Welcome!

- Purple folder: Agenda, handouts, contact lists
- Presentations: [www.researchintegrity.northwestern.edu/research-administration-training-seminar](http://www.researchintegrity.northwestern.edu/research-administration-training-seminar)
- Questions/participation
- Breaks, bathrooms, food
- Feedback

Introduction
Jay Walsh, PhD, Vice President for Research

Introduction

Research Administration Training

- To better understand our role at the University
- To protect the research:
  - Data
  - Participants
  - Funding
  - Integrity of the research
  - The public’s trust
- Research funding and fiscal fiduciary duty
  - Northwestern received $676.5 million in sponsored research funding in FY 2017
  - Northwestern ranked 16th in NIH and 45th in NSF research funding to universities in FY 2016
- Mandatory regulations and policies

Ensuring compliance remains a priority for the federal government and Northwestern University
Training Objectives

- Discuss research administration roles and responsibilities
- Review the regulatory fundamentals that form the foundation of research administration
- Explain the research administration process and award lifecycle
- Discuss financial and non-financial policies and procedures
- Describe the roles of the central research offices and other research-related resources

Questions?
Agenda
Monday, July 16
9am – 12:30pm

- Research Roles and Responsibilities
- Office for Sponsored Research:
  - OSR: An Overview
- Office of Research Development
- Institutional Review Board
- Conflict of Interest / Commitment
- Research Portal
- NURAP

Research Roles and Responsibilities
Michelle Stalilonis
Senior Compliance Specialist
Office for Research Integrity
Research Administration Roles

Everyone works together to support research, the research process, and research administration.

Principal Investigator

- Directs and oversees all research activities
- Fosters a culture of research integrity
- Conducts research in an objective and unbiased manner, in compliance with policies and regulations
- Responsible for fiscal and administrative management of research

Department Chair / Center Director

- Liaison to other University units
- Ensures research objectives of the department, school, and University are consistent
- Confirms commitment to policies and regulations, and takes appropriate actions to ensure compliance
- Oversees the faculty in relation to their research activities
- Ensures resources are sufficient to meet departmental research needs and strategic vision
- Communicates research-related training requirements to faculty and staff

Unit Administrators

- Provides support for PI's research pursuits, while ensuring adherence to regulations and policies
- Supports PI with fiscal and administrative management of research
- Communicates proposal deadlines, pre-award processes, and policies to PI
- Completes post-award administration of research grants and/or contracts
- Communicates with PI to complete effort commitment profile and to track and monitor effort commitments
University Policies and Procedures

Example:
Northwestern’s Grant or Contract Terms
http://www.researchroles.northwestern.edu
Northwestern’s Effort Reporting Roles & Responsibilities
Policies and Procedures
https://www.northwestern.edu/coststudies/links.html

University Policies and Procedures

Northwestern determines how to meet these guidelines via its Effort Reporting policies

Sponsor-Specific Policies
NIH and NSF further define expectations

Federal Policies
Uniform Guidance sets requirements for effort reporting
Vice President for Research

• Oversees Office for Research and University research operations
• Fosters new research initiatives
• Oversees partnerships with industry, government, and partner institutions
• Acts as the University representative at national committees and labs
• Official institution nominator for limited submission candidates

Associate Vice Presidents for Research

• Work with the VP for Research to guide the strategic direction of research and improve the Office for Research’s customer service orientation
• Oversee OR compliance and operational units, Research Centers, and Core Facilities
• Represent OR on University committees

Office for Research

Sponsored Research

• Identifies funding sources
• Assists in proposal development
• Reviews and endorses proposals
• Accepts and appropriates awards
• Promotes compliance with agency and University policies

Office of Research Development

• Identifies funding opportunities
• Provides research administration support for large and/or complex grants
• Assists with grant proposal development
• Provides grantsmanship training
• Provides assistance with institutional commitments and cost-sharing for proposals
• Assists in establishing external partnerships

Office for Research Integrity

• Promotes research integrity and the responsible conduct of research
• Helps researchers navigate the complex research compliance and administrative arenas
• Serves as a confidential source for reporting research-related concerns
• Facilitates review of alleged research misconduct
• Coordinates quarterly research administration training seminars
• Tracks compliance with NSF RCR training requirements
Office for Research

### Institutional Review Board (IRB) Office
- Supports the IRB
- Assists PIs and research community in minimizing risk to human subjects
- Ensures compliance with laws and policies regarding human subject research
- Responds to allegations of human subject research noncompliance
- Conducts quality assurance and training

### Institutional Animal Care and Use Committee (IACUC) Office
- Supports IACUC
- Works with CCM to protect welfare of animal subjects
- Ensures compliance laws and policies regarding animal subject research
- Inspects animal facilities and laboratories
- Responds to allegations of animal subject research noncompliance
- Conducts post-approval monitoring and training

### Center for Comparative Medicine (CCM)
- Supports faculty using animals
- Oversees the humane care and use of animals
- Houses research animals, maintains support space and services for the use of animals
- Provides training in the care and use of animals

### Office for Research Safety
- Oversees training and compliance programs for chemical, biological, radiation, and lab safety
- Manages collection and proper disposal of chemical, radioactive, and biological waste generated by the research, teaching, and clinical operations
- Provides emergency response resources and information
- Provides security oversight for materials of national security interest

### Conflict of Interest Office (NUCOI)
- Oversees and implements the faculty and staff conflict of interest policies and procedures
- Ensures compliance with applicable conflict of interest regulatory requirements
- Provides guidance and support regarding conflict of interest policies, systems, standards, and procedures
- Administers and supports the activities of conflict of interest committees

### Export Controls Compliance
- Establishes and oversees a centralized resource ensuring compliance with export control regulations
- Provides education and outreach
- Maintains records demonstrating steps taken to comply with the regulations
- Conducts restricted party screenings
Office for Research

**Innovation and New Ventures Office (INVO)**
- Entrance point for moving Northwestern's inventions to the public
- INVO handles:
  - Invention Management – commercialization of scientific inventions
  - Patent, Licensing and Legal Issues
  - New Business Ventures, Venture Fund Programs, Technology Marketing
  - Startup Resources and Work Spaces
  - Mentorship and Training Programs

**Core Facilities Administration**
- Core facilities are recharge centers, operating under a fee-for-service model
- CFA provides financial support, administrative oversight, professional development, assessment, and communication of shared research resources such as:
  - Electron and confocal microscopes
  - Mass spectroscopy facilities
  - Functional MRI facilities

**Northwestern Scholars**
- Searchable database of research expertise across all disciplines
- Explore the profiles and research output of 4,450+ faculty, and learn about 50+ core research facilities
- 200,000+ publications (updated weekly)
- View collaboration networks among researchers within Northwestern and with external scholars [https://www.scholars.northwestern.edu](https://www.scholars.northwestern.edu)

Other Research-Related Offices
Roles & Responsibilities

ASRSP and Office of Cost Studies

President
  Provost
  Vice President for Research
  Office for Research
  Office of Accounting Services for Research and Sponsored Projects (ASRSP)
  Office of Cost Studies

Executive Vice President
  Vice President of Financial Operations & Treasurer
  Executive Director for Research Financial Operations

Vice President

Roles & Responsibilities

Office of Accounting Services for Research and Sponsored Programs (ASRSP)
- Assists in financial status reporting, sponsor reimbursements, and award close-out
- Approves transactions over 90 days
- Coordinates financial audits
- Inventories government-titled equipment
- Administers the effort certification process
- Processes subcontract invoices
- Promotes compliance with policies

Office of Cost Studies
- Oversees conformance with Northwestern’s policies and procedures related to cost accounting and effort reporting for sponsored programs
- Manages development and negotiation of Northwestern’s F&A Rate
- Maintains Effort Reporting System/Committed Effort Management (ERS/CEM)
- Provides determination of cost transfer policies and review of cost transfers
Research Centers

President

Provost

Dean

Office for Research

School-based Research Centers

University Research Centers

- 52 university research centers
- University Research Institutes and Centers Administration (URICA) office facilitates the planning and deployment of strategic resources coordination

http://www.research.northwestern.edu/centers

Questions?
Sponsored Research: An Overview

Why research?

“Skin Gel Stops Breast Cancer Growth”

“Why Do Families Keep Secrets?”

“Printing Human Organs”

“Reducing the Achievement Gap”

“New HIV Test will Help Developing World”

“Touch Screens That Touch You Back”
The University – Sponsor Relationship

Why universities engage in research
– Generate and disseminate knowledge
– Maintain high-quality educational environment
  (sponsored research helps maximize available resources)

Why sponsors provide research support
– Common ideology
– Large, established university infrastructure
– Top faculty and student talent

What is a Sponsored Project?
Specific research, training, service, or similar activity for which funding, data and/or material support is provided by an external sponsor under an agreement with the University
Common Sponsor Types

**Federal government**
- National Institutes of Health (NIH)
- National Science Foundation (NSF)
- Department of Defense (DOD)
- Department of Energy (DOE)

**State and local governments**

**Foundations/nonprofits**

**Industry**

**International entities**

Funding Mechanisms

Formal means through which a sponsor contracts with a recipient institution to provide funding

**Common Types of Funding Mechanisms**

- Grants
- Cooperative Agreements
- Contracts
- Subcontracts

For more: [SPOT – Introduction to Sponsored Research](#)
## Grants vs. Gifts

<table>
<thead>
<tr>
<th>Grants</th>
<th>Gifts</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Funding from sponsors</td>
<td>• No specified statement of work, deliverables, budget, or period of performance</td>
</tr>
<tr>
<td>• Specified statement of work, deliverables, budget, and period of performance</td>
<td>• Minimal reporting requirements</td>
</tr>
<tr>
<td>• Technical and financial reporting requirements</td>
<td>• Irrevocable</td>
</tr>
<tr>
<td>• Subject to terms and conditions of sponsor</td>
<td>• Work with Research Development</td>
</tr>
<tr>
<td>• Must be routed through sponsored research</td>
<td>• Subject to University policy</td>
</tr>
<tr>
<td>• Subject to University policy</td>
<td></td>
</tr>
</tbody>
</table>

For Additional Information: [http://osr.northwestern.edu/policies/sponsored-projects-versus-gifts](http://osr.northwestern.edu/policies/sponsored-projects-versus-gifts)

## Non-Financial Research Agreements

- Data Use Agreements (DUA)
- Non-Disclosure Agreements (NDA)/Confidentiality Disclosure Agreements (CDA)
- Facility Use Agreements
- Material Transfer Agreements (MTA)

Find out more: [SPOT – Introduction to Sponsored Research](https://osr.northwestern.edu/agreements) and [https://osr.northwestern.edu/agreements](https://osr.northwestern.edu/agreements)
Northwestern By The Numbers

For FY 2017, we had:

– 291 proposals submitted a month (3,502 proposals submitted)

– 277 awards set-up per month (3,328 awards total)

– 359 contracts executed per month (4,308 contracts)

Sponsored Research Mission

Sponsored Research assists investigators in proposing and managing sponsored programs in support of Northwestern University’s mission of innovative research, excellent teaching, and public service.

• Northwestern’s central research administration office
• Institutional point of contact for external research sponsors
• Comprehensive pre-award and post-award services
• Assistance with the interpretation of regulatory requirements and policy
The Sponsored Project Life Cycle

Summary of Sponsored Research Responsibilities

- **Facilitating all** Northwestern sponsored research activities
- **Advising** faculty and staff on proposal development and broader sponsored research issues (including cost accounting standards)
- **Interpreting** agency and Northwestern policy, guidelines, and terms and conditions
- **Endorsement of** Institutional proposals and resulting awards
- **Negotiation** and acceptance of awards
- **Award establishment**
- **Subawards issuance**
- **Reporting** on Northwestern sponsored research activity
- **Guidance** on award management issues
- **Represent** Northwestern nationally
- **Respond** to audits and subpoenas
- **Train and provide** educational materials for the sponsored research community
Sponsored Research Organization Chart

Roles & Responsibilities: Grants Team

**Grants Officers**
- Pre-award services
- Award review and negotiation
- Post-award non-financial management
- Liaison with sponsors and funding agencies on behalf of faculty and administrators

**Grants Assistants**
- Pre- and post-award support services to Grants Officers
- Award set-up
- Liaison with ASRSP, research administrators, and other departmental administrators

*Review budgets for accuracy and compliance with NU and sponsor requirements*

Find out more: [https://osr.northwestern.edu/agreements](https://osr.northwestern.edu/agreements)
### Roles & Responsibilities: Contracts Team

<table>
<thead>
<tr>
<th>Contracts Officers</th>
<th>Research Analyst / Coordinators of Administration and Grants</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Draft, review, and negotiate agreements and contracts</td>
<td>• Provide administrative support for industry-sponsored clinical trial budgets</td>
</tr>
<tr>
<td>• Ensure compliance with sponsor &amp; University policies and processes</td>
<td>• Process support Contract Officers with related agreements</td>
</tr>
<tr>
<td></td>
<td>• Review and maintain proposal and award data in InfoEd</td>
</tr>
</tbody>
</table>

*Ensure compliance with sponsor and University processes*

### Roles & Responsibilities: Info Team

<table>
<thead>
<tr>
<th>Systems and Data</th>
<th>Communications &amp; Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Provide functional assistance for InfoEd and ESPR</td>
<td>• Manage sponsored research website and listservs</td>
</tr>
<tr>
<td>• Analyze and report research data</td>
<td>• Provide a centralized help resources</td>
</tr>
<tr>
<td>• Ensure data integrity for proposal and award activity</td>
<td>• Create and deliver sponsored research learning resources</td>
</tr>
<tr>
<td>• Maintain institutional ERA accounts and assist individuals with external ERA systems (<em>e.g.</em> eRA Commons, Fast Lane)</td>
<td>• Collaborate with research offices and university partners to develop resources and implement electronic projects</td>
</tr>
</tbody>
</table>
With Whom Does Sponsored Research Collaborate?

Organizations and their Acronyms

- Accounting Services for Research and Sponsored Programs (ASRSP)
- Center for Clinical Research (CCR)
- Conflict of Interest at Northwestern University (NUCOI)
- Innovation and New Ventures Office (INVO)
- Institutional Animal Care and Use Committee (IACUC)
- Institutional Review Board (IRB)
- Export Controls Compliance
- Foundation Relations
- Office of General Counsel (OGC)
- Risk Management

*not an exhaustive list, examples of common engagements

Sponsored Project Online Training (SPOT)

Web-based training resulting from a partnership between Sponsored Research and Training Advisory Committee

- **Mini-courses:** 20-to-30 minute interactive videos which cover introductory topics
- **Microlearning modules:** 5-minute functionally-oriented videos addressing a discrete task or topic

Resources are available via Northwestern’s digital learning platform, myHRLearn

Find out more: [http://osr.northwestern.edu/training/spot](http://osr.northwestern.edu/training/spot)
Sponsored Research In-Person Training

- Complement the online SPOT offerings
- Current offerings cover introductory topics in sponsored research administration
- Register for classes online at myHRLearn

Questions?

Visit the Sponsored Research website: http://osr.northwestern.edu
Office of Research Development

Office for Research
Our Mission

The Office of Research Development promotes, stimulates and advances the diverse research enterprise across Northwestern University through:

- Facilitating Interdisciplinary Research Programs
- Supporting the Pursuit of Funding Opportunities
- Promoting the Submission of Outstanding Proposals
- Guiding Early Career Investigators

Constituents and Stakeholders

- Northwestern Research Community
  - Deans, Faculty, Researchers, Research Administrators, Post-docs, Graduate and Undergraduate Students
- Federal Funding Agencies
- Office of Foundation Relations
- Office of Government Relations
- Office of Corporate Engagement
- Office for Sponsored Research
- Partners: Affiliates, Industry, Academic and Non-Academic Institutions
Facilitating Interdisciplinary Research Programs

- Supporting the Pursuit of Funding Opportunities
- Promoting the Submission of Outstanding Proposals
- Guiding Early Career Investigators

Research Program Development

- Anticipate New Interdisciplinary Federal Agency Initiatives
- Support Investigator Initiated Ideas & Centers
- Identify, Connect, and Guide Formation of Collaborative Teams
- Coordinate Preliminary Workshops
- Assist in Development of a "white paper"
- Support Proposal Development Process
Large Interdisciplinary Proposal Development

Programmatic Support

- Develop “Writer’s Outline”
- Guide the conceptual development and writing of: vision, administrative core, management plan, broader impact, education, outreach, postdoc mentoring plan, data management plan, data sharing plan, etc.
- Advise on budget development
- Letters of support
- Sponsor’s summary statements
- Resubmission

Large Interdisciplinary Proposal Development

Project Management Support

- Generate time-line/roles and responsibilities framework
- Coordinate video/audio conference meetings (PIs, administrators)
- Prepare meeting agenda
- Provide meeting minutes
- Liaise with local RA, OSR, external partners, internal resources, local and external grant writers
- Manage internal and/or external review
- Coordinate site visits
Large Interdisciplinary Proposal Development

Research Administration Support

• Liaise between RA and technical team
• Confirm registrations for all personnel
• Facilitate subcontract procurement
• Budget development
• Format current & pendings and biosketches
• Consolidate facilities documents
• Review all documents as 2nd set of eyes

ORD

NU-Interdisciplinary Program 1-2-3

**I1**: $1,000 for a workshop; rolling submission
**I2**: $15,000 for expenses pertinent to the submission of a large proposal; rolling submission
**I3**: $95,000/year for up to 2 years for promoting effective team assembly, developing track record of collaboration, generating preliminary data and submitting a large/center proposal to an external sponsor; annual due date

Requirements:
- Interdisciplinary team (at least 2 schools and 3 departments)
- Innovation
- Societal impact

http://www.research.northwestern.edu/interdisciplinary123/
ORD LINC Series

- Quarterly Event
- Promote anticipated federal funding opportunities
- Bridge communication between schools on a federal agency initiative
- Transfer knowledge between disciplines
- Establish new interdisciplinary connections

Past Events: “Microbiome”, “Internet of Things”, “Quantum Sciences”

Facilitating Interdisciplinary Research Programs
Supporting the Pursuit of Funding Opportunities
Promoting the Submission of Outstanding Proposals
Guiding Early Career Investigators
New Weekly Funding Opportunity Alert (ORD INSIGHT)

Anticipate, monitor, identify, and disseminate federal funding opportunities and related information to faculty and staff

- **News and Events**
  - Agency strategic plans, proposer days, meetings/webinars
  - Notice of intent to publish a FOA – NIH
  - Dear Colleague Letters – NSF
  - Information on new federal funding initiatives

- **Funding Opportunities**
  - FOAs screened weekly for eligibility and relevance to NU research
  - FOA summary is hyperlinked to Pivot database listing
  - "Limited Submission" funding opportunities
  - Divided into 6 research areas: Biomedical & Life Sciences; Engineering & Computer Science; Learning Sciences; Media, Arts & Humanities; Physical Sciences; Social Sciences & Law
I. Facilitating Interdisciplinary Research Programs

II. Supporting the Pursuit of Funding Opportunities

III. Promoting the Submission of Outstanding Proposals

IV. Guiding Early Career Investigators

Promote the Submission of Outstanding Proposals

- Personalized service to faculty from all disciplines (smaller scale proposals, single investigator, etc.)
  - Clarify and confirm sponsor’s expectations and guidelines
  - Enhance faculty communications with program officers
  - Advise on strategic approaches to developing a proposal
- Outreach and resources
  - “ORD Presents” workshops (DARPA, large grant proposal, shared instrumentation, NSF CAREER)
  - Bring program officers to Northwestern
  - Provide institutional subscription to “Research Development and Grant Writing News”
- Manage the Institutional Limited Submissions Process
Limited Submission

- Funding opportunities for which the sponsor limits the number of applications that may be submitted per institution
- ORD manages the institutional process for selecting nominees for Federal, Foundation, and Corporation funding opportunities
- Northwestern has established a transparent, efficient and effective process for selecting successful nominees

https://ord.northwestern.edu/limited-submissions

Northwestern’s Limited Submission (LS) Process

Identification of LS funding opportunities → Dissemination of announcements → Collect Internal Letters of Intent → Collect Internal Proposals → Notification → Internal Review → Nomination → Sponsor Proposal Due
Limited Submission: Dissemination of Announcements

• Targeted and inclusive dissemination
• Subject: LIMITED FUNDING OPPORTUNITY: …..
• Summary of opportunity and eligibility criteria
• Link to the sponsor’s website
• Key dates: LOI, internal proposal submission, notification, sponsor deadline
• Instructions: LOI form, internal proposal components, upload information
• All announcements and their status are posted on ORD’s website
• You can opt-in to receive all announcements

Limited Submission: LOIs

• Submission of the LOI by the deadline is **required**, but no binding
• Based on institutional interest:
  o First come, first served
  o Applicants are authorized by ORD to submit a proposal to sponsor
  o A competition is required, all applicants are invited to submit internal proposals
Limited Submission: Review Process

- The Limited Submission Advisory Committee is charged with selecting the most nationally competitive applicants
- Senior faculty from FSM, WCAS, McC, SESP and SoC
- Humanities ad hoc panel is invited as necessary
- Ex officio and ad hoc reviewers are invited as appropriate
- Panel review (video-conference between campuses)
- Selection is requires approval by the VPR

Limited Submission: Notification

- All candidates are notified by email by the stated deadline
- Feedback is provided to all applicants
- Nominees are invited to work with the Office of Foundation Relations on Foundation proposals
- OSR GO is notified
Limited Submission: Outcomes

- Packard Science and Engineering Fellows
  National awardee each year 2007-11, 2013
  (of an annual total of 16 fellows from 50 Universities)

- Pew Biomedical Scholars
  (of an annual total of 21 scholars nationally)
Guiding Early Career Investigators

- Reach out to new faculty, present at new faculty orientations
- Consult and perform customized funding opportunities search, recommend collaborators
- Develop a strategy of applying to prestigious fellowships
- Provide NSF CAREER consultations
- Provide resources for early career investigators on ORD’s website
- Host “ORD Presents” Series

Guiding Early Career Investigators: ORD Presents

- NSF CAREER Workshop
- Introduction to Funding Opportunities
- Early Career Funding Opportunities
- Broader Impacts Forum
Please contact ORD if you…

- Are working on a complex proposal
- Find a limited submission opportunity not on our website
- Want to receive ORD Insight and LS FOAs
- Have a question about a federal funding opportunity
- Want to advertise internal seed funding or research events
- Have ideas for future events or thoughts on ways we can improve
Contact Information

Nicole Moore, DSc
Director
nicole.moore@northwestern.edu

Karen Lapidos Cielo, PhD
Senior Associate Director
k-cielo@northwestern.edu

Rebecca McNaughton, PhD
Assistant Director
rebeccam@northwestern.edu

Megan McConnell
Program Assistant 4
megan.mcconnell@northwestern.edu

ORD-NU
@NU_ResearchDev
Follow Us on Social Media

Thank you!

Questions??
What is an IRB?

An Institutional Review Board (IRB) is a committee established to review and approve research involving humans.

The purpose of the IRB is to ensure that all human research be conducted in accordance with all federal, institutional, and ethical guidelines.

The sole mission of the IRB is the protection of humans who participate in research.
The structure of the NU IRB

NU IRB Facts

- >14,000 Submissions a Year
- 6 IRB Review Boards (2 Campuses)
- 70% Biomedical and 30% Social Behavioral
Three administrative areas:

- IRB
- Human Research
- Compliance
- Training and Education

Northwestern IRB Affiliated Partners:

- Northwestern Medicine
- Shirley Ryan Ability Lab
- Lurie Children’s Hospital
- Research Privacy Board
Why do we need IRB?

- Tuskegee Syphilis Study
- Willowbrook Hepatitis Study
- Stanford Prison Study
- University of Minnesota Psychosis Study

Source: NIH Office of Extramural Research
But really--why do we need IRB in this day and age?

- No one can be objective about their own work – history bears this out but it is true.
- People underestimate the risks involved with areas they are very familiar (procedures, CT scans, adding supplements, surveys on sensitive issues, etc.)
- People overestimate the benefit of things that are important to them.

Day-to-day IRB
When Does the IRB Get Involved?

When it is Human Research.

It’s Research when there is a systematic investigation.

It’s Human Research when there are:

- Living individual(s) about whom information is collected through intervention or interaction; or
- Identifiable Private Information

When it is a systematic investigation that involves living people or their identifiable information about whom the information collected is intended to develop or contribute to generalizable knowledge the IRB needs to see it.

Other resources: Human Research Determination Form (HRP-303) HRP-310 WORKSHEET Human Research Determination

The IRB evaluation of the conduct of research involves:

- Codes of Ethics Standards of practice NU HSPP 5.0
- Academic / Professional Values
- Ethical decision making
- Legal / Regulatory Standards
- Moral philosophy Framework for ethical decision making Moral Virtue
- CFR, FDA, FERPA, HIPAA, MHDDCA, etc.
## IRB Review Categories

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Description</th>
</tr>
</thead>
</table>
| Exempt      | - Minimal risk  
              - Belmont Principles still apply  
              - Does not apply to FDA regulated research unless it falls under Emergency Use |
| Expedited   | - Minimal risk, identifiable, more personal information  
              - Reviewed in the office except for vulnerable populations.  
              - If expedited reviewer does not approve, the study must go to the full board. |
| Full Board  | - Minimal risk research not in exempt or expedited review categories  
              - Research that is more than minimal risk  
              - Certain research with vulnerable populations (children, pregnant women, prisoners) |

### .111 Regulatory Criteria

- Participant Selection
- Vulnerable Populations
- Voluntary Consent
- Benefits
- Risks
- Research Design
Speaking “IRB”

What the IRB is looking for:

1. The research methodology is reasonable and will accomplish the purpose of the study.
2. Risks to participants are minimized and are reasonable in relation to anticipated benefits.
3. Selection of participants is equitable.
4. Informed consent is sought from each participant and is appropriately documented.
5. The researcher has adequate training and experience and there is not a conflict of interest.
6. Privacy and confidentiality of participants is protected.
7. Additional safeguards are included for vulnerable populations.
8. Data collection is monitored to ensure participant safety.
9. Participants are fully debriefed if deception used.
NU IRB Submission Process

1. **PI Submits New Application**
2. **IRB Coordinator Pre-Review**
3. **Assigned to Reviewer or Panel**
4. **Approval Criteria Met?**
   - If not met, **Modification Required for Formal Review**
   - If met, **Changes Requested**
   - If approved, **Post Approval Modifications Continuing Review Reportable new information**

---

**Pop Quiz!**

**Which study meets the definition of research with human subjects?**

a) A physician plans to conduct a study of comments posted on a blog for patients with diabetes.

b) A psychologist proposes videotaping interactions between groups of toddlers and their caregivers to determine which intervention methods most effectively manage aggression.

c) A grad student proposes asking the director of a local free clinic about the number of patients in the last two years with newly diagnosed HIV/AIDS.

d) A university designs an in-house study to improve the mentoring of students with the proposed outcome consisting of a report of recommendations for the department.
Correct Answer: b

a) A physician plans to conduct a study of comments posted on a blog for patients with diabetes. (Publicly available info)

b) A psychologist proposes videotaping interactions between groups of toddlers and their caregivers to determine which intervention methods most effectively manage aggression.

c) A grad student proposes asking the director of a local free clinic about the number of patients in the last two years with newly diagnosed HIV/AIDS. (No human subjects—no identifiers collected)

d) A university designs an in-house study to improve the mentoring of students with the proposed outcome consisting of a report of recommendations for the department. (Not generalizable knowledge)
NIH Single IRB Policy

The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.

This policy, which is consistent with 45 CFR Part 46.114, is intended to:

• Enhance/streamline IRB review process in multi-site research
• Eliminate duplicative IRB review
  – Reduce administrative burdens/inefficiencies
  – Maintain human subject protections
  – All IRB’s to concentrate on single site protocols

NIH Single IRB Implementation Plan (Phase 1)

➢ Pre-Consultation
➢ Dedicated Webpage
➢ Template Letters of Support
➢ SOP’s
General Contact Information

For additional information on IRB submission templates, regulatory guidance, upcoming education/training opportunities, and staff contacts, please visit our website:

https://eirbplus.northwestern.edu

- Main number (Bio-medical): 312-503-9338
- General IRB Questions: irb@northwestern.edu
- Social and Behavioral Questions: sbirb@northwestern.edu
- Reliance Agreements: irbreliance@northwestern.edu
- eIRB assistance/queries: eirb@northwestern.edu
- Compliance queries/issues: irbcompliance@northwestern.edu
- Training queries/issues: irbtraining@northwestern.edu
- Social and Behavioral IRB: 847-467-1723

Contact Information

Marcella Oliver
IRB Reliance and Education Lead
Northwestern University, IRB Office
312-503-6071
m-oliver2@northwestern.edu
irbreliance@northwestern.edu
Conflict of Interest/Commitment
Conflict of Interest Office (NUCOI)

Kate Booth
Director, NUCOI
Overview

1. Defining COI, regulations & polices
2. Northwestern’s COI process – theory
3. Northwestern’s COI process – systems / workflow

Defining a Conflict of Interest

A situation where an individual’s external financial interests may bias or compromise – or appear to bias or compromise – an individual’s judgment, objectivity, or decision-making
Why Are We Concerned About COI?

1. To protect the objectivity, credibility, and trustworthiness of our research, our research community, and our institution

2. To meet regulations that require the University to have policies and procedures for soliciting disclosure, review, and management of COIs

COI Regulatory Environment

Federal Regulations (UG, PHS, NSF)  Sponsor Requirements

Sources

Project Terms and Conditions  Institutional Policies
Applicable Policies

Northwestern has three policies:
- Policy on Conflict of Interest and Conflict of Commitment
- Conflict of Interest in Research
- Institutional Conflict of Interest in Research

Applicability of Northwestern’s COI in Research Policy:

- All **federally-sponsored** research
  - PHS, NSF, DOD, DOE, DOJ, etc.
- All **industry-sponsored** research
- All **human subjects research**, regardless of funding source
- Agencies that have adopted PHS COI regulations:
  - AHA, PCORI, Susan G. Komen, etc.
- Other sponsors with specific COI requirements

http://www.northwestern.edu/coi/policy/coi_by_sponsor.pdf
How Does Northwestern Handle COI?

Disclosure of external interests and relationships

Review of interests and research to identify COIs

Elimination, reduction, or management of COIs

Monitoring compliance with management strategies

Disclosure Requirements: Who

Q: Who needs to disclose?
A: Investigators

• Any individual acting as project director or principal investigator, AND
• Any other person, regardless of position or title, who is independently responsible for the design, conduct, or reporting of research
### Who are Investigators?

<table>
<thead>
<tr>
<th>Role on Project/Proposal</th>
<th>Is that person an Investigator?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Personnel</td>
<td>YES - ALWAYS</td>
</tr>
<tr>
<td>Consultant</td>
<td>MAYBE – are they independently responsible for the design, conduct or reporting of the research? If there is any question as to whether an individual is an Investigator, the PI must confirm the assignment of project role.</td>
</tr>
<tr>
<td>Other Significant Contributor</td>
<td></td>
</tr>
<tr>
<td>Research Coordinator</td>
<td></td>
</tr>
<tr>
<td>Graduate Student / Postdoc</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Role on IRB Study</th>
<th>Is that person an Investigator?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>YES - ALWAYS</td>
</tr>
<tr>
<td>Co-Investigator</td>
<td>YES - ALWAYS</td>
</tr>
<tr>
<td>Study Team Member</td>
<td>NO</td>
</tr>
</tbody>
</table>

**Q:** What if a person is **Key Personnel**, but has **0% effort**?

**A:** That person **is an Investigator** and needs to complete the COI requirements.

Effort is unrelated to the definition of Investigator.

*For example:*

- The mentor of a graduate student or postdoc on a fellowship may have 0% effort because they are advisory, and may only meet with the trainee quarterly.
- Do they significantly contribute to the design, conduct, or reporting of research? **YES.**
Disclosure Requirements: What?

Q: What do Investigators need to disclose?
A: Significant Financial Interests (SFIs) related to their Institutional Responsibilities

- **SFI** =
  - Any equity / ownership / investment in a non-publicly traded company
  - Payment, reimbursed travel, equity in a publicly traded company, or IP licensed outside of Northwestern valued at / exceeding $5,000
  - Common related activities include: Editing, Scientific Advisory Board, Consulting, Training

Disclosure Requirements: When?

Q: When do Investigators need to disclose?
A: Prior to proposing or initiating a project, and on an ongoing basis:

- ✓ when they have a new financial interest, and
- ✓ at least annually

Note! A grant cannot be submitted until all Investigators have completed a disclosure.
Disclosure Requirements: Where?

Log-in link:
https://coi.northwestern.edu

Disclosure Requirements

Investigators are required to disclose outside financial interests / activities that are related to their Northwestern responsibilities before proposing or participating in research, when they get a new interest, and at least annually.
How Does Northwestern Handle COI?

Disclosure of external interests and relationships

Review of interests and research to identify COIs

Elimination, reduction, or management of COIs

Monitoring compliance with management strategies

Review: What Does a COI Look Like?

Not every disclosed interest/relationship is a COI

COIs are not necessarily bad things

Examples of apparent or actual COIs related to research:

- Extensive consulting or other relationship with, or equity interest in, an entity sponsoring research
- Intellectual property rights for product being tested in research
- Use of students/support staff/university resources on external activities
- University dealings with entities with which a personal relationship exists
How Does Northwestern Handle COI?

- Disclosure of external interests and relationships
- Review of interests and research to identify COIs
- Elimination, reduction, or management of COIs
- Monitoring compliance with management strategies

Manage: How do you manage a COI?

Transparency:
- Disclosure in publications, presentations & press releases
- Disclosure to research team members

Oversight / Firewalls / Separate Activities:
- Restrictions on use of resources (space, personnel, time, supplies) in company activities
- Requiring an SSJ for any purchases / vendor activity from company
How Does Northwestern Handle COI?

- Disclosure of external interests and relationships
- Review of interests and research to identify COIs
- Elimination, reduction, or management of COIs
- Monitoring compliance with management strategies

Where Does COI Fit in Workflows?

NUCOI works with OSR and the IRB to align processes and respond to shifting priorities
Disclosure Review Process: Grants

Projects are not reviewed until the status is set to JIT, Prespend, or an Award status.

- Proposal can be submitted: All investigators have disclosed.
- JIT Notification received: Proposal status set to JIT; NUCOI begins review.
- NOA is received: Proposal enters Award Workflow; OSR checks for COI determinations.
- Project can draw funds from sponsor: Disclosures are reviewed, any conflicts are managed & reported.

Compliance Page Status:
- Review Complete
- Under Review

Investigator Statuses:
- Disclosed
- Disclosed
- Disclosed

- NUCOI Reports to sponsor (if required)
- Compliance Page Status: Review Complete
- Compliance Page Status: Review Complete
- Compliance Page Status: Review Complete

COI
Compliance Checkpoints: Grants

All investigators have:

- Disclosed SFIs
- Completed training

NUCOI & School Deans have:

- Reviewed each Investigator and made a determination
- Managed any identified conflicts
- Reported any conflicts, as needed / applicable

Proposal can be submitted

Chartstrings can be issued

Disclosure Review Process: IRB Study

Proposal is submitted in eIRB+ and imported into eDisclosure

Study can be Approved by IRB

Disclosures are reviewed, any conflicts are managed & reported

COI tab status: Conflict Managed

NUCOI / School communicates with Investigator & study team to manage any identified conflicts

At the time of import, NUCOI will reach out to any individuals who have not disclosed

COI tab status: Under Review
Compliance Checkpoints: IRB Study

All investigators have:
✓ Disclosed SFIs
✓ Completed training

NUCOI & School Deans have:
✓ Reviewed each Investigator and made a determination
✓ Managed any identified conflicts
✓ Reported any conflicts, as needed / applicable
✓ Communicated with Investigator/study team to request any needed changes to the study

Study can be Approved by IRB

Tools for Meeting Compliance Points

• COI Compliance Page in eDisclosure

• COI tab in eIRB+

COI Compliance Page in eDisclosure

COI tab in eIRB+

COI
Roles & Responsibilities

**Investigators**
- Disclose financial interests related to their institutional responsibilities
- *(PI)* Identify all individuals who are Investigators on projects

**NUCOI**
- Review disclosed interests relative to research projects
- Work to manage, reduce or eliminate conflicts
- Report to sponsors, as needed
- Assist all other parties

**RAs / OSR – RCs / IRB**
- Verify compliance of disclosure & training dates prior to proposal submission / project initiation / study approval
- Assist PIs in identifying all Investigators on a project

**School Deans / Committees**
- Review cases referred by NUCOI
- Assist in managing, reducing or eliminating conflicts for faculty and the institution

Resources

- **Policy on Conflict of Interest and Conflict of Commitment:**
  http://www.northwestern.edu/coi/policy/core_coi_policy.pdf

- **Policy on Conflict of Interest in Research:**
  http://www.northwester.edu/coi/policy/research_policy.pdf

- **Northwestern’s Conflict of Interest Office:**
  http://www.northwestern.edu/coi/index.html

- **FDP Clearinghouse:**
  http://sites.nationalacademies.org/PGA/fdp/PGA_070596
Questions?

Help/Assistance

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

Kate Cosgrove Booth – Director
k-cosgrove@northwestern.edu / 847.491.4163

Garth Huskey – Compliance Analyst
garth.huskey@northwestern.edu / 847.467.6050

Paula Foster – Program Assistant
p-foster@northwestern.edu / 847.467.4515
Significant Financial Interest

- Compensation and/or other payments for service (e.g., salary, consulting, advisory, and/or lecturing fees, paid authorship, gifts, and honoraria) exceeding $5,000*
- Equity interests (e.g., stock, stock options, or other ownership interests) in a publicly-traded entity for which the value exceeds $5,000
- Any equity interests (e.g., stock, stock options, or other ownership interests) in a non-publicly-traded entity
- Intellectual property rights and interests exceeding $5,000* (e.g., patents, copyrights), upon receipt of income related to such rights and interests
- Reimbursed or sponsored travel exceeding $5,000*

*FSM has a $0 value disclosure threshold.

Exclusions to SFI

- Compensation less than $5,000 (unless FSM)

- Any compensation received for lectures, seminars, teaching engagements, or service on advisory committees or review panels relating to federal, state, or local government agencies, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education, and compensation received from Northwestern funds
Exclusions to SFI

- Sponsored/reimbursed travel less than $5,000 (unless FSM)
- Travel reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education
- Intellectual property interests valued at less than $5,000 (unless FSM)
- Royalties received from Northwestern funds
- Unlicensed intellectual property that does not generate income
- Interests in publicly-traded entities valued at less than $5,000, as well as equity interests in any entity through personal retirement accounts and mutual funds

Research Portal

Susan Held, FFRA
(Finance, Facilities and Research Administration)
Agenda

- Why do we have a Research Portal?
- What is it?
- Where does the information come from?
- Who can see what?
- Tips and favorite features
- What are the future plans for the project?

Background

- Information stored in many systems with different login and security procedures
- High level of training and effort required to answer simple questions such as “what is my balance?”
- No “faculty-friendly” options
Solution
researchportal.northwestern.edu

- Modern web application using Amazon Web Services
- Developed with significant faculty and staff input

Proposal Information

- Basic demographics from InfoEd available

- For full details, run the GM085
Proposal Information

- You can send a message to OSR requesting that a proposal be marked Unfunded

Award Information

- Data comes from NUFinancials
- Default view is high-level summary
Award Information
• Project page contains further detail

Award Information
• Drillable transaction detail

• Non-Sponsored contains similar info
Protocol Information

• Approved animal (IACUC) and human subjects (IRB) protocol numbers and demographic information

• Open security – any user can see any protocol information

<table>
<thead>
<tr>
<th>Study #</th>
<th>Study Name</th>
<th>Study Expired Date</th>
<th>Study Status</th>
<th>In-study study approved date</th>
<th>Last approval date</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTL001</td>
<td>1</td>
<td>Jan 10, 2018</td>
<td>Approved</td>
<td>Dec 27, 2015</td>
<td>Jan 17, 2017</td>
</tr>
<tr>
<td>CTL002</td>
<td>2</td>
<td>May 6, 2018</td>
<td>Approved</td>
<td>Apr 28, 2011</td>
<td>May 6, 2017</td>
</tr>
<tr>
<td>CTL003</td>
<td>3</td>
<td>May 6, 2018</td>
<td>Approved</td>
<td>May 11, 2013</td>
<td>May 6, 2017</td>
</tr>
<tr>
<td>CTL004</td>
<td>4</td>
<td>Apr 16, 2018</td>
<td>Approved</td>
<td>Jul 13, 2014</td>
<td>Apr 30, 2017</td>
</tr>
<tr>
<td>CTL005</td>
<td>5</td>
<td>May 2, 2018</td>
<td>Approved</td>
<td>Jul 23, 2012</td>
<td>May 5, 2017</td>
</tr>
</tbody>
</table>

Administrator Security: Sponsored Funding

• Anyone with Cognos research report access can see any proposal or sponsored project in the Portal

• Helpful for managing faculty with projects in multiple departments

• Salary detail is restricted to those with InfoEd access
Administrator Security: Non-Sponsored Funding

- Research Portal security is based on Cognos/NUFinancials Row Level Security
- Salary detail is limited to those with Cognos salary detail access

Security: Faculty

- Investigators (faculty) can see:
  - All sponsored projects where they are an investigator (any role)
  - All non-sponsored projects where they are the project manager and have NUFinancials security access
  - Salary detail on sponsored projects where they are PI or Subproject PI
  - Salary detail on non-sponsored projects they can see in the portal if they have the Cognos salary access role
General Cool Features

• Searching

• Sorting
General Cool Features

- Transaction download
- Feedback button

Future Development

- More non-financial information
- More transparency into sponsored life cycle
- Ability to identify and process pending action items
- Continuing opportunity for staff to serve on focus groups
For More Information

www.it.northwestern.edu/supportcenter/

Questions?
Northwestern University Research Administration Professionals (NURAP)

An organization to support research administration professionals

Mission

NURAP strives for a diverse membership of research administration and support professionals in departments, divisions, centers, schools and central administration units.

With an emphasis on operations and organizational management, NURAP provides an educational forum to discuss current policies, exchange best practices/ideas and network.
Grassroots Leadership

Nathan Youngblood, President, MEAS, Research Administration, EV
Julieen Morford, Vice President, FSM, Preventive Medicine/IPHAM, CH
Maria Galent, Secretary, School of Communication, EV
Jody Hirsh, OR, Chemistry of Life Processes Institute, EV
Maura Cleftti, OR, NAISE, EV
Aaron DeLee, OR, OSR, EV
Susan Hall-Perdomo, OR, Center for Sleep & Circadian Biology, EV
Brent Bell, FSM, RA
Elzbieta Klapczynska, WCAS, Research Administration, EV
Nadia Hajjar, FSM, Preventive Medicine/IPHAM, CH
Helaine Miller, OR, ISEN, EV
Rebecca McNaughton, ORD
Rosa Ortiz, School of Communication, CH
Yael Mayer, MEAS, Research Administration, EV

Education and Information

NURAP Newsletter
Information
Member recognition, advice column, organizational news

NURAP Listserv
Information
Job opportunities, event announcements, internal training

NURAP Website
Information
Organizational information, list of previous events, membership information, resources for research administrators
www.nurap.northwestern.edu

NURAP at Noon
Programming
Informal informational sessions

Certified Research Administrator Exam
Study Sessions (Continuing Education)
FY2017 NURAP@NOON Sessions

Best Practices for Sponsored Projects
Travel – presented by ASRSP

Stored Value Cards – presented by Treasury Financial Operations

Project Closeout – panel discussion

NCURA Webinar on Research Terms and Conditions

Website:

http://www.nurap.northwestern.edu/
Joining NURAP

How do you become a member of NURAP?

✓ Join the listserv by emailing us at nurap@northwestern.edu

✓ Membership in NURAP is free!

✓ Membership in NURAP is open to all members of the Northwestern University community involved in any aspect of research

Please Join us on Twitter, Facebook or LinkedIn

Questions?