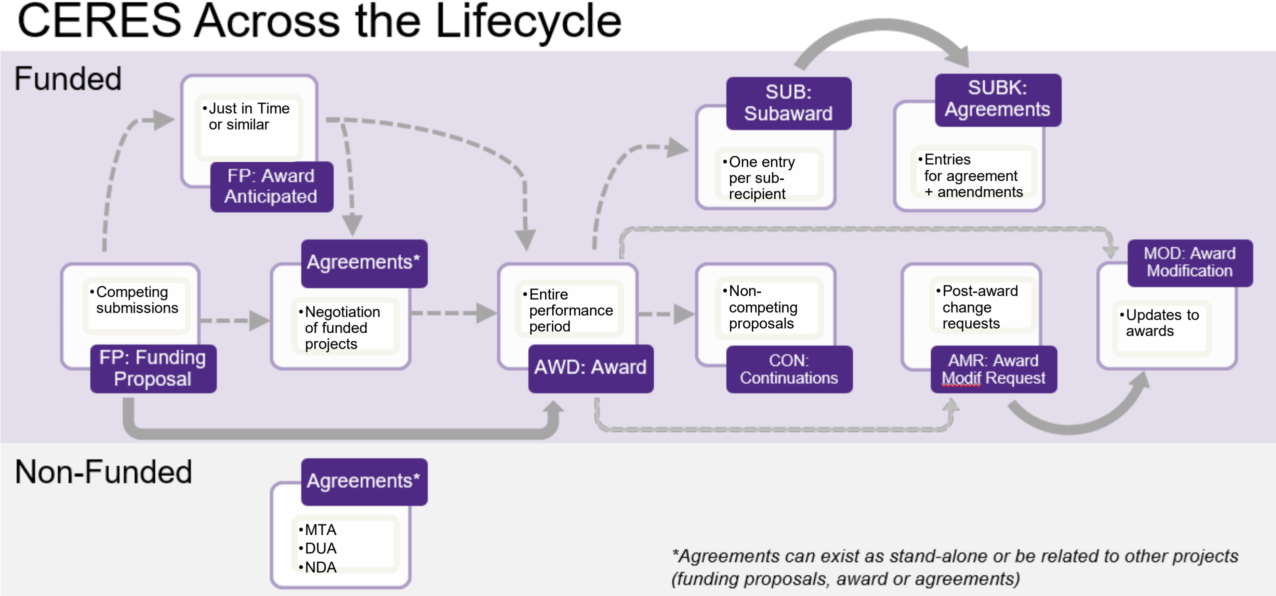
InfoED

CERES

SINGLE ID	MULTIPLE IDs
Currently, Proposals and Awards are tracked as one item with one identified, known as the SP Number.	Proposals, awards, and agreements are distinct elements within CERES, each with a separate unique identifier, tied together and easy to navigate between on related records.

STATUS DIFFICULT TO FIND	VISUAL WORKFLOW
The process of viewing workflow status requires users to navigate to multiple screens depending on context.	Insight into workflow progress will be easily visible in CERES, bringing transparency to processes. The drill downs work similarly from screen to screen.

CERES Across the Lifecycle



Agreements can exist as stand-alone or be related to other projects (funding proposals, award or agreements)

Grants Module		Agreements Module	
Pre-Award	**Post-Award**	**Funded**	**Non-Funded**
•Funding Proposals •SF424 •Budget	•Awards •Award Modification Request •Award Modification •Subaward	•Clinical Trial •Sponsored Research Agreement •Subcontract	•MTA •DUA •NDA •LOI •MOU •Master •Collaboration

Agreements with Funding

Bilateral Awards

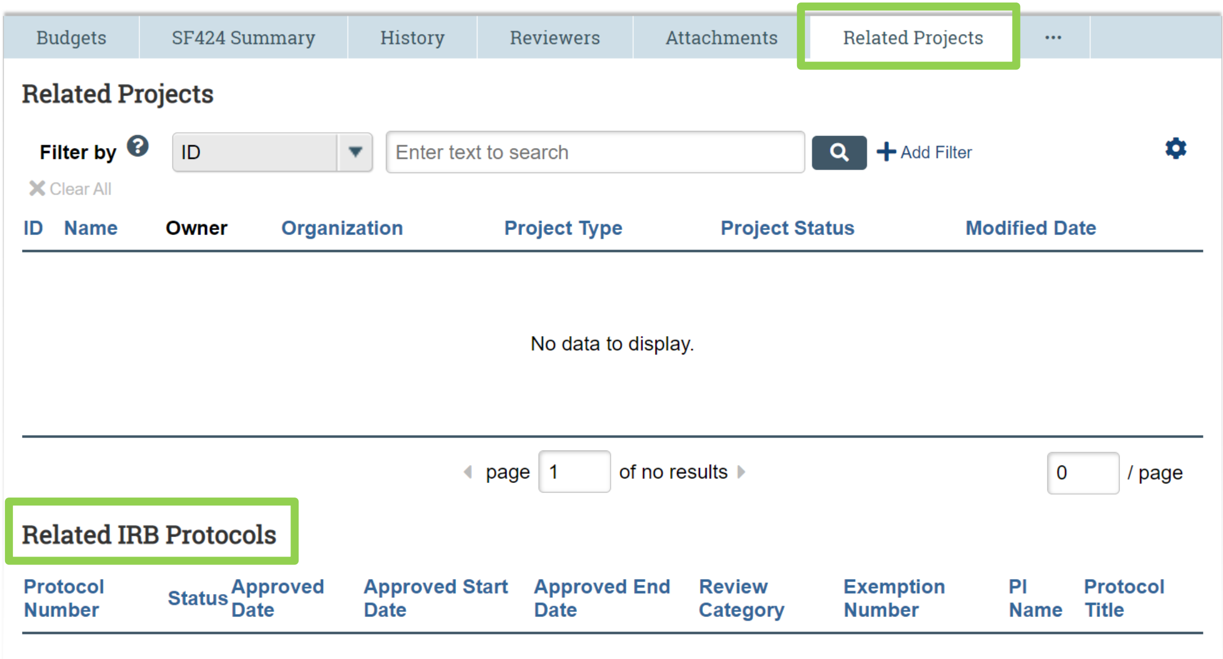
- Sponsored Research will create an Agreement record once a notice of award arrives if needed

Industry Clinical Trials

- Departments will create Funding Proposal record and budget, which will route for approval
- Once the Funding Proposal is approved, Departments will create related Agreement record, with questions specific to the clinical trial
- Negotiations begin once Agreement record is routed

Once fully executed, Sponsored Research will create an Award record and complete the setup.

Integrated with eIRB+



Create an Industry Clinical Trial Funding Proposal + Agreement

Create an Industry Clinical Trial Agreement

- The industry clinical trial workflow spans both the Grants and Agreements modules in CERES
- Two main components:
  1. **Funding Proposal** in CERES Grants, which the RA creates including budget and effort, then submits to route for Department Review and on to Specialist Review.
  2. **Clinical Trial Agreement** in CERES Agreements
     - Before the RA submits the FP for routing, create the Clinical Trial Agreement. *Note: The Negotiation Information page is for SR to complete*
     - RA submits the CTA after all department approvals are in place for the funding proposal.

Funding Proposal Workflow

1. Funding Proposal in CERES Grants, which the RA creates, including budget, then submits to route for Department Review and on to Specialist Review.

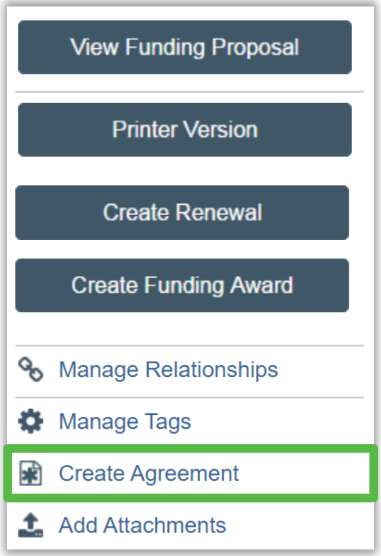
Agreement Workflow

2. **Clinical Trial Agreement** in CERES Agreements

- Before the RA submits the FP for routing, create the Clinical Trial Agreement. *Note: The Negotiation Information page is for SR to complete*
- RA submits the CTA after all department approvals are in place for the funding proposal.

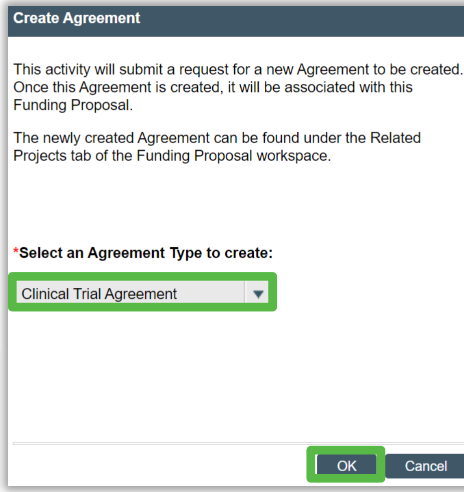
Create an Industry Clinical Trial Agreement

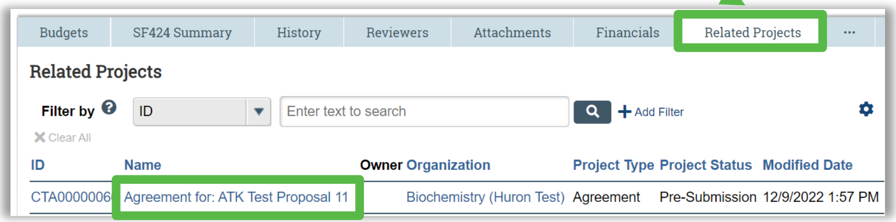
1. From the related Grants funding proposal workspace, click **Create Agreement**.



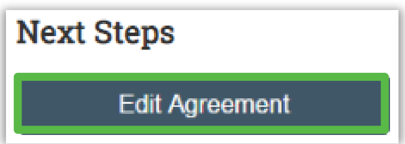
Create an Industry Clinical Trial Agreement

2. On the Create Agreement activity form, select **Clinical Trial Agreement** then click **OK**.
3. From the funding proposal workspace, click the **Related Projects** tab and click the agreement name to go to the workspace.



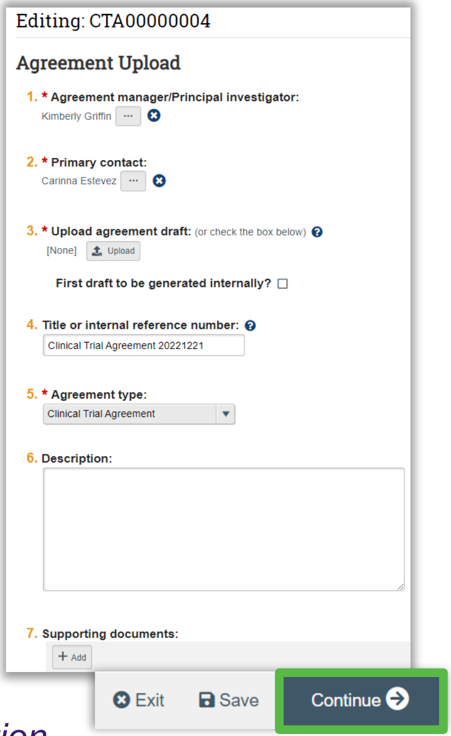


4. From the agreement workspace, click **Edit Agreement** to open the SmartForm.



Create an Industry Clinical Trial Agreement

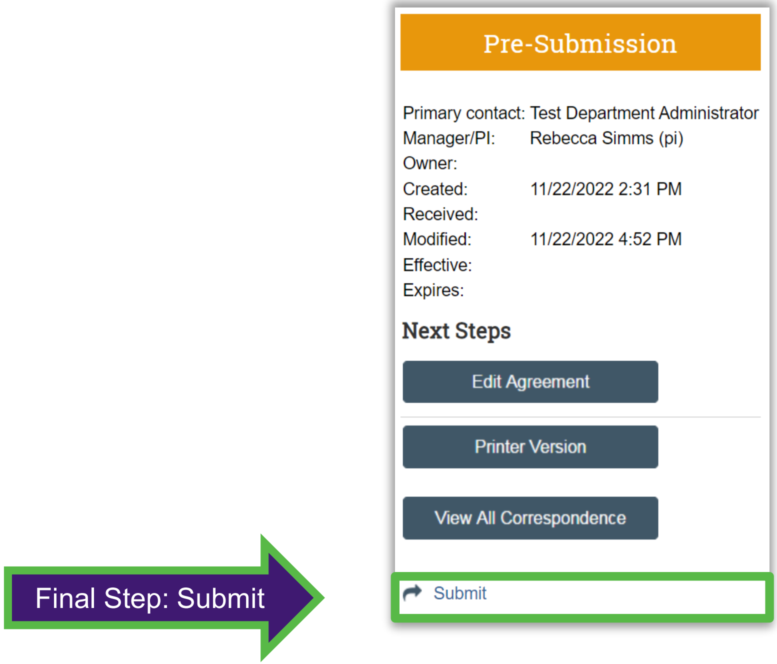
5. Complete all required fields on the *Agreement Upload* page.
   - Question 3 – if the agreement has already been drafted, attach it by clicking **Upload**.
     - If SR will create the first draft, check the **First draft to be generated internally?** box instead.
6. Click **Continue** to move through the pages and enter all required information.
   - On the *General Information* page under question 6, list yourself as an **Agreement Collaborator**.
7. When you reach the final page, click **Finish**.



Note: Do *not* complete the *Negotiation Information* page as this section is only to be filled in by SR.

Create an Industry Clinical Trial Agreement

8. From the agreement workspace, click **Submit**. Click **OK** to accept the statement and submit the clinical trial agreement.



Note: Failure to fill out the agreement correctly and completely will cause delays and it will be routed back to the department.

Create a Non-Funded Agreement

Create a Non-Funded Agreement

Non-funded Agreement Types	ID Prefix
Material Transfer Agreements	MTA
Data Use Agreements	DUA
Non-Disclosure Agreements	NDA
Collaboration Agreements	CA
Letter of Indemnification*	LOI*
Memorandum of Understanding	MOU

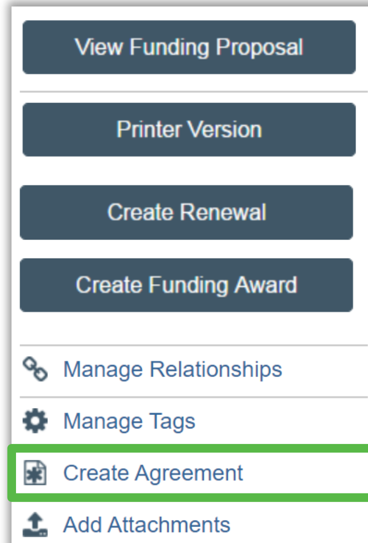
Note: Agreements related to a Grants proposal or award should be created using the **Create Agreement** activity from the Grants workspace to link the records.

*LOIs are used when a funded industry clinical trial is coming through a Clinical Research Organization (CRO)

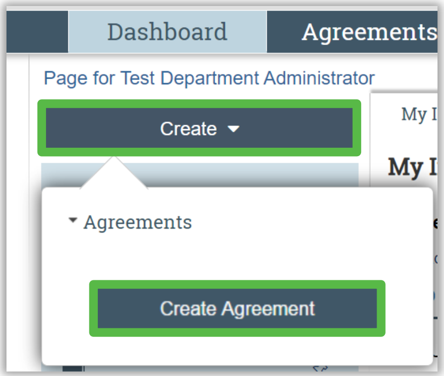
Create a Non-Funded Agreement

1. From the related (and editable) Grants funding proposal workspace, click **Create Agreement**.
   - If this will be a standalone agreement (unrelated to an existing Grants proposal) then initiate the agreement from the CERES Dashboard by clicking **Create** and then select **Create Agreement**.

Create/link to FP



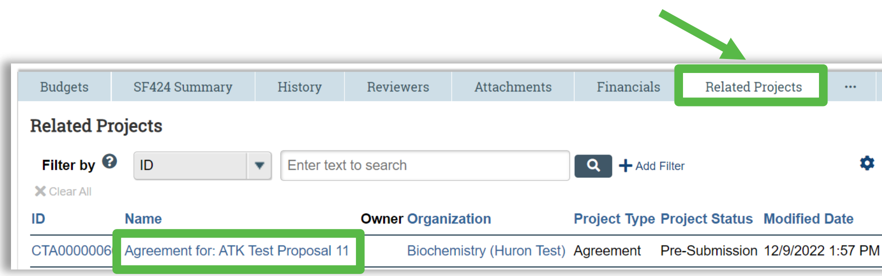
or

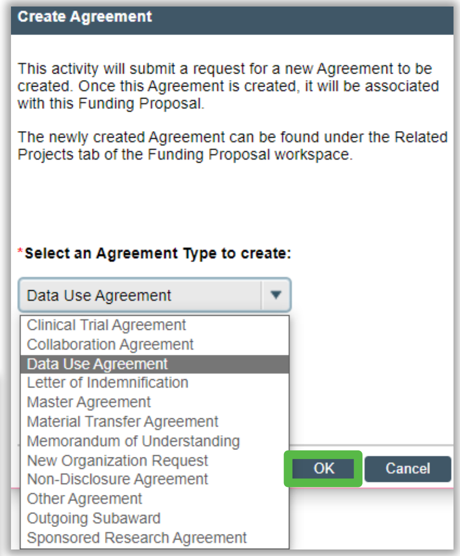


Create standalone

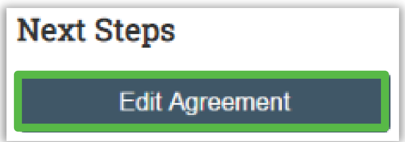
Create a Non-Funded Agreement

2. On the Create Agreement activity form, select the appropriate agreement type then click **OK**.
3. From the funding proposal workspace, click the **Related Projects** tab and click the agreement name to go to the workspace.



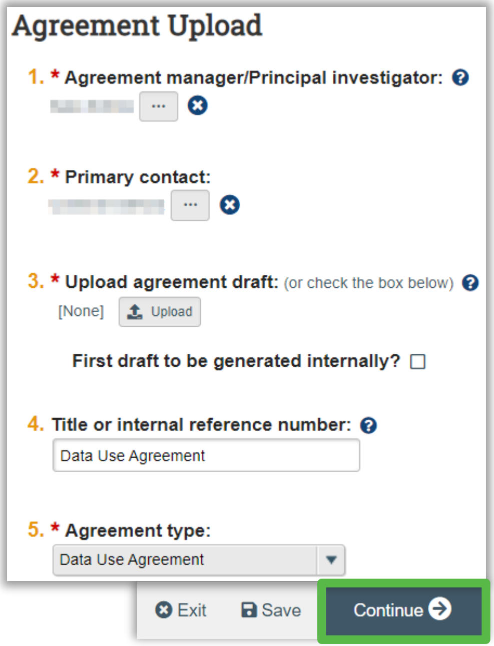


4. From the agreement workspace, click **Edit Agreement** to open the SmartForm.



Create a Non-Funded Agreement

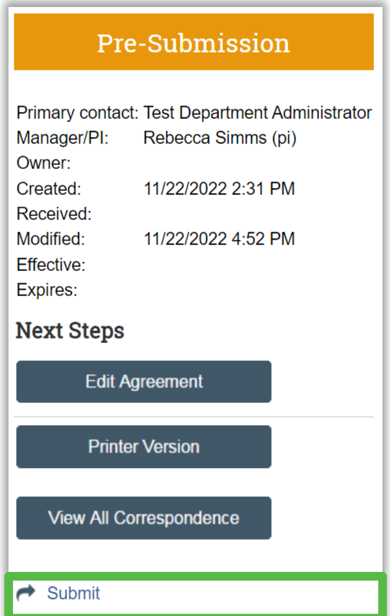
5. Complete all required fields on the *Agreement Upload* page.
    - Question 3 – if the agreement has already been drafted, attach it by clicking **Upload**.
        - If SR will create the first draft, check the **First draft to be generated internally?** box instead.
    - Question 5 – select the appropriate non-funded agreement type
        - **Note:** If you created the agreement from the related Grants record, this question will be pre-populated based on your prior selection.
6. Click **Continue** to move through the pages and enter all required information.
    - On the *General Information* page under question 6, list yourself as an **Agreement Collaborator**.



Note: Do *not* complete the *Negotiation Information* page as this section is only to be filled in by SR.

Create a Non-Funded Agreement

7. When you reach the final page, click **Finish.** From the agreement workspace, click **Submit.** Click **OK** to accept the statement and submit the non-funded agreement.



Final Step: Submit

Note: Failure to fill out the agreement correctly and completely will cause delays and it will be routed back to the department.

Resources to Learn More

CERES 101 is here!

The Northwestern research community can learn more about CERES via the CERES 101 Computer-Based Learning course. CERES 101 includes an overview of what the system is, how it is used, and how CERES benefits all users. This 65-minute, on-demand course takes learners on a tour the system and teaches you where and how to find records in the system and related information. CERES 101 is available via MyHR Learn. REGISTER NOW

Concepts Overview

Before viewing CERES 101, step through the following overviews of the key CERES concepts and workspaces: the funding proposal, agreements, awards, and subawards. (CERES Training page)

Resources to Learn More

How-To-Videos

- Create a Funding Proposal
- Complete a Budget

CERES Job Aids: Locate CERES-related job aids in the Northwestern Knowledge Base, including Create and Submit a Non-Funded Agreement and Create and Submit a CTA

Questions?

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