

# CLEAR Meeting

## June 14, 2022

Hosted by Sponsored Research

# Today's Agenda

- Announcements
- CERES
- Budget Account Codes & Multi-Year Award Setup
- Single IRB Consultation
- INVO

# Sponsored Research Staffing

- **Award Management**
  - Awards Management Associate  
(Multiple openings)
  
- **Subcontracts**
  - Assistant Sponsored Research Officer  
(Multiple openings)

# Upcoming NIH Due Dates

Due Date	Description
July 5	<ul style="list-style-type: none"><li>• <b>R01 Research Grants</b></li><li>• <b>U01 Research Grants - Cooperative Agreements</b> <i>renewal, resubmission, revision</i></li></ul>
July 12	<ul style="list-style-type: none"><li>• <b>K Series Research Career Development</b> <i>renewal, resubmission, revision</i></li></ul>
July 16 (Saturday)	<ul style="list-style-type: none"><li>• <b>Other Research Grants and Cooperative Agreements</b> (R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3) <i>renewal, resubmission, revision</i></li></ul>
August 8	<ul style="list-style-type: none"><li>• <b>F Series Fellowships <i>Individual</i> NRSA</b> (including F31 Diversity) <i>new, renewal, resubmission</i></li></ul>
August 12	<ul style="list-style-type: none"><li>• <b>R13, U13 Conference Grants &amp; Cooperative Agreements</b> <i>All - new, renewal, resubmission, revision</i></li></ul>

# NIH July 5<sup>th</sup> Deadline: Submit Early

- Submission date falls the day after a Federal holiday
- Northwestern University, including Sponsored Research, will be **closed Monday, July 4**
- Recommended submission timeline:
  - Admin components by **Tuesday, June 28**
  - Full proposal (administrative and technical components) by **Thursday, June 30**

CERES

## Why Change?



### Northwestern's Research Portfolio Continues to Grow

Northwestern has increased research revenue 34% from FY17-21 and is now approaching \$1B. A growth trajectory like that of Northwestern's requires best-in-class research support and infrastructure to scale to meet the continued growth.



### Scaling Our Support

To better enable the research community in the context of this growth, we have identified needed changes to the technology.



### Our Current System No Longer Met Our Needs

The structure of our current system did not continue to match our growth. Since implementing a new system was needed, we looked for a system that was the best fit for Northwestern's research aspirations.



6/7 Announcement -  
[Recording Available  
Online](#)



# Budget Account Code & Multi-year Award Set-up

# Budget Account Code Expansion

- At award setup, SR will interface a set of standard budget accounts in NU Financials.
- This will significantly reduce the number of Change Requests required to open new budget account categories on qualifying awards based on sponsor's terms and conditions.
- Compliance with standard cost accounting principles - allowability, allocability, reasonability, and consistent treatment of costs – still applies when incurring award expenditures.
- More information coming via listserv.

# Budget Account Codes that would be opened automatically include...



# Multi-Year Award Set-up

- SR will implement a standard operating procedure for recognizing all years of an award in cases where
  - The sponsor provides all the funding up-front **and**
  - Does not require authorization to move into the next budget period.
- As an example, a 3-year award would have all three years with system statuses of Active, as opposed to only the first year “Active” and the remaining two as “Anticipated.”
- This will reduce the number of annual set-ups, at-risk account requests that create administrative burden and delays for projects, departments and SR.
- More information coming via listserv.

# Reliance Considerations

Monica Kane, IRB Reliance Analyst  
Institutional Review Board Office | Northwestern University

# Table of Contents

- Key Concepts
- When is Reliance Required?
- How do I Prepare for Reliance?
- Reliance Tips
- Resources

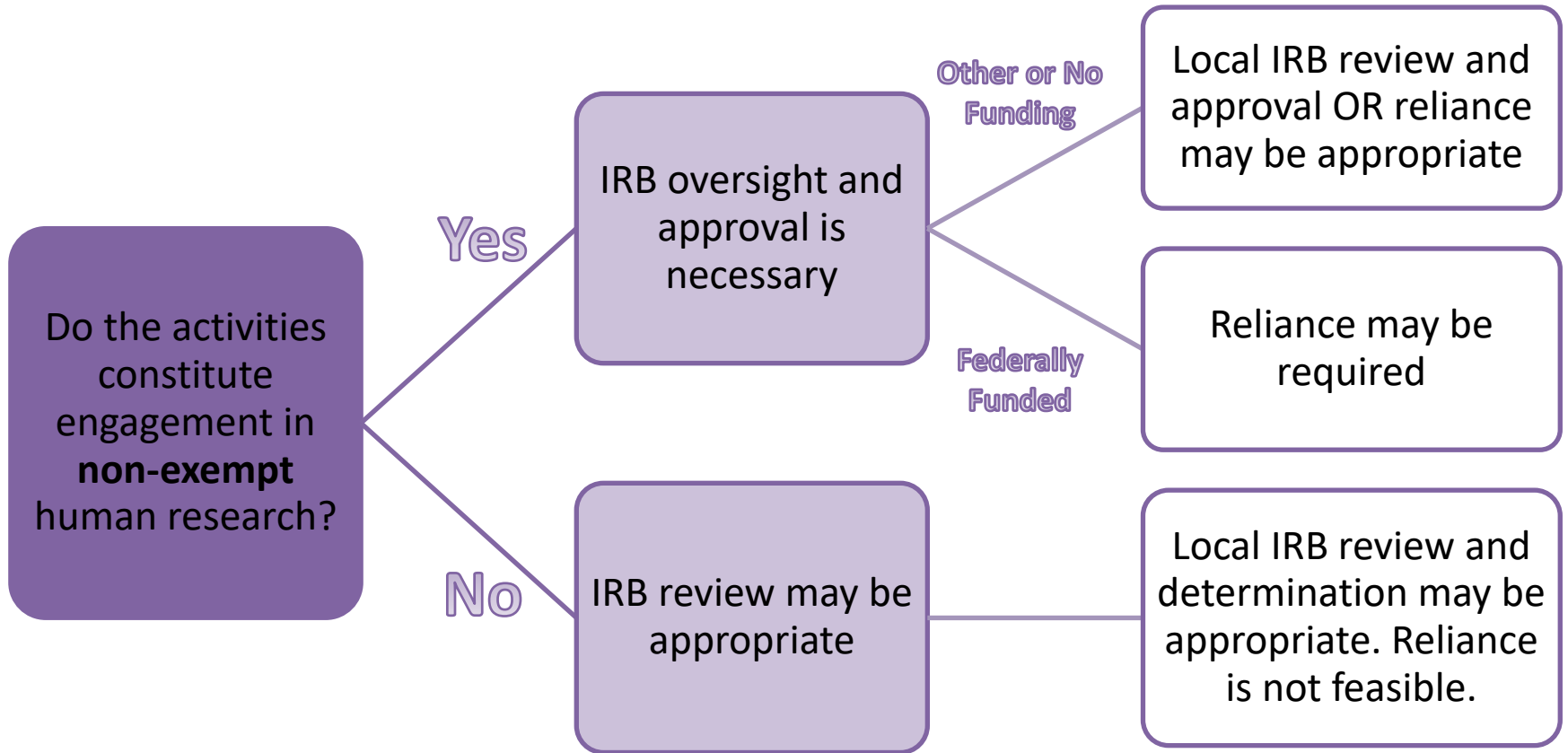
# Key Concepts

# Research at Multiple Sites

- Local IRB Review
  - All sites obtain their own separate IRB review and approval of the activities happening at their site
- Reliance
  - An IRB serves as the IRB of Record / Reviewing IRB / Single IRB for their site and external site(s)
  - An IRB/site cedes review / relies on an external IRB
  - These roles are established via reliance agreements



# Engagement vs Reliance



# When is Reliance Required?

# When is Reliance Required?

## Required

When reliance, or a Single IRB, is required by the federal regulations

When reliance is a prerequisite for participation

## Optional

When reliance is preferred by the study team or IRB/site

When it is appropriate and feasible for an IRB to serve

# When is a Single IRB Required?

When the research involves :

- federal funding,
- human participants,
- non-exempt activities,
- & multiple domestic research locations.



Why? Due to two complementary federal policies:

- Cooperative Research Requirement
- NIH Single IRB Mandate

# Single IRB Scenarios

## Scenario 1

- Northwestern investigators are awarded a grant and they will conduct de-identified data analysis. A subcontract site (University of Chicago) will conduct informed consent, interviews, and data collection.

If a subcontract site is engaged in human research, then the prime awardee is automatically engaged – regardless of the prime's local activities. All sites engaged in human research must have a Single IRB.

# Single IRB Scenarios

## Scenario 2

- Northwestern investigators are collaborating with a tech company that is the prime recipient of a Small Business grant from NIH (Northwestern is a subcontract). Engaged human research activities will only occur at Northwestern and only be conducted by Northwestern staff.

If a subcontract site is engaged in human research, then the prime awardee is thus engaged, and all sites must have a Single IRB. It is not standard practice for Northwestern to serve as the IRB for corporate entities. The Northwestern IRB Office will assist in identifying an appropriate IRB.

# Single IRB Scenarios

## Scenario 3

- Northwestern investigators are trying to secure IRB approval/determinations at JIT. The Northwestern study team submits its own scope of work and obtains a Not Human Research determination. The subcontract site believed their activities constituted **exempt** Human Research but their IRB notified them that the activities will be **expedited**.

If a subcontract site is engaged in human research, then the prime awardee is automatically engaged. Create a sIRB plan, notify the Northwestern IRB Office, Sponsored Research Office, and the funder ASAP.

# How do I Prepare for Reliance?



# Single IRB Consultation

- Single IRB Consultation is required for all federal funding proposals (both Prime and Sub-Award) involving two or more domestic sites.
  - Required for requests to serve and cede.
- Submit our consultation intake form before your grant application due date.
- We will issue a Letter of Support to serve (*subject to fees*), or to cede, as appropriate.

# Serving as the IRB of Record

- If your study involves federal funding, a Single IRB Letter of Support is required to proceed with IRB review and approval.
  - If you don't have a Single IRB Letter of Support, please submit a Single IRB Consultation intake form as soon as possible.
- The Single IRB Letter of Support should be uploaded within the eIRB+ application under “Supporting Documents”

# Preparing for Reliance

- Whether you are submitting a new study, or adding a new site to an existing study, the protocol should detail all proposed multi-site or collaborative activities for Northwestern and any external site(s) as part of a reliance plan.

**Multi-Site Study:** Non-exempt Human Research involving more than one institution and/or site participating in the same research protocol, with each site completing all research activities outlined in the protocol.

**Collaborative Study:** Human Research involving more than one institution and/or site participating in the same research protocol, where each site complete a portion or portions of procedures.

# Reliance Tips

# Reliance Tips

- Plan for a Single IRB
- Federal Funding changes how we review submissions
  - Make sure you are using the InfoEd chooser in eIRB+
- Submit in eIRB+ only if you plan to conduct the research upon approval/determination.

# Have a great day!

**Email:** [irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu)

**Website:** <https://www.irb.northwestern.edu/reliance/>

# **INNOVATION & NEW VENTURES OFFICE (INVO) AT NORTHWESTERN**

Kimberly Griffin and Michael Fiske  
June 14, 2022

# Where does INVO sit within the university?





# What does INVO do?

INVO is the technology transfer office of Northwestern

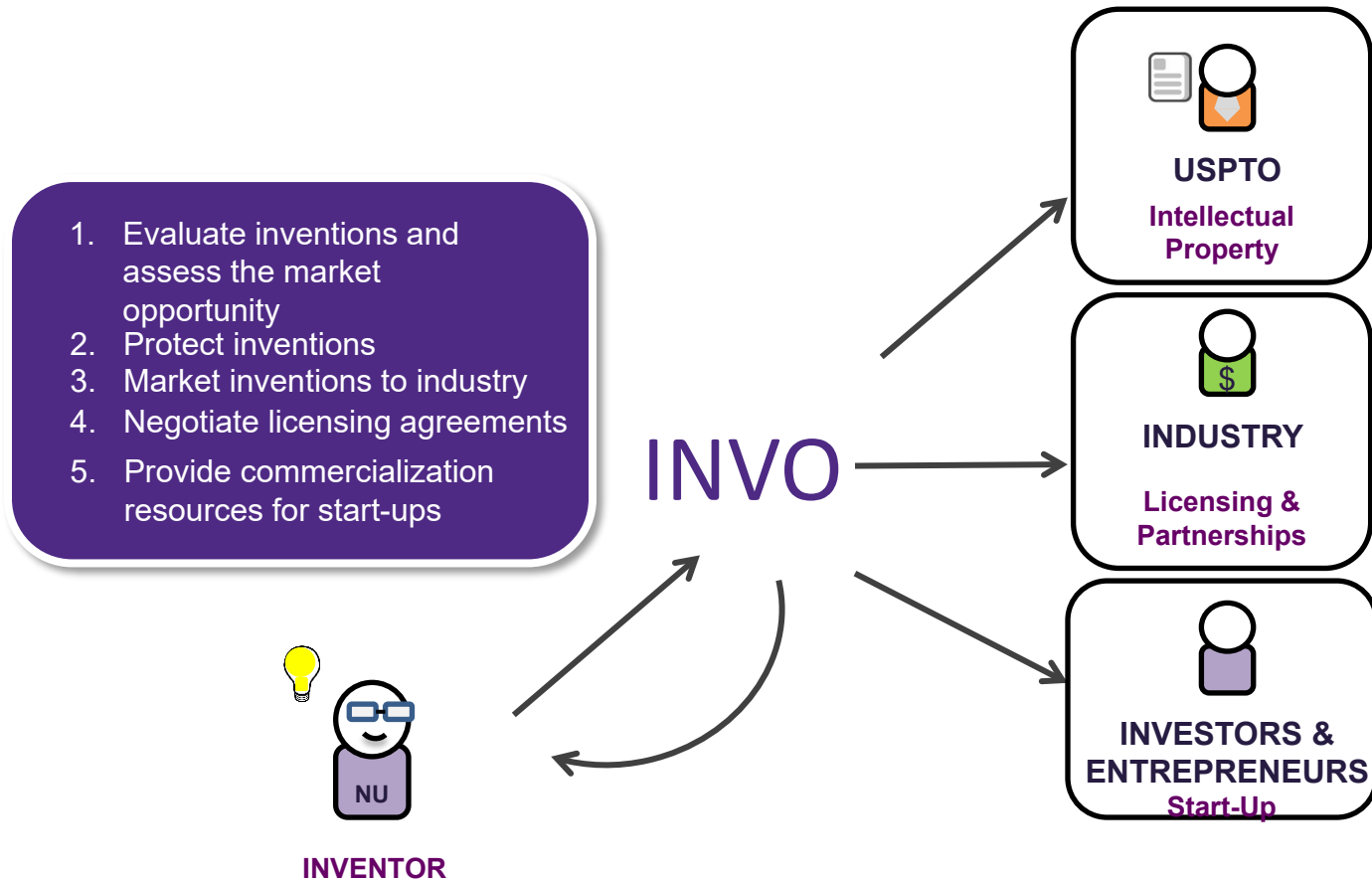
Tech transfer activities focus on moving technology and research from the university to the public domain

Grants received by university researchers from government agencies are funded by taxpayers

Often, universities do not have the financial resources to fully develop and commercialize technologies

INVO works to help technologies reach commercial potential to benefit the public good

# What does INVO do?



# What does INVO do?

## FY 2021 Metrics

**235**

INVENTIONS DISCLOSED

**695**

PATENT APPLICATIONS

**220**

AGREEMENTS EXECUTED

**4.8**

MILLION IN LICENSING  
REVENUES, DOLLARS

**240**

PATENTS ISSUED

**15**

STARTUPS WITH  
NORTHWESTERN IP

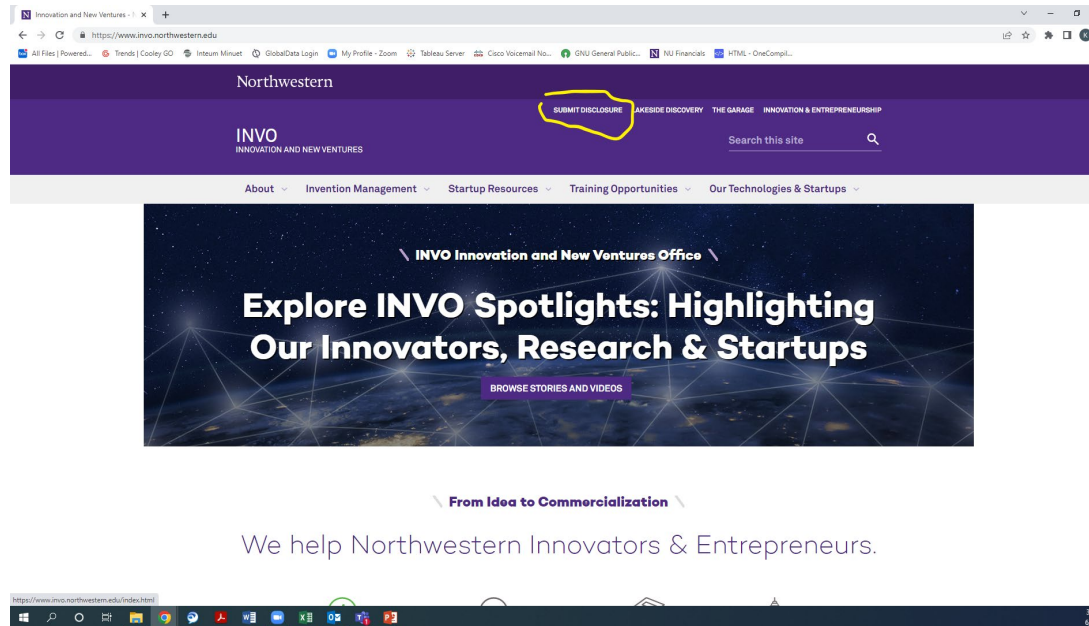
# When would you need to interact with INVO?

## 1. Invention Disclosures

- Invention disclosures start the patent process at Northwestern
- A patent application must be filed PRIOR to any manuscript submission, poster presentation, or oral presentation
- Reach out to INVO if your lab is concerned about patenting in view of an upcoming public disclosure

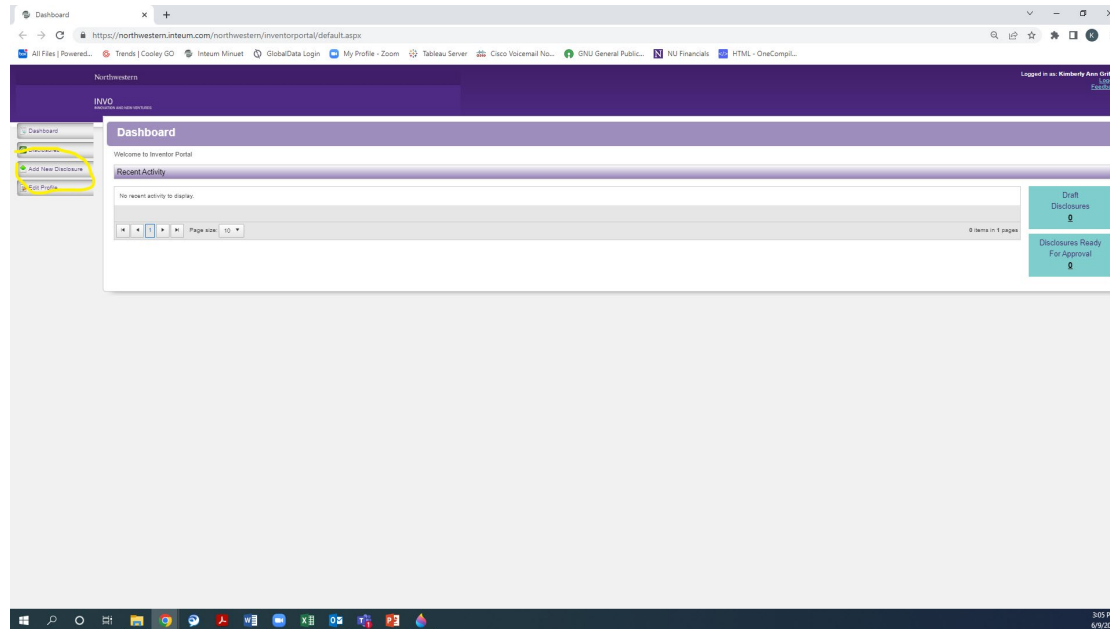
# When would you need to interact with INVO?

## 1. Invention Disclosures- use our Inventor Portal



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## 1. Invention Disclosures- use our Inventor Portal



# When would you need to interact with INVO?

## 1. Invention Disclosures

- Invention disclosures need to list all funding used in support of the project
  - Includes both federal and non-federal funding!
- INVO reports inventions to funding agencies to ensure researchers and Northwestern are compliant with funding requirements

# When would you need to interact with INVO?

## 2. Annual grant reports

- Some grants require all patent and licensing activity for the previous year to be included in an annual report
- INVO can provide this information to include in annual reports



# When would you need to interact with INVO?

## 3. Agreements

- Both INVO and SR negotiate agreements for researchers

### SR:

- Confidentiality Agreements (CDAs) for sponsored research, data sharing with other universities
- Material Transfer Agreements (MTAs)
- Sponsored Research Agreements (SRAs)
- Clinical Trial Agreements
- STTR/SBIR Subcontract Awards

# When would you need to interact with INVO?

## 3. Agreements

- Both INVO and SR negotiate agreements for researchers

### INVO:

- Confidentiality Agreements (CDA) for licensing and patenting activity
- License Agreements
- Consulting Agreements: we do NOT review but can provide information for faculty related to consulting
- STTR/SBIR Subaward assistance: IP Management Plan Agreements and Letters of Support

# When would you need to interact with INVO?

## 3. Agreements

- Both INVO and SR negotiate agreements for researchers

### Overlap:

- Confidentiality Agreements (CDAs)
- STTR/SBIR Subcontract Awards
  
- The purpose of the CDA determines if it goes through SR or INVO
- INVO has limited role in STTR/SBIR Subcontract Awards

# INVO Staff



Alicia Löffler, PhD  
Executive Director



Andrea Minogue  
Senior Director of Finance & Administration



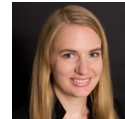
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## INVENTION MANAGEMENT TEAM

## NEW VENTURES TEAM

# Thank you!

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Join us for the  
next CLEAR webinar:

Tuesday, August 9, 10:00am