Administrative Business

• Breaks, bathrooms, food
• Slides
• Different presenters
• Purple folder
• Questions/participation
• Survey after each day
Check Your Knowledge
Agenda – Day One

- Research Roles and Responsibilities
- Policies and Procedures overview
- Intuitional Review Board (IRB)
- Institutional Animal Care & Use Committee (IACUC)
- Center for Comparative Medicine (CCM)
- Institute for Northwestern University Clinical and Translational Sciences (NUCATS)
- Innovation & New Ventures Office (INVO)
- Office for Research Safety (ORS)
- Conflict of Interest
Deception at Duke: Fraud in cancer care?

Did Anil Potti, Former Duke Cancer Researcher, Conduct Research Fraud?

The group is seeking compensatory and punitive damages in the case, alleging that Duke tried to cover up questions about the research and performed unnecessary chemotherapy on people in hopes of patenting and spinning off a cancer-screening test.
Jay Walsh, Vice President for Research
Research Administration Training

The need for research administration training exists because of the large dollar amounts in research funding and the importance of compliance:

- Northwestern received $621.3 million in research funding in FY 2015
- Northwestern ranked 22nd in NIH and 34th in NSF research funding to universities in FY 2014
- Ensuring compliance remains a federal priority

Research Administration Training

Research Administration training helps Northwestern:

- Decrease compliance risks
- Administer grants more consistently & efficiently
- Provide support for research administrators, faculty & staff
- Meet federal government expectations regarding training and communication
Training Objectives

During this seminar we will:

• Explain the research administration process

• Discuss the roles & responsibilities of research faculty and staff

• Describe the roles of the central research offices

• Review the regulatory fundamentals that form the foundation of research administration
Questions?
Roles & Responsibilities

Beth Irwin
Research Training Manager
Office for Research Integrity
bethirwin@northwestern.edu
Research Administration Roles

Central

Unit

Principal Investigator
PI Responsibilities

- Develop research project
- Reflect accurate costs in proposal budgets
- Ensure costs are compliant with regulations
- Provide sufficient time to process proposals
- Disclose and manage conflicts of interest/commitment
- Comply with grant terms and conditions
Unit Responsibilities

• Support PIs by:
  – Completing appropriate forms
  – Developing budgets
  – Conducting quality assurance on proposals and sub-contracts
  – Submitting proposal to sponsor, when appropriate

• Knowledge of rules and regulations

• Monitor financial and compliance controls for external funding
Department Chair Responsibilities

- Provide departmental resources to administer a project
- Monitor appropriate use of students
- Allocate space and other resources to meet project needs
- Ensure project goals and the objectives of the Department, School, and Northwestern are consistent
- Manage and absorb overdrafts for PI's
AVPs for Research Responsibilities

- Oversight of CCM, IACUC Office, IRB Office, NUCOI Office, OECC, ORI, OSR, and Research IT Strategy & Operations
- Oversight of Research Centers and Core Facilities
- Strategic planning for University research
- Liaison to basic science and clinical research communities
- Liaison to Northwestern University Clinical and Translational Science Institute (NUCATS)
- OR representative on University committees
INVO Responsibilities

• Provides support for NU’s expanding innovative culture

• Entrance point for moving NU’s inventions to the public

• INVO consists of:

1. Intellectual Property and Licensing group
2. The New Ventures group
3. The Community Outreach group
ORS Responsibilities

• Chemical, biological, radiation, and general laboratory safety

• Compliance oversight (all of the above) — interactions with multiple state and federal agencies

• Hazardous waste disposal

• Emergency response

• Security oversight (materials of national security interest)

• Various safety committees administration
ORPAF and ORC Responsibilities

• Strategic planning and financial analyses to define alternatives for the optimal use of resources

• Develops human resources practices and operational processes that lead to enhanced effectiveness

• Provides administrative support for the University research centers

• Manages communications and publications to foster the flow of information between OR and its constituents.
CCM Responsibilities

• 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
Core Facilities Responsibilities

• Provides centralized services and/or state of the art equipment that a single researcher cannot support on their own

• Recharge centers that recover most of its expenses by charging its user base a “fee for service”

• Concentrated within OR, FSM and WCAS
ORD Responsibilities

- Identifies appropriate funding opportunities
- Research administration support for large and/or complex grants
- Grant proposal development
- Provides Grantsmanship training
- Assistance obtaining institutional commitments and cost-sharing for proposals
- Assistance establishing external partnerships and affiliated subcontracts
OSR Responsibilities

• Proposal validation and submission

• Negotiates, executes, and accepts contract and grant awards

• Award notification

• Account establishment

• Issues sub-awards

• Award terms and conditions interpretation
ORI Responsibilities

• Partners with the research community to minimize and manage research risks

• Coordinates training, education and communication

• Proactively identifies and manages research risks

• Manages research misconduct investigations

• Monitors and corrects other non-compliance
IRB Office Responsibilities

• Supports the Institutional Review Board (“IRB”)

• Assists PIs and research community in minimizing risk to human subjects

• Ensures compliance with federal law and NU policy regarding human subject research

• Responds to allegations of human subject research non-compliance

• Conducts quality assurance and training
OECC Responsibilities

• Establishes and oversees a centralized resource ensuring university compliance with the various export control regulations

• Provides education and outreach

• Partners with offices across both campuses to ensure a unified approach and message regarding compliance

• Maintains records demonstrating steps taken to comply with the regulations

• Conducts restricted party screenings
Research IT Strategy & Operations

- Identification and implementation of research technical solutions and infrastructure
- Champions the application of IS solutions and technologies to the Northwestern research enterprise
IACUC Office Responsibilities

• Supports the Institutional Animal Care and Use Committee (“IACUC”)

• Works with CCM to protect welfare of animal subjects

• Ensures compliance with federal law and NU policy regarding animal subject research

• Inspects animal facilities and laboratories

• Responds to allegations of animal subject research non-compliance

• Conducts post-approval monitoring and training
NUCOI Responsibilities

- Oversees and implements the University faculty and staff conflict of interest policies and procedures

- Ensures University compliance with applicable conflict of interest regulatory requirements

- Provides guidance and support to the University community regarding conflict of interest policies, systems, standards, and procedures

- Administers and supports the activities of University Conflict of Interest Committees
ASRSP Responsibilities

• Financial status reports, sponsor reimbursements, and award close out
• Approve transactions over 90 days
• Coordinate audits
• Inventory government-titled equipment
• Administer effort certification process
• Process subcontract invoices
• Promote compliance with policies
Effort Reporting Responsibilities

- Work with Effort Coordinators to enable quarterly effort certification
- Maintain Effort Reporting System/Committed Effort Management (ERS/CEM)
- Provide training on effort reporting policies and ERS/CEM
- Work with OSR/departments to resolve issues/answer questions
- Coordinate communications to sponsors regarding changes in effort, personnel status, and significant salary changes
- Assist in cases with high commitments of effort
Cost Studies Responsibilities

• Development and negotiation of the university F&A Rate
• Analysis of F&A cost allocation, fringe benefit costs, etc.
• Oversight and analysis of recharge activities
• Monitor compliance with A-21 cost accounting practices
• Distribution of the *Monthly Indirect* Cost Report
• Determination of cost transfer policies and review of cost transfers
• Review of selected sponsored project expenditures
Research Centers

NU President

NU Provost

Office for Research

Respective School Dean

University Research Centers

School Based Research Centers

http://www.research.northwestern.edu/centers
Science in Society

- Science outreach events
- Science in Society magazine
- Scientific Images contest
- One-on-one training in effective written and oral science communication with faculty, staff, and graduate students
- Partners with Chicago-area schools and community groups
Questions?
Policies & Procedures

Beth Irwin
Research Training Manager
Office for Research Integrity
bethirwin@northwestern.edu
Regulatory Pyramid

- Federal Policies
- Sponsor Specific Policies
- University Policies & Procedures
- Contract Terms
- Grant or

Policy & Procedure
Federal Policies

• For Example:
  
  – Office of Management and Budget (OMB) Omni Guidance:
    
    • A reform that supersedes and streamlines language from eight existing OMB Circulars into one consolidated set of guidance.

    • Applied to audit periods starting on December 26, 2014.
Sponsor Specific Policies

NIH Grants Policy Statement (GPS)

• Contains:
  – Policy requirements that serve as the terms and conditions of NIH grants
  – Info on NIH as an organization
  – NIH grant process

NSF Grants Policy Manual (GPM)

• Contains:
  – Policies and procedures used by grantees and NSF
  – NSF award process
  – Guidance for unique grant requirements


Sponsor Specific Policies

Federal Demonstration Partnership (FDP):

• Cooperative agreement between federal agencies and awardees
• Established to increase research productivity
• Minimizes the administrative burden on principal investigators
• Gives designated Universities more freedom to manage federal awards
• NSF is the host of participating agency documents relating to FDP

For Example:
•

http://sites.nationalacademies.org/PGA/fdp/PGA_055518
University Policies & Procedures

- Focused on establishing how NU complies with federal guidelines

- For Example:
  - A-21 establishes a need for effort reporting
  - NIH GPS and NSF GPM further define expectations
  - NU must determine how to meet these guidelines via its Effort Reporting Policies
    - Issued June 2004
Grant or Contract Terms

• The grant may specify even more detailed terms, conditions, and research administration procedures

• For Example:

  1. Carry Forward Balance

  2. Human Research Participant Training
Questions?

“Are these just guidelines, or are they actual new policies?”

“I think it’s time we established new guidelines for corporate behavior.”
Networking/Break
IRB Role in Research

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

It is not to annoy researchers.
The structure of the NU IRB
NU IRB Facts

- >10,000 Submissions a Year
- 6 IRB Review Boards (2 Campuses)
- Avg. 655 Studies Reviewed at Panel each Year
- Research Distribution: 60% Bio/40% SB)
Four administrative areas:

- IRB
- Post Approval Monitoring
- Special Projects
- Training and Education

Human Research
Northwestern IRB Affiliated Partners

Northwestern Medicine (NMFF, NMPG, NMH)

Rehabilitation Institute of Chicago

Lurie Children’s Hospital

Research Privacy Board
Why do we need IRB?
Timeline of Events

Explore the Timeline by clicking on an event.

- Willowbrook Hepatitis Study
- Humphrey “Tea Room Trade” study
- Stanford Prison Study
- Tuskegee
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.
The IRB evaluation of the conduct of research involves:

- Codes of Ethics
  - Standards of practice
  - NU HSPP 5.0

- Legal / Regulatory Standards
  - CFR, FDA, FERPA, HIPAA, MHDDCA, etc.

- Academic / Professional Values
  - Belmont

- Ethical decision making
  - Moral philosophy
  - Framework for ethical decision making
  - Moral Virtue
IRB Ethical Responsibilities

Belmont Report (1979)

3 Ethical Principles

1. Respect for Persons
2. Beneficence
3. Justice
Trust is the highest honor and obligation in research
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 Considerations: Tool: HHS Determination Decision Charts
## IRB Review Categories

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Description</th>
</tr>
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</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)                                                |

*Tool: Exempt and Expedited Categories Comparison Chart*
.111 Regulatory Criteria

- Participant Selection
- Vulnerable Populations
- Voluntary Consent
- Benefits
- Risks
- Research Design
Speaking “IRB”
What the IRB is looking for:

1. Risks to participants are minimized.
2. Risks 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. The research methodology is reasonable and will accomplish the purpose of the study.
10. Participants are fully debriefed if deception used.
Special considerations for International Research:

- Observation, privacy, and boundaries in the field
- Cultural sensitivity in recruitment, consent and data collection.
- Data management plan to protect confidentiality.
- Researching illegal activity
- When there are two IRBs involved

Special considerations with Internet Research:

- Private v public forum
- Is it just text or is it a ‘person’?
- Who owns the information on the Internet?
NU IRB Submission Process

- PI Submits New Application
- IRB Coordinator Pre-Review
- Assigned to Reviewer or Panel
- Approval Criteria Met?
  - Modification Required for Formal Review
  - Changes Requested
  - Post Approval Modifications
    - Continuing Review
    - Reportable new information
Quick Quiz: Which study meets the definition of research with human participants?

A. A researcher plans to conduct a linguistic study of comments posted on a local public blog.

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

C. A researcher 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 women students in engineering with the proposed outcome consisting of a report of recommendations for the department.
Which are the ethical pros and cons of:

Recruitment of participants using:
1. Paper flyers or posters posted on bulletin boards
2. Email solicitation
3. Craigslist
4. Facebook
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 (BioMedical): 312-503-9338
- General IRB queries: irb@northwestern.edu
- eIRB assistance/queries: eirb@northwestern.edu
- Compliance queries/issues: irbcompliance@northwestern.edu

- Social and Behavioral IRB: 847-467-1723
QUESTIONS?
Institutional Animal Care & Use Committee (IACUC)

Heidi Levin
Senior Coordinator
The IACUC Office – Office for Research
h-levin@northwestern.edu
Humans and animals have many comparable physiological processes. Genetically modified animals, usually mice, can be bred to increase these similarities with humans.

**Basic** research (compared to **applied**) provides the underpinnings for development of new medical and veterinary treatments.

New medical treatments are required by law to be tested on animals before entering human clinical trials.
For example:

- In the early 20th century, most medical professionals suspected polio was an infectious disease, but had little proof. In 1908, investigators used extracts from the spinal cord of a boy who had died from polio to replicate the disease in *monkeys*. In 1955, announcement came of a successful polio vaccine for humans.

- In the 1970s, *armadillos* were used to develop antibiotic treatments and vaccines for leprosy.

- Today *cats* are used to understand deafness and to develop effective therapies to treat it.
Why is there an IACUC?

- To regulate the use of animals in research
- To provide protections for animals used in research
- To assure ethical standards of research with animals are maintained

The IACUC ensures research personnel are trained to conduct animal research *in a humane manner.*
The IACUC balances the possible harm to an animal against the potential benefit of the research involving each animal.

The IACUC makes recommendations to improve animal welfare. *Better standards of animal welfare produce better quality research.*
The IACUC encourages investigators to discover alternative methods when applicable by:

- **Replace** animals with other research methods
- **Refine** procedures to minimize potential pain/distress
- **Reduce** animal numbers
Regulatory Agencies

Organizations ensuring humane care and use of animals in research:

- The United States Department of Agriculture (USDA)
- The Public Health Service (PHS)
- The Office of Laboratory Animal Welfare (OLAW)

Northwestern has chosen to request accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)
IACUC Shared Responsibility

- Institutional Responsibility
- PI/Research Team Responsibility
- CCM Responsibility
- IACUC Responsibility
- Humane Treatment of Animals
The IACUC Committee

Expert Consultants
Office for Research Safety
Office for Research Reps
Community Members
Veterinarian
Faculty

Animal Subject Protection
The IACUC Office Personnel

- Director
- Laboratory & Facility Inspection Coordinator
- Department Assistant
- Post Approval Monitoring Department Assistant
- Post Approval Monitoring Coordinator
- Administrative Coordinators

Animal Subject Protection
## IACUC and CCM

**Center for Comparative Medicine (CCM)**

- Maintains animal facilities on both campuses
- Provides veterinary care to animals

**Institutional Animal Care and Use Committee (IACUC)**

- Reviews research protocols on both campuses
- Evaluates the animal care program
- Inspects the central animal facilities and labs where animals are used twice a year
Training

Institutional Animal Care and Use Committee

Training & Occupational Health Safety Program

PROTOCOL REQUIREMENTS for PERSONNEL APPROVAL

IACUC Training Services and Occupational Health Safety Program (OHSP)

All project investigators and research staff handling and caring for animals are required to take the basic IACUC on-line training and be enrolled in the Occupational Health and Safety Program (OHSP). In addition, anyone seeking facility access (CCM) or having contact with animals must be listed on an approved protocol.

Training Services

All Principal Investigators (PIs) and research personnel must complete the basic on-line training provided through the AALAS Learning Library.

- Contact Bruce Roberts at OPRS/IACUC at 312-503-0330 or 312-503-2818 or by e-mail at b-roberts@northwestern.edu. Provide the spelling of your name and he will assign a Username and Password. You will then have a Northwestern University account with AALAS Learning Library, which you will need in order to take classes.

http://www.northwestern.edu/oprs/acuc/trainingOHSP/
Protocols are reviewed by Designated Review or the Full Committee

- **Designated Reviews** are completed by at least two committee members and a veterinarian

- **Full Committee Review** involves primary and secondary reviewers presenting to the full committee
IACUC Review Process

1. PI submits the study application to the IACUC.
   - Application reviewed by IACUC coordinator for completeness.
2. Application is assigned to Designated or Full Committee review.
   - Application may require clarification or modification.
3. Application is approved.
   - Application is returned to the PI for revisions and resubmission.
4. Revised application is returned to the IACUC for re-review.
   - Process continues until Reviewers are satisfied.

Bubble Color Legend:
- PI Action is Required
- IACUC Action
IACUC Approval

- The IACUC approves protocols for a three year period, even if sponsored funding is for a longer term.

- Protocols involving work with **USDA covered species** must be submitted for annual re-certification.

- A **de novo protocol** must be submitted to the IACUC prior to the end of the three year approval period to avoid inactivation.
What Does It Mean to Be Approved?

The project may begin!

- The PI may order animals (through CCM)

- Project personnel may gain access to the animal facilities (through CCM)

- The PI works with OSR to open accounts to spend their grant money
A Numerical Summary

In the last 12 months, the IACUC approved approximately:

- 280 new protocols
- 840 addenda requests

Approximately 800 protocols are active
June 2015 Census

Total Mice and Rats

- Rats
- Mice
Questions?

Contact ACUC:

Phone: (312) 503-9339
Email: acuc@northwestern.edu
Center for Comparative Medicine (CCM)

Jeremiah Dunlap
Assistant Manager, Quality & Training
Center for Comparative Medicine
What is ‘comparative medicine’?

“A field of study concentrating on similarities and differences between veterinary medicine and human medicine”

At its most basic level, it is the study of animals to learn more about humankind.

First chair of comparative medicine was appointed in 1862 in France.

AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care, International) accredited since 1985.

Member of AALAS (American Association for Laboratory Animal Science) since 1962.
CCM’S Mission

• The service and teaching unit supporting all animal use in research, testing, and education at Northwestern University

• Animals are housed either in CCM facilities or in facilities administered by academic departments for which CCM provides the primary care and oversight
Types of Animal Facilities

- **Centralized**: Animal care is handled by a dedicated, wholly separate department
  - The Center for Comparative Medicine (CCM) is a centralized operation

- **Decentralized**: Every department using live animals for research are responsible for the housing and care of these animals
  - Necessitates separate animal facilities and operating budgets
Basic Functions

- Issue monthly bills for animal orders, per diem charges, and any incurred special service charges
- Train research personnel in animal care & experimental procedures
- Provide for the welfare and care of all research animals
  - Provide access to animal housing areas
- Work with the IACUC to review and approve Animal Study Protocols (ASPs)
Partnership with the IACUC

• IACUC and CCM work together to:
  – Review, approve, and provide assistance with ASPs
  – Perform semi-annual inspections
  – Generate/modify policies
  – Generate/modify training

• New research personnel work with both the IACUC and CCM
How is CCM Organized?

- Veterinary
- Husbandry
- Procurement, Receiving, Census
- Business
- Quality & Training
Veterinary Staff

• Mandatory members of an IACUC committee

• Provide training on and assistance during study-related procedures

• Manage surgical suites and other facility resources

• Organize quarantine and rodent sentinel programs

• Organize enrichment program for all research animals
  – Implement certain enrichment for USDA-covered species

• Treat animal health problems
Husbandry Staff

• Comprised of Animal Care Technicians (ACTs), Cage Wash Technicians, and their supervisors

• Perform daily checks on every animal housed in CCM facilities

• Report animal health problems to the Veterinary Staff

• Clean, stock, and otherwise maintain CCM facilities

• Work with the Procurement, Receiving, & Census (PRC) Office to capture weekly census of all research animals
PRC Staff

- **Procurement**: Place orders and provide updates of new research animals
- **Receiving**: Initially receive shipments of animals
- **Census**: Maintain a database tracking all animal housing
Sample Census Graph

Daily Cage Count SnapShot

2011-XXXX; Housing Type, AHR#

2011-XXXX; Housing Type, AHR#
Business Staff

- Uses information collected by PRC to bill laboratories on a monthly basis

- Bills are comprised of per diem costs, fees, and any special service charges
# Monthly Billing

## Protocol Bill

- **Billing Month:** MAY 2011
- **Billing Cycle:** 05/1/2011 - 05/31/2011
- **Protocol:** 2011-XXXX
- **Account:** [redacted]
- **Date Paid:** June 21, 2011

### Per Diem Charges

<table>
<thead>
<tr>
<th>PI Last Name, First Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
</tr>
<tr>
<td>Rat</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>Total Case Days</th>
<th>Rate</th>
<th>Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>104</td>
<td>$6.95</td>
<td>$667.20</td>
</tr>
<tr>
<td>Rat</td>
<td>120</td>
<td>$1.56</td>
<td>$187.20</td>
</tr>
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</table>

**Per Diem Sub-Total:** $2,574.40

### Animal Orders

<table>
<thead>
<tr>
<th>PI Last Name, First Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received Date</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>05/11/2011</td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Animal Order Sub-Total:** $1,330.45

**Protocol Bill Total:** $1,837.41
Quality & Training Staff

- Provide orientation sessions for new research personnel

- Provide training on:
  - Specific pieces of equipment
  - Technical procedures
  - Work in specific areas within the animal facility

- Train other CCM staff members at least once per month

- Setup security access for anyone entering the vivarium

- Coordinate TB testing for anyone accessing areas with non-human primates
Welcome

The Center for Comparative Medicine (CCM) is the centrally administered animal resource that acts as the service and teaching unit supporting all animal use in research, testing, and education at Northwestern University. Animals used in biomedical research at Northwestern University are housed either in CCM facilities or in facilities administered by academic departments for which CCM provides the primary care and oversight. CCM has been AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care, International) Accredited since 1985 and a member of AAAS (American Association for Laboratory Animal Science) since 1962.

The Spring 2015 issue of CCM Speaks

- Update - RFID Application for Animal Census
- New Features in Chicago’s Containment Suites
- Blood Collection in Mice - Cardiac Puncture
- Pain Management: Buprenorphine HCL vs. Buprenorphine Sustained Release (SR)
- Monthly Satellite Visits
- Chronic Quarantine - Frequently Asked Questions
- The Cost of Caring: Human Emotions in the care of Laboratory Animals
- Did You Know? Biometric Wristbands
- IACUC Policy Release - Working with Human Derived Materials in Rodents
- CCM Office Renovations
- Previous Issues

CCM Business Office News and Announcements

CCM periodically contacts Principal Investigators and their staff with important announcements via email. If you would like to receive these messages, please contact ccms@northwestern.edu.

Archived Announcements are available to those currently listed on an active protocol as well as CCM and IACUC staff.

FY15 Per Diem Rates and Service Charges

Guide to CCM Cage Cards

In our efforts to continually improve communications between the Center for Comparative Medicine (CCM) and laboratory personnel, CCM has developed a "Guide to CCM Cage Cards." This document prints best on 11 x 14 paper. Poster size versions of this document are also hanging in the Lurie and Ponce animal facilities after July 12, 2012.

http://www.research.northwestern.edu/ccm
Online Resources

• Online training provides easy access to important information
  – Can be viewed as often as one wishes, in a quick but secure fashion
  – Especially convenient for research personnel on the Evanston Campus

• Animal User Manual provides a comprehensive source of information on many different CCM operations
  – Great resource for new PIs and their staff
Online Resources (continued)

- CCM Speaks is a semiannual online newsletter packed with an assortment of useful articles.
- Information on and access to CCM’s Rodent Technical Service Unit (RTSU) is also available on the website.
Questions?
The NUCATS Institute

Speeding transformative research discoveries to patients and the community
What Is NUCATS

NUCATS: Northwestern University Clinical and Translational Sciences (Institute).

We are a collaboration between Northwestern University and its clinical partners: Northwestern Medicine®, Ann & Robert H. Lurie Children’s Hospital of Chicago and the Rehabilitation Institute of Chicago

Our goal is to promote Northwestern's culture of collaboration, innovation and translation through team-building, education, and training to empower the multidisciplinary translational research teams of tomorrow.

We are the infrastructure that makes it easy for researchers and research support staff to find and utilize all the available services at Northwestern and beyond.
Center for Education and Career Development (CECD)

- **Graduate Education:**
  - Master of Science in Clinical Investigation (MSCI)
  - Master of Science in Regulatory Compliance (MSRC)

- **Career Development Awards (KL2 & TL1)**

- **Early Career Faculty Development Programs:**
  - First Mondays Faculty Development Seminar Series
  - Responsible Conduct of Research Training (required by NIH)

- **Mentor Development Workshops & Feinberg Mentor Development Academy**

- **GCP and Research Staff Training (Live & Online Education)**

- **Team Science**
Center for Clinical Research (CCR)

- Study budget preparation, billing and reconciliation support
- Regulatory compliance support
- Research participant recruitment assistance
- Clinical research nurse and non-nurse coordinators for hire
  - Part-time or full-time
- Clinical Research Unit (CRU)
  - Ann & Robert H. Lurie Children’s Hospital of Chicago
  - Northwestern Memorial Hospital (NMH)
  - For inpatient and outpatient visits (bionutrition, core laboratory and nursing services)
Meet Dennis West, PhD
Professor in Dermatology and Pediatrics-Dermatology

• **Research project(s):** Dermatology clinical and translational research studies (among the largest units in the U.S.)

  – **Research needs:** Management of 150 actively funded and/or investigator-initiated human research studies under IRB purview for Dermatology at Lurie Children’s Hospital and at Northwestern

  – **NUCATS solution:**
    – Center for Clinical Research services including:
      • Regulatory (local and federal), Recruitment (targeted media and web based) and Financial (income and expenses) management
    – CRC Basic Training for all authorized research personnel
    – NITRO Study Tracker for study management software

  – **Outcome:**
    – IRB compliant studies with subject accrual goals met
    – Formally trained research staff in Good Clinical Practice
    – Electronically recorded research subject data

  “The Center for Clinical Research has quite successfully been able to meet the challenges associated with rapid and large expansion of human research projects while maintaining compliance and effectively meeting subject accrual goals. This has been a “win-win” partnership for Dermatology and NUCATS,” said Dr. West.
Center for Translational Innovation (CTI)

- Partnered with INVO to create CTI
- Support for new drug and device development
  - New Venture Kit
  - Commercialization Clinic
  - SBIR/STTR Information Sessions
  - Chicago Innovation Mentors (CIM)
  - Entrepreneurs-in-Residence
- Funding and Pilot funding opportunities
  - NITRO Competitions
  - Across NU and beyond
Meet Jonathan Gunn, JD, PhD
Adjunct Professor, NU School of Law

- **Research project:** Develop a technology that detects blood vessels and other sensitive tissues during surgery

- **Research needs:**
  - Internal and external connections
  - Introduction to animal study facilities
  - Business approach and market need validation

- **NUCATS solution:**
  - Chicago Innovation Mentors
    - Created first NU fellowship position with CIM to help with project
    - Assisted in evaluating and interviewing potential research candidates
  - Connection to surgeons for market need validation and N-CASE for early animal testing
  - Fostered a relationship with Insight Product Development

- **Outcome:**
  - Turned idea into functional technology; Formed Briteseed and raised over $1M
  - Competition awards from Techweek, Rice Business Plan, Chicago Innovation, New York City Health, EMT Summit, NCIIA/VentureWell, iBIO PROPEL, Kauffman, and SPIE

"NUCATS walked along side us as we transformed from researchers into entrepreneurs and turned our idea into a company," said Dr. Gunn.
Center for Data Science and Informatics (CDSI)

- Secure, web-based applications for studies
  - REDCap (Research Electronic Data Capture): Data Collection Forms
  - NITRO Study Tracker (formerly eNOTIS): Clinical Trial Management System
  - NITRO Recruit (formerly Registar): Research Registry System

- Analytics Services
  - Advanced Bioinformatics and Bio-Computation (ABBC) Core: Big data and computation support
  - Northwestern Medicine® Enterprise Data Warehouse (NMEDW) and i2b2: Repository of clinical and research data from NU healthcare affiliates
  - Biostatistics Collaboration Center (BCC): Support for biostatistical, epidemiological, programming, and data management needs

- Education and Training
Meet Emilie Powell, MD/MBA
Assistant Professor in Emergency Medicine and Center for Healthcare Studies

• **Research project:** Improve sepsis care in the ED
• **Research needs:** Identify quality metrics that were not being met and why
  – **NUCATS solution:** Collaboration with NMEDW Data Analysts to identify 376 patients with severe or septic shock over a 2-year period and gather demographics, vital signs, lab values, and more
  – **Outcome:**
    – Published findings in American Journal of Emergency Medicine in 2013
    – Collaborated with Dr. David Salzman to create a real-time simulation of a sepsis patient’s presentation at the ED
    – Translated simulation findings into a high-fidelity patient simulator to train EM residents-in-training

"The information about sepsis patients from the NMEDW was very powerful, enabling Dr. Salzman and I to create a realistic patient case simulation and plug it directly into the workflow of the ED to get a better grasp of the real-time influencers of care," said Dr. Powell.
• **Clinical Support**
  – Clinical Informationists
  – Systematic Review Services
  – Clinical Key License

• **Research Services**
  – Computing cluster
  – Consultations
  – Training and Workshops
    • EndNote and PubMed
    • Creating Posters with PowerPoint
    • NIH Public Access Policy and Publication Management
    • Computational Skills for informatics
    • Galaxy

• **Scholarly Services**
  – Impact and Evaluation
  – NIH Public Access Policy
  – New NIH biosketch requirements

Galter Health Sciences Library
Meet Amee Seitz, PT/PhD
Assistant Professor in Physical Therapy and Human Movement Sciences

- **Research project(s):** Treatment outcomes of individuals with upper extremity musculoskeletal disorders
- **Research needs:** Revising K23 grant and submitting for New Investigator Foundation Training Initiative (NIFTI)
  - **NUCATS solution:**
    - Biosketch review with Galter Library’s Metrics and Impact Core
    - CECD Navigator consultation for connection to:
      - 1st Mondays Faculty Development Seminar Series & Grant Writers Groups
      - RCR syllabus and boilerplate language and CECD resources statement
      - Referral to MSCI, BCC, and Voucher and Pilot Programs
  - **Outcome:**
    - Robust didactic training sections that utilizes CTSA infrastructure
    - Compliant biosketch that meets new NIH biosketch format requirements and reinforces impact of science
    - NIFTI fellowship ($73,000 plus $5,000 stipend over two years)

“...resources to assist with preparation of my grants and found these to be outstanding. The weekly grant writers group with Rick McGee, the library specialists’ consultation service and the formal research training offered to junior investigators have all strengthened my proposals. I know this will help me meet my funding and ultimately my long-term research career goals,” said Dr. Seitz.
Center for Community Health (CCH)

- Supported by IPHAM and NUCATS
- Patient and stakeholder engagement
- Partnership brokering and development
- Workshops, seminars and programs on community and stakeholder engagement
- Seed grants offered through the ARCC and PBR programs for community-academic research teams
- Community-engaged research proposal review and support
- Consultations for design and implementation of community engaged/based projects
Meet Shyam Prabhakaran, MD
Associate Professor in Neurology

• **Research project:** Address stroke disparities in Chicago
• **Research needs:**
  – New approach to making an impact in stroke behavior in the south and west sides of Chicago
  – Guidance on community-engaged research and preparing a PCORI application

  – **NUCATS solution:**
    – ARCC workshop on community review processes to gather feedback from community-academic teams
    – Connections to ARCC community-academic partners and volunteers for community advisory board
    – Collaboration to develop a PCORI grant

  – **Outcome:** 3 year, $1.4 million PCORI grant

“I knew Dr. Ackermann and Jen Brown were experienced in community-engaged research (CER). When we discussed the project and their services, we knew we could collaborate together on a PCORI grant. Our committee members were not familiar with CER methods prior to this and they guided us through the learning curve,” said Dr. Prabhakaran.
Clinical & Translational Research Program at Stanley Manne Children’s Research Institute of Ann & Robert H. Lurie Children’s Hospital of Chicago

- Resources and services for Lurie Children’s researchers
- Research Scientist Navigator
- Coordinator and Research Staff Services Pool
  - CRCs can be deployed on an hourly basis according to study needs
- Discounts for biostatistical support
- Pilot funding
- Business Associates Agreement for REDCap utilization
- IRB Authorization Agreement for joint review panel
  - For studies that involve both adults and children
Services NUCATS Offers

*Navigator Consultation Form

- You can contact one of our navigators by requesting a NUCATS consultation: 
  [http://www.nucats.northwestern.edu/request-a-nucats-consultation.html](http://www.nucats.northwestern.edu/request-a-nucats-consultation.html)

REQUEST A NUCATS CONSULTATION

Not sure who to contact in NUCATS? Let us know which areas you need more information or help and one of our Research Navigators will contact you.

- [ ] First Name *
- [ ] Last Name *
- [ ] Email *
- [ ] Phone

Please contact me or send me information about: *
- [ ] NUCATS Overview Consultation
- [ ] Pilot Funding
- [ ] Collaboration Resources
- [ ] Education, Career Development and Mentoring
- [ ] Community-Engaged Research
- [ ] Recruiting for Clinical Trials
- [ ] Regulatory Support
- [ ] Biomedical Informatics
- [ ] EDW - Enterprise Data Warehouse
- [ ] Data Management
- [ ] Clinical Research Resources
- [ ] Ann & Robert H. Lurie Children's Hospital of Chicago Investigator
- [ ] Commercialization and Entrepreneurship
- [ ] Research Studio Consultations
- [ ] Other
Services NUCATS Offers

*NUCATS C&T Research Studio Consultations:*
– For investigators in the planning stages of a new program or center grant at NU and affiliate organizations
– Brings together leadership from NUCATS and our affiliates to identify relevant resources that support and enhance grant submissions
– Opportunity to leverage in-kind or heavily subsidized existing NUCATS resources and services

*Chicagoland Clinical and Translational Science Award (CTSA) Shared Resources:*
– NU, University of Chicago and University of Illinois in Chicago CTSAs are committed to providing seamless access to all relevant resources for translational researchers
– Investigators and research staff at Chicagoland CTSAs have access to each institute’s shared resources and services
– Universities are also partners in the Open Access Initiative that allows access to each other’s core facilities
Meet Richard D’Aquila
Professor in Medicine-Infectious Diseases

- **Research project**: Center for AIDS Research P30 NIH grant
- **Research needs**: Infrastructure and collaboration support
- **NUCATS solution**: Studio Consultation that identified the following to support grant application:
  - Connections to University of Chicago
  - Software tools: NITRO competitions, NMEDW, NITRO Recruit
  - Core Facilities Open Access Initiative
  - Biostatistics support
  - Early Career Faculty Development workshops
  - Clinical Research Unit
  - Community engaged research support
  - Impact and evaluation consultations
  - Research Navigation
  - Voucher and Pilot Programs
- **Outcome**: 5 year, $6.25 million P30 NIH grant

“The NUCATS Studio opened my eyes to all that NUCATS offers and how we could leverage existing infrastructure. They helped with every core in our application. We didn’t have to re-invent the wheel, duplicate services or spend grant money on resources that already existed,” said Dr. D’Aquila.
Services NUCATS Offers

*myNUCATS: NUCATS Membership Portal

- Become a member for access to all free services, plus enhanced services and resources that are only available to members (funding opportunities, vouchers for services, etc.)
- It takes less than 60 seconds to become a member

https://membership.nubic.northwestern.edu/people/sign_in
Cite and Acknowledge the CTSA

• NUCATS Institute provides essential infrastructure, resources and services at NU to support the translational research enterprise through the CTSA grant

• Publications are the key metric that Congress, the NIH, and NU use to demonstrate effective use of grant funding

• When you site the NUCATS grant in your publication you help NUCATS, NU, Yourself and NIH

• Learn how to link your research results: nucats.northwestern.edu/about/ctsa-resources.html
Key Takeaways

• NIH expects researchers to leverage CTSA infrastructure in grant applications

• Researchers who utilize CTSA infrastructure are more competitive for federal funding

• NUCATS Navigators are here to assist you at any stage of the biomedical research pipeline

• Join myNUCATS to stay connected and for access to NUCATS resources and services

• Cite and acknowledge the NUCATS CTSA to continue to have essential infrastructure at NU
Contact Information

Camille Vicino, NUCATS Marketing and Communications
• Rubloff, 11th Floor
• 312-503-2229
• Camille.vicino@northwestern.edu

Andrea Minogue, Administrative Director
• Rubloff, 11th Floor
• 312-908-1721
• a-minogue@northwestern.edu

http://www.nucats.northwestern.edu
Questions?
INVO | Innovation and New Ventures Office

Sonia Kim, PhD
Manager, Marketing & Industry Partnerships

Nicole Janovick, PhD, JD
Intellectual Property Associate
What is INVO?

Innovation and New Ventures Office

Prior to 2011, Tech Transfer Program (TTP)

What is Tech Transfer?
THIS IS NOT TECHNOLOGY TRANSFER.
Technology Transfer

Tech transfer activities focus on moving technology from the University to the public domain

• Grants received by University researchers from government agencies funded with taxpayer dollars

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

• Licensing helps inventions reach commercial potential and returns them to the public domain to do good
What INVO does:

1. Evaluate inventions and assess the market opportunity
2. Protect inventions
3. Market inventions to industry
4. Negotiate licensing agreements
5. Provide commercialization resources for start-ups
Moving inventions toward commercial applications

**TRANSLATION**
- Center for Developmental Therapeutics (CDT)
- Center for Device Development (CD2)
- NU Clinical & Translational Sciences (NUCATS)
- NU Funding Opportunities

**TRANSACTION**
- Disclosures
- Intellectual Property
- Agreements
- Compliance

**COMMERCIALIZATION**
- License Inventions to Companies
- Partner with Companies, Investors & Advisors
- Start-up Companies
- Commercialization Clinics
DISCLOSURE
A record of an invention, the inventor(s) involved, sponsorships, and other public disclosures and publications

ONLINE VIDEO
- What?
- When?
- Where?
- Why?
- How?
INVO Forms

- Invention Disclosure Form
- Copyright Disclosure Form - Includes but not limited to literary and artistic works
- Software Disclosure Form - Includes but not limited to source code
- Research Tool Disclosure Form
- Disclosure Assessment Form
- Confidentiality Disclosure Agreement Forms (CDAs)
- Student Petition to Release IP
- Internship Petition to Release IP

Related Forms
INVENTION DISCLOSURE FORM

NU #: ____________

Date Received: ____________

Please COMPLETE, SIGN and SEND with any relevant attachments by EMAIL to: invodisclosure@northwestern.edu

INVENTION TITLE

INVENTOR(S)
- Please place an asterisk next to the principal investigator's name.
- List all inventors, inside and outside Northwestern, and where they were employed at the time of invention and investigation.

<table>
<thead>
<tr>
<th>NAME (first, middle initial, last)</th>
<th>NU SCHOOL or Joint Institution</th>
<th>DEPT. OF APPOINTMENT (or Division if Medical)</th>
<th>POSITION</th>
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SOURCES OF SUPPORT, RESEARCH SPONSORS AND GRANT NUMBERS

* All Funding Sources and Grant Numbers must be correct. If applicable, please include subcontract information corresponding to the funding listed. Please list all digits in funding sources and grant numbers, including zeros.

** Definition of Primary Agency: Federal agency that provided the greatest contribution to the invention. It is usually determined by the percent of contract or grant funding.

PLEASE CHECK THE WEBSITE FOR UPDATES
USE MOST RECENT FORMS
Common Issues that Slow Down Disclosure Processing

• Distinguishing between inventorship and authorship

• Accuracy of data for invention’s funding sources

• Thorough completion of inventor information
  (address, phone, email, NU ID number, citizenship)

• Signatures for all inventors
Disclosure process

- Invention Disclosure Submitted to INVO
- Inventor Meeting to Discuss Disclosure
- Patentability Assessment
- Market Research & Commercialization Assessment
- IP Protection Strategy & Commercialization Recommendations
INVO INVENTION MANAGEMENT TEAM:
- Oversees invention from cradle to commercialization
- Provides technology, legal, and commercial expertise
- Decides whether to pursue patent or not
- Protects intellectual property

PATENT COSTS:
- $25,000 to $35,000 over U.S. patent life*
- US Patent and Trademark Office (USPTO) fees
- Patent attorney/agent costs

*over $100,000 for foreign coverage
COMMERCIALIZATION
Plan to determine best path to bring the technology to the public domain
• License to an outside company or a start-up

INVENTION MANAGERS:
• Discuss with inventor
• Consult with industry experts and potential investors

TYPICAL CRITERIA FOR PLANS
• Risk Factors
• Technical Issues
• Market Area
• Financial Resources
• Regulatory Hurdles
• Management Capabilities
• Licensing Potential
LICENSING TO AN OUTSIDE COMPANY

- What companies are within this technology sector?
- What individuals at these companies does INVO have contact information for who would be able to evaluate for licensing opportunity?
- Market and promote technologies via INVO’s website, emails and company visits
LICENSENG TO A START-UP

• Faculty interests and background in the commercial space
• Potential commercialization partners
• Match faculty with entrepreneurs and local organizations like Chicago Innovation Mentors (CIM)
• Offer resources for startup grants (SBIR, STTR)
MOST IMPORTANT TAKE-HOME:

Be sure you disclose to INVO as early as possible.

If you aren’t sure, please contact us.
Sonia Kim, PhD
Marketing Manager, INVO
sonia.kim@northwestern.edu

Nicole Janovick, JD, PhD
Intellectual Property Associate, INVO
nicole.janovick@northwestern.edu
ORS Office and Contact Information

Evanston: Tech NG-71, 847-491-5581
Chicago: Ward B-106, 312-503-8300
E-mail: researchsafety@northwestern.edu
ORS Leadership

Michael B. Blayney, Ph.D.
Executive Director

Andrea Hall, Ph.D.
Director, ORS Chicago

Markus Schaufenle
Director, ORS Evanston
Why does NU need ORS?

- Identify hazards
- Control risks
- Manage compliance
Regulatory Agencies

OSHA

CDC

IEMA

IATA

NIH

U.S. NRC

Evanston Fire Department

FDA

United States Environmental Protection Agency

Center for Devices and Radiological Health

Research Safety
Consequences of Noncompliance

• Employee exposure to hazards

• Fines

• Loss of funding
ORS Programs

- Biological Safety
- Laboratory and Chemical Safety
- Radiation and Laser Safety
- Emergency Response
- Hazardous Waste Disposal
- Training
Biological Safety

Programs:

• Laboratory Safety Reviews - Chicago
• Recombinant DNA registration
• Human gene transfer
• Bloodborne pathogens
• Infectious agents
• Biohazard waste
• BSL3 laboratories
• Select agents
• Biosecurity
Laboratory and Chemical Safety

Programs:
- Laboratory Safety Reviews - Evanston
- Laboratory Safety and Chemical Hygiene Plan
- Lab design review
- General safe work practices
- Engineering controls
- Personal protective equipment
- Respiratory protection
- Safety equipment
- Hazardous processes
- Chemical Fume Hood Inspections
- Engineered nanoparticles
Radiation and Laser Safety

Program Areas:

Radiation Safety
- Training and Audits
- Radioactive material use authorization
- RAM inventory, accountability, receiving/shipping
- Xray
- Irradiator Security

Laser Safety
- Training and Audits
- Laser use authorization
- Laser Inventory
Emergency Response

- Hazmat response
- Spill kits
- Incident reporting
Hazardous Waste Disposal

Clean Harbors Environmental Services

- Chemical waste
- Biological waste
- Radioactive waste

http://www.research.northwestern.edu/ors/forms/purpleguide.pdf
Training

RESEARCH SAFETY TRAINING

University Faculty, Staff, and Students must have a University NetID and Employee (or Student) ID to complete Safety Training.

Not University Faculty, Staff, or Student? Click Here.

I work in a lab

GO

I don't work in a lab

View Training

LEARN @ Northwestern
Online system designed to inform PIs, Cores and Lab Workers about safety specific to their workplace:

- Regulations
- Engineering controls
- Safe work practices
- Personal protective equipment

https://www.nsis.northwestern.edu
Principal Investigators: If you are new to the University and need to create an NSIS profile, send an email to ors-operations@northwestern.edu. Include your name, NetID, department, anticipated date of arrival, and a contact phone number and/or email address. You will receive email notification once your profile has been set up.
### Safety Evaluation Summary

Here is the summary of your responses to the Safety Evaluation Wizard. To add or remove safety forms, modify the appropriate evaluation question response.

<table>
<thead>
<tr>
<th>Evaluation Question</th>
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<tbody>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use or store hazardous chemicals other than household cleaning chemicals?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use or store compressed or liquefied gases?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use or store controlled substances on DEA schedules?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use animals for research?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use human blood, blood products, body fluids or other potentially infectious materials, including human-derived cell lines?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use biological agents at Biosafety Levels 1, 2, or 3?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you ship hazardous materials or dangerous goods?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use recombinant or synthetic nucleic acid molecules?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Does your work involve Human Gene Transfer?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use select agents?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Does your work involve physical hazards?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use equipment with alarms that would sound after hours?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you currently use radioactive materials or plan to in the future?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use Class 3b and/or Class 4 lasers in your laboratory space?</td>
</tr>
<tr>
<td><strong>Yes</strong>  <strong>No</strong> Do you use x-ray equipment in your laboratory space?</td>
</tr>
</tbody>
</table>
NSIS: Lab Workers

Your "To Do" List
- Complete Hepatitis B Vaccination Consent/Waiver Form
- Complete ORS Safety Training

View PI Safety Forms
- Emergency Information
- Laser Equipment
- X-Ray Equipment
Laboratory Safety Review

- Initial visit for new labs then annual*
- Interview PI/Safety Designate and Lab Workers
- Visual inspection
- Deficiencies require follow-up
Safety Services from Other Depts.

Risk Management
- Fire safety, evacuation plans, workers compensation

University Services
- Purchasing, compressed gases, dry ice and liquid nitrogen

University Police
- Personal safety, security threats and breaches

http://www.research.northwestern.edu/ors/info/whodoeswhat.html
Visitors and Volunteers

- Safety regulations extend to visitors and volunteers
- Training required if the person will work unsupervised
- See Human Resources site

http://www.research.northwestern.edu/ors/training/visitor-volunteer.html
What Now?

- Review ORS website
- Review the Essential Guide
- Acquire Department Administrator access to NSIS
- Review your department info in NSIS

http://www.research.northwestern.edu/ors
Questions?
Conflict of Interest/Commitment

Conflict of Interest Office (NUCOI)

Maria Daniele
Compliance Administrator
maria.daniele@northwestern.edu
Conflicts of Interest & Commitment

<table>
<thead>
<tr>
<th>Conflicts</th>
<th>COI</th>
<th>COI in Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Financial, professional or other personal activities that affect, or <em>appear</em> to affect, a person’s judgment, commitment, or ability in carrying out University duties or responsibilities</td>
<td>• A situation where an individual engages in outside activities, either paid or unpaid, that interferes with his or her primary obligation and commitment to the University</td>
<td>• The risk that an individual’s external financial interests may bias or compromise – or <em>appear</em> to bias or compromise – an individual’s judgment, objectivity, or decision-making in research</td>
</tr>
</tbody>
</table>
COI & COC at Northwestern

3 Disclosure Types:

- **Annual Faculty Disclosure** – completed in the “Joint Affiliate Annual Disclosure” once/year in February by all faculty:
  - FSM faculty of External Professional Relationships Survey
  - All other faculty complete their annual disclosure in FASIS

- **Annual Staff Disclosure** – completed once/year in February by all staff in FASIS

- **Research Disclosure** – completed prior to engaging in research subject to NU’s policy and on an ongoing basis

If a person is an Investigator, their annual survey will contain the research questions to update their research disclosure at least annually.
What Does a COI Look Like?

1. COIs are not necessarily bad
2. Not every external interest is a COI

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
Why Are We Concerned About COI?

1. To protect the objectivity, credibility, and trustworthiness of our research, our research community (i.e., YOU), and our institution.

2. To meet regulations that require the University to have policies and procedures for soliciting disclosure, review, and management of COIs.
In 2011, new regulations were released by the Public Health Service (PHS)

Federal Regulations - in 2011, new regulations were released by the Public Health Service (PHS)

Sponsor Requirements

Institutional Policies

Project Terms & Conditions

COI Regulatory Environment
Applicability of PHS regulations at NU

- NU’s COI policy applies PHS regulations to:
  - PHS agencies
  - Agencies that have adopted PHS COI regulations:
    - NSF
    - All industry-sponsored clinical trials
    - Other sponsors with specific COI requirements

http://www.northwestern.edu/coi/policy/coi_by_sponsor.pdf
Important Terms and Definitions

Investigator

Any individual acting as project director or principal investigator

AND

Any other person, *regardless of position or title*, who is responsible for the design, conduct, or reporting of research.
## Important Terms

### Investigator

<table>
<thead>
<tr>
<th>Role on Project</th>
<th>Investigator?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Personnel</td>
<td><strong>YES - ALWAYS</strong></td>
</tr>
<tr>
<td>Consultant</td>
<td>Individuals in these categories <em>may</em> or <em>may not</em> be Investigators subject to COI requirements.</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>
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</tbody>
</table>

If there is any question as to whether an individual is an Investigator, the PI must confirm the assignment. Department administrators or NUCOI may “deactivate” someone as an Investigator on a particular project in FASIS, with PI affirmation.
Important Terms

Whether someone is an investigator is **not related** to their effort!

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.**
Important Terms

Institutional Responsibilities

• Any activity that is relevant to what you do at Northwestern. Common related activities include:
  – Editing, Scientific Advisory Board, Consulting, Training

• Things that are likely not related to an Investigator’s institutional responsibilities:
  – Retirement funds, Community Involvement (church groups, PTA service), etc.
Important Terms

Institutional responsibilities is a “grey area” –
Example: Your family owns a pizzeria. Disclose or not?

*Does it relate to your teaching, research, or clinical responsibilities?*

- “Getting a bigger piece of the pie: Capturing a larger share of a crowded market”

- Taste research on a secret formula that could be commercialized by your family’s restaurant

- Research on the health benefits of a gluten free crust that your restaurant uses.
What Needs to be Disclosed

New regulations broadened what needs to be disclosed

• Investigators must disclose significant financial interests (SFIs) that relate to any of their institutional responsibilities – *not just interests that may relate to the specific research activity*
Important Terms

Significant Financial Interest (SFI)

An external financial interest, when aggregated for the 12 months preceding disclosure from a single entity consisting of one or more of the specific interests in the definition.
Important Terms

**Significant Financial Interest (SFI)**

SFIs include (see Appendix slides for full definition):

- Any equity in a non-publicly traded company
- Payment*, reimbursed travel*, equity in a publicly traded company†, or IP licensed outside of NU valued at / exceeding $5,000♦

*Excluding federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical center or research institutes affiliated with an institution of higher education

†Excluding retirement accounts and mutual funds

♦FSM has a $0 disclosure threshold for some categories.
Important Terms

Financial Conflict of Interest (FCOI)

An SFI that could directly or significantly affect the design, conduct, or reporting of research
How Do We Handle COIs?

• Disclosure

• Review

• Elimination, reduction, or management
Investigator names are entered into InfoEd in Personnel Section

Investigator names are fed (overnight) into FASIS COI system – New, non-faculty Investigators can now disclose

**Compliance Checkpoint:** Before **submitting** the grant, ALL investigators must have disclosed within the last year (365 days)

InfoEd Proposal Status of the project is updated to “JIT,” “Prespend,” or “Awarded” – this triggers NU COI review of the project

**Compliance Checkpoint:** Before **opening the chartstring**, ALL investigators must have “clear” COI statuses (either “No Conflict” or “Conflict Managed”)
A Note on Prespending

- Prior to drawing funds from the sponsor, a final COI determination must be on record, but prespending accounts can be opened before then, without a determination on file.
Where To Disclose

COI

FASIS COI portal:
https://nupa.northwestern.edu/psp/pa91prod/EMPLOYEE/EMPL/h/?tab=P APP_GUEST
Disclosure Review Process

Proposal can be submitted
All investigators have disclosed

JIT Notification received:
Proposal status set to JIT; NUCOI begins review

NOA is received:
Proposal status set to Awarded; OSR checks for COI determinations

Project can draw funds from sponsor
Disclosures are reviewed, any conflicts are managed & reported

Project Status

Investigator Statuses

Disclosed

NUCOI Status & School Status
No conflict

Disclosed

NUCOI Status
Potential conflict

Disclosed

School Status
No Conflict

NUCOI Status
Potential conflict

School Status
Conflict Managed

Projects are not reviewed until the status is set to JIT, Prespend, or Awarded

NUCOI Reports to sponsor (if required)
Key Compliance Points (Initial)

Investigators:
- ✓ Disclose SFIs
- ✓ Complete COI training

OSR & Departments
- Proposal Submission
- ✓ FCOI determination made
- ✓ FCOI managed, as applicable
- ✓ FCOI reported, as applicable

NUCOI & School Deans
- OSR, ASRSP, & Departments

Funding Released
Key Compliance Points (Ongoing)

Investigators must:

- Disclose new SFIs within 30 days

- Disclose SFIs annually
  - All Staff & Faculty Investigators can now do this during the Annual Disclosure process!

- Complete COI training every 4 years (or more frequently if required)
Tools for Meeting Compliance Points

- FDP Clearinghouse: http://sites.nationalacademies.org/PGA/fdp/PFA_070596

- Monitor Compliance in FASIS: https://nupa.northwestern.edu/
Resources

Forms, Trainings & Tip Sheets!

http://www.northwestern.edu/coi/index.html
Resources

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

- **Policy on Conflict of Interest in Research:**
  - [http://www.northwestern.edu/coi/policy/research_policy.pdf](http://www.northwestern.edu/coi/policy/research_policy.pdf)

- **NU Conflict of Interest Office:**
  - [http://www.northwestern.edu/coi/index.html](http://www.northwestern.edu/coi/index.html)

- **FDP Clearinghouse:**
  - [http://sites.nationalacademies.org/PGA/fdp/PGA_070596](http://sites.nationalacademies.org/PGA/fdp/PGA_070596)
Questions?
Help/Assistance

Northwestern Conflict of Interest Office (NUCOI)

nucoi@northwestern.edu / 847.467.4515

Julia Campbell – Director
juliacampbell@northwestern.edu / 847.467.3938

Kate Cosgrove Booth – Sr. Compliance Analyst
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Maria Daniele – Compliance Administrator
maria.daniele@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 received less than $5,000,

– 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 NU funds
Exclusions to SFI

– Travel remuneration or sponsorship less than $5,000
– 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
– 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
Day 1 is Complete!

Thank you for attending day 1 of the Research Administration Training Seminar!

I will be emailing a brief survey regarding day 1 of this training. Please take a few minutes to fill it out as we are always looking for suggestions for improvement!

The next session is on Thursday, 1/21 at 1:00pm in McGaw Pavilion, Daniel Hale Williams Auditorium. If you have any questions or concerns, please do not hesitate to contact me.