Research Administration Training Seminar
Administrative Business

- Breaks, bathrooms, food
- Slides
- Different presenters
- Purple folder
- Questions/participation
- Survey after each day

• Introduction
Agenda – Day One

• Research roles and responsibilities
• Policies and Procedures overview
• Institutional 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)
• Export Controls
• Conflict of Interest (COI)

• Introduction
Check Your Knowledge

- Introduction
Aired February 12, 2012 and highlights one of the biggest medical research frauds ever.

Potti resigned from his position in 2010 when questions were raised regarding his research on experimental treatments that would match chemotherapy to a patient’s own genetic makeup.

May 2015: Duke University settled lawsuit involving families of eight patients who were treated in clinical trials based on Potti’s discredited work. Terms of lawsuit were confidential.

November 2015: Federal Office for Research Integrity concludes that Potti engaged in research misconduct.
Jay Walsh, PhD, Vice President for Research
Research Administration Training

The need for research administration training exists because of the importance of compliance with regulatory requirements as research funding continues to increase. It also serves to protect research integrity, researchers and research participants, and the public’s trust in Northwestern.

- 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
Fiduciary Duty

- Fiscal Fiduciary Duty:
  - Northwestern University, faculty and staff have a duty to ensure research funding is spent as intended
  - Funding agencies have to rely on institutional and personal integrity
  - Rules and regulations provide us with parameters
  - Regulations will always be a part of research
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
**Research Roles + Responsibilities**

**OVERVIEW**

**WHAT ARE THE RESEARCH ROLES AND RESPONSIBILITIES DOCUMENTS?**

All members of the Northwestern University research community are responsible to uphold the highest standards of ethical and professional conduct as defined in our University policies, procedures and guidelines and sponsoring agency policies and regulations.

The goal of these Research Roles and Responsibilities documents is to provide concise descriptions of the duties of key individuals that conduct or support research activities at Northwestern University.

Choose the title below for more information about each role.

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Research Administration Roles

All 3 levels work together to support research and the research administration process.
PI Responsibilities

- Direct and oversee all research activities
- Foster a culture of research integrity
- Responsible for fiscal and administrative management of research
- Conduct research in an objective and unbiased manner in compliance with policies and regulations
- Manage all research staff, including co-investigators, post-doctoral trainees, fellows, students, technicians and lab managers
- Assure that all key research personnel have met training requirements
- Ensure appropriate resources for research conduct
Unit Responsibilities

- Provide support for PI’s research pursuits while ensuring adherence to all applicable regulations and policies
- Support PI with fiscal and administrative management of research
- Communicate proposal deadlines, pre-award processes and policies to the PI
- Complete post-award administration of research grants and/or contracts
- Communicate with PI to complete effort commitment profile and to track and monitor effort commitments
- Assist PI to prepare IRB or IACUC protocol submissions, when applicable
Department Chair Responsibilities

- Act as liaison to other University units
- Ensure research objectives of the department, school, and University are consistent
- Confirm commitment to policies and regulations and take appropriate actions to ensure the Universities commitment to compliance
- Oversee the faculty in relation to their research activities, including collaborative, large-scale research initiatives
- Ensure infrastructure, personnel and other resources are sufficient to meet departmental research needs and strategic vision
- Communicate all research-related training requirements to faculty and staff
AVPs for Research Responsibilities

- Oversee all Office for Research (OR) compliance and operational units
- Oversee 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)
- Manages communications to foster the flow of information between OR and its constituents
- OR representative on University committees
- Oversight of OR strategic planning
INVO Responsibilities

• Provide support for Northwestern’s expanding innovative culture

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

• INVO consists of:
  – Intellectual Property and Licensing group
  – The New Ventures group
  – The Community Outreach group
Northwestern Scholars

- Searchable database of research expertise across all disciplines at Northwestern University

- Ability to explore the profiles and research output (publications, patents, visual works, performances, etc.) of thousands of scholars, and learn about core research facilities at Northwestern

- View collaboration networks among researchers within Northwestern and with external scholars.

https://www.scholars.northwestern.edu/
ORS Responsibilities

- Chemical, biological, radiation, and general laboratory safety training and oversight

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

- Hazardous waste disposal

- Emergency response

- Security oversight for materials of national security interest

- Administration of various safety committees
Core Facilities Responsibilities

• Provide centralized services and/or state of the art equipment that a single researcher cannot support on their own
  – Electron and confocal microscopes
  – Functional MRI facilities

• 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

- Identify appropriate funding opportunities
- Provide research administration support for large and/or complex grants
- Assist with grant proposal development
- Provide grantsmanship training
- Provide assistance obtaining institutional commitments and cost-sharing for proposals
- Provide assistance establishing external partnerships and affiliated subcontracts
OSR Responsibilities

- Proposal validation and submission
- Negotiate, execute, and accept contract and grant awards
- Award notification
- Account establishment
- Issue sub-awards
- Interpret award terms and conditions
ORI Responsibilities

- Promote research integrity
- Help researchers navigate the complex research compliance and administrative arenas
- Raise awareness of research integrity issues and policies
- Serve as a confidential source for reporting research related concerns
- Manage investigations of alleged research misconduct
- Coordinate quarterly research administration training seminars
- Track compliance with NSF RCR training requirements
IRB Office Responsibilities

- Support the Institutional Review Board (“IRB”)
- Assist PIs and the research community in minimizing risk to human subjects
- Ensure compliance with federal laws and Northwestern policy regarding human subject research
- Respond to allegations of human subject research non-compliance
- Conduct quality assurance and training
OECC Responsibilities

• Establish and oversee a centralized resource ensuring University compliance with the various export control regulations

• Provide education and outreach

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

• Maintain records demonstrating steps taken to comply with the regulations

• Conduct restricted party screenings
Research IT Strategy & Operations

- Identify and implement research technical solutions and infrastructure
- Support the application of information systems solutions and technologies to the Northwestern research enterprise
CCM Responsibilities

• Support faculty using animals

• Oversee the humane care and use of animals

• House research animals, maintain support space and services for the use of animals

• Provide training in the care and use of animals
IACUC Office Responsibilities

• Support the Institutional Animal Care and Use Committee ("IACUC")

• Work with CCM to protect welfare of animal subjects

• Ensure compliance with federal laws and Northwestern policy regarding animal subject research

• Inspect animal facilities and laboratories

• Respond to allegations of animal subject research non-compliance

• Conduct post-approval monitoring and training
NUCOI Responsibilities

- Oversee and implement the University faculty and staff conflict of interest policies and procedures
- Ensure University compliance with applicable conflict of interest regulatory requirements
- Provide guidance and support to the University community regarding conflict of interest policies, systems, standards, and procedures
- Administer and support the activities of University Conflict of Interest Committees
Other Related Northwestern Offices

Roles & Responsibilities
ASRSP Responsibilities

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

- Development and negotiation of the University’s F&A Rate
- Oversee and analyze recharge activities
- Review of selected sponsored project expenditures
- 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
- Provide determination of cost transfer policies and review of cost transfers
- Monitor compliance with Uniform Guidance (2 CFR 200) cost accounting practices
Research Centers

Roles & Responsibilities

http://www.research.northwestern.edu/centers
Questions?
Policies & Procedures

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

1. Federal Policies
2. Sponsor Specific Policies
3. University Policies & Procedures
4. Grant or Contract Terms

Policies & Procedures
Federal Policies

• For Example:

  – Office of Management and Budget (OMB) Uniform Guidance:

    • A reform that supersedes and streamlined 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

http://sites.nationalacademies.org/PGA/fdp/PGA_054588
University Policies & Procedures

- Focused on establishing how Northwestern complies with federal guidelines

- For Example:
  - Uniform Guidance establishes a need for effort reporting
  - NIH GPS and NSF GPM further define expectations
  - Northwestern must determine how to meet these guidelines via its Effort Reporting Policies
    - Last revised on 6/26/2014
Grant or Contract Terms

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

• For Example:
  - Carry Forward Balance
  - Human Research Participant Training
  - Rebudgeting Restrictions
Questions?

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

“I think it’s time we established new guidelines for corporate behavior.”

Questions?
Networking/Break
Northwestern University
Institutional Review Board (IRB)

Marcella Oliver
IRB Education Specialist
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
- 60% Biomedical and 40% Social Behavioral
Three administrative areas:

- IRB
- Human Research
- Compliance

Training and Education
Northwestern IRB Affiliated Partners

Northwestern Medicine (NMFF, NMPG, NMH)

Lurie Children’s Hospital

Research Privacy Board

Rehabilitation Institute of Chicago
Why do we need IRB?
**Timeline of Events**

- **1947**
  - Nuremberg Code
  - American Psychological Association

- **1946**
  - Nuremberg Doctors' Trial

- **1939-1945**
  - Nazi Medical War Crimes

- **1948**
  - Universal Declaration of Human Rights

- **1947**
  - Syphilis Study at Tuskegee

- **1944-1974**
  - Cold War Human Radiation Experiments

- **1953**
  - First U.S. Federal Policy for Protection of Human Subjects

- **1963**
  - Jewish Chronic Disease Hospital Study

- **1963-1966**
  - Willowbrook Study

- **1966**
  - Henry Beecher's Publication

- **1969**
  - Declaration of Helsinki

- **1968**
  - The Belmont Report

- **1974**
  - Publication of FDA Regulations

- **1980**
  - CIOMS Guidelines

- **1982**
  - Publication of FDA Regulations

- **1981**
  - HHS & FDA Revise Regulations

- **1991**
  - Publication of the Common Rule

- **1993-1994**
  - Advisory Committee on Human Radiation Experiments

- **1995**
  - Establishment of The National Bioethics Advisory Commission

- **1999**
  - The Death of Jesse Gelsinger

- **2004**
  - SACHRP

- **2006**
  - HIPAA Privacy Rule

- **2000**
  - OHRP

**Key Events:**

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

Source: NIH Office of Extramural Research-Training Modules
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:

- **Academic / Professional Values**
- **Legal / Regulatory Standards**
- **Ethical decision making**

Codes of Ethics
Standards of practice
NU HSPP 5.0

Moral philosophy
Framework for ethical decision making
Moral Virtue

Belmont

CFR, FDA, FERPA, HIPAA, MHDDCA, etc.
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 resources: Human Research Determination Form (HRP-503)

HRP-310 WORKSHEET Human Research Determination
## IRB Review Categories

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<tr>
<th>Review Type</th>
<th>Description</th>
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<tr>
<td><strong>Exempt</strong></td>
<td>- Minimal risk</td>
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<tr>
<td></td>
<td>- Belmont Principles still apply</td>
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<td></td>
<td>- Does not apply to FDA regulated research unless it falls under Emergency Use</td>
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<tr>
<td><strong>Expedited</strong></td>
<td>- Minimal risk, identifiable, more personal information</td>
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<td>- Reviewed in the office except for vulnerable populations.</td>
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<td></td>
<td>- If expedited reviewer does not approve, the study must go to the full board</td>
</tr>
<tr>
<td><strong>Full Board</strong></td>
<td>- Minimal risk research not in exempt or expedited review categories</td>
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<tr>
<td></td>
<td>- Research that is more than minimal risk</td>
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<td></td>
<td>- Certain research with vulnerable populations (children, pregnant women, prisoners)</td>
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111 Regulatory Criteria
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: 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
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)
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. Craigslis list
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
- Training queries/issues: irbtraining@northwestern.edu
- Social and Behavioral IRB: 847-467-1723
Contact Information

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QUESTIONS?
Institutional Animal Care & Use Committee (IACUC)

Jeremiah Dunlap
PAM Compliance Analyst
The IACUC Office – Office for Research
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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 research) provides the underpinnings for development of new medical and veterinary treatments.

- **Basic** research seeks to expand our knowledge
- **Applied** research seeks to answer a specific question or need (e.g., create a new device)
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, it was announced that a successful polio vaccine for humans had been discovered.
Why is there an IACUC?

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

- To regulate the use of animals in research, and ensure that they are afforded humane care.

- To assure ethical standards of research are maintained.

- The law requires research institutions to have an IACUC!
  - Mandated by the Health Research Extension Act (HREA), the Animal Welfare Act (AWA), and Public Health Service (PHS) Policy.
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)

• Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)
COMPONENTS OF AN ANIMAL CARE AND USE PROGRAM

INSTITUTIONAL LEADERSHIP

PI RESPONSIBILITY

Animal Welfare

IACUC

DAILY ANIMAL CARE (CCM)
Our Mission

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.*
When applicable, the IACUC encourages investigators to discover alternative methods by:

- **Replacing** animals with other research methods
- **Refining** procedures to minimize potential pain/distress
- **Reducing** animal numbers
Key Functions of the IACUC

- Protocol Review
- eIACUC Training & Support
- Assist New Research Personnel
- Facility/Lab Inspections & Satellite Review
- Program Policy & Training Requirements
- Post Approval Monitoring (PAM)
- Animal Subject Protection
CCM & IACUC

Center for Comparative Medicine (CCM)
- Maintains animal facilities at all NU research sites
- Manages access to the animal facilities
- Provides husbandry and veterinary care to the animals
- Provides training to research personnel

Institutional Animal Care and Use Committee (IACUC)
- Reviews research protocols for work at all NU research sites
- Evaluates the animal care program (e.g., PAM, inspections)
- Advises on program policy and training requirements
- Facilitates online training and occupational health for research personnel
Before Protocol Approval…

IACUC
Institutional Animal Care and Use Committee

TRAINING AND OCCUPATIONAL HEALTH SAFETY PROGRAM

PROTOCOL REQUIREMENTS FOR PERSONNEL APPROVAL

- Anyone seeking facility access (CCM) or having contact with animals must be listed on an approved protocol.
- All principal investigators and research staff handling and caring for animals are required to take the basic IACUC Online Training and Occupational Health Safety Program (OHSP) Training. Please see below.

GETTING STARTED

There are three necessary steps to getting started in the IACUC: IACUC Online Training, Occupational Health Training and training on the electronic IACUC system, eIACUC.

1. IACUC ONLINE TRAINING

All training modules must be completed by EACH individual listed on an animal study protocol or an addendum prior to the document being submitted to the IACUC.

- Contact Bruce Roberts at 312-503-6939 or 312-503-2818 or by e-mail at br.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.research.northwestern.edu/oprs/acuc/training.html
Review: How It Works

Protocols receive either Designated Review or Full Committee Review

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

- **Full Committee Review** involves a presentation to the full Committee by two members, assigned to review that protocol in advance of the meeting
IACUC Review Process

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

IACUC Action
PI Action is Required

Bubble Color Legend
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 works with OSR to open accounts to spend their grant money

- Project personnel may gain access to the animal facilities (through CCM), following training and individual approval

- The PI may order animals (through CCM)
September 2016 Census

Total Animal Census (w/ Mice)

- Mice
- Other
A Numerical Summary

- This year the IACUC has approved 223 new protocols.
- Currently 717 protocols are active.
- In the previous quarter, the IACUC approved 472 changes/updates to active protocols.

Metrics?! Yum!
Questions?

You are also welcome to contact the IACUC Office:

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

• What is ‘comparative medicine’?
  – “is a distinct discipline of experimental medicine that uses animal models of human and animal disease in translational and biomedical research.”

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

• PHS Assurance- receive federal funding

• USDA registration- use USDA covered species in biomedical research
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 centralized facilities or decentralized facilities where CCM provides primary care or in Satellites where primary care and oversight is done by the PI.
Types of Animal Facilities

- **Centralized** - CCM “assigned” and managed space

- **Decentralized** - Typically department “assigned” space but CCM manages animal care

- **Satellite** - Department or PI “assigned” space where PI manages all animal care. Requires IACUC review and approval. PI must justify why use of a satellite is necessary versus animals housed in a CCM managed space. A satellite is defined when rats and mice are kept in the space for greater than 24 hrs and USDA covered species are kept in the space for greater than 12 hrs.
CCM – Units 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, veterinary and husbandry 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 veterinarians 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

• Attending veterinarian is a mandatory member of the IACUC committee and all CCM veterinarians review ASPs and provide guidance to researchers

• 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 on the availability of new research animals

• **Receiving:** Initially receive shipments of animals

• **Census:** Maintain a database tracking all animal housing activities.
  – Per Diem (by the day) charge for every cage, pen and tank housed in facilities.
  – Census is taken on Friday’s with the assistance of Husbandry ACTs
Business Staff

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

• Bills are comprised of the following:
  – Research animal procurement costs
  – Per diem costs
  – Fees
  – Special service charges
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 new and existing CCM staff members

• 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 AALAS (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 Wildcards
- IACUC Policy Release - Working with Human Derived Materials in Rodents
- CCM Office Renovations

Previous Issues

<table>
<thead>
<tr>
<th>CCM Business Office News and Announcements</th>
<th>Procurement Receiving and Census</th>
</tr>
</thead>
</table>

CCM periodically contacts Principal Investigators and their staff with important announcements via email. If you would like to receive these messages, please contact iacuc@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 Pancos animal facilities after July 12, 2012.

Form for Animal Procurement

Remember to send the completed Animal
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. The following services are offered currently:
  – Drug Dosing Studies/Compound Administration (Oral, Topical, IV, SC and IP)
  – Blood Collection (Submandibular, Retro-Orbital and Tail Vein)
  – Animal Identification (Ear Tag, Ear Punch or Tail Tattoo)
  – Tail Biopsy
  – Administration of Special Feed or Fluid
  – Weighing of Animals
Questions?
Networking/Break
Northwestern University Clinical and Translational Sciences Institute (NUCATS)

Speeding transformative research discoveries to patients and the community
NUCATS is.....

• A centralized hub of resources for research teams at 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
• Provide a research infrastructure to support investigators and research research across the research spectrum
New Faculty Onboarding

nucats.northwestern.edu/new-faculty-onboarding
Center for Education and Career Development

*Training the entire spectrum of the translational research workforce*

- **Opportunities for research staff**
  - Master of Science in Regulatory Compliance (MSRC)
  - Good Clinical Practice and Clinical Research Coordinator Training (Live & Online Education)
  - Introduction to Research Online Modules
  - Annual translational research conference

- **Opportunities for investigators**
  - Training grants and workshops for early career faculty
  - Team Science training modules
  - Mentor development

900 clinical research professionals have participated in good clinical practice training
Center for Clinical Research

Provides resources, services and guidance for study teams

- 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) at Lurie and NMH

Supported 667 studies from Sept. 2015-April 2016
Center for Translational Innovation

*Accelerates dissemination through commercialization*

- Partnership with INVO
- Support for new drug and device development
- Funding opportunities
Center for Data Science and Informatics

- Secure, web-based applications
  - REDCap (Research Electronic Data Capture): Data collection forms
  - Study Tracker: Clinical trial management system
  - NITRO Recruit: Research registry system

- Northwestern Medicine® Enterprise Data Warehouse (NMEDW) and i2b2:
  - Repository of clinical and research data from Northwestern Medicine
  - i2B2: a free tool to determine the feasibility of conducting a clinical trial

- Additional support
  - Advanced Bioinformatics and Bio-Computation (ABBC) Core: Big data and computation support
  - Biostatistics Collaboration Center (BCC): Support for biostatistical, epidemiological, programming, and data management needs

NMEDW contains data on more than 6 million people
Galter Health Sciences Library

*Fully integrated information and knowledge management hub*

- **Research Services**
  - Training and workshops
    - EndNote
    - PubMed
    - Computational Skills for informatics
    - Enhancing the impact of your research
    - Google for biomedical research

- **Scholarly Services**
  - Impact and Evaluation
  - NIH Public Access Policy
  - NIH biosketch
  - DigitalHub

**Access to:**
- 8,600 e-journals
- 3,000 e-books
- 300 databases
Center for Community Health

Supports community and stakeholder engagement in research

- Develops community, clinical, public health and policy sectors partnerships
- Workshops, seminars and programs on community and stakeholder engagement
- Seed grants for community-academic research teams
- Community-engaged research proposal review and support
- Consultations for design and implementation of community engaged/based projects

Close partnerships with 55 community-based organizations and 140 community healthcare practice sites in Chicago and northern Illinois
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
- Lurie Clinical Research Units
- Coordinator and Research Staff Services Pool
- Pilot funding
- IRB Authorization Agreement for joint review panel for studies that involve both adults and children
Additional services

- **NUCATS Studio Consultations:**
  - For investigators in the planning stages of a new program or center grant at Northwestern University and affiliate organizations
  - Brings together NUCATS leadership to identify resources to 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:**
  - Investigators and research staff at Northwestern University, University of Chicago and University of Illinois at Chicago CTSA have access to select resources at the other institutions
Become a NUCATS member

- **NUCATS Membership allows you to:**
  - Request NUCATS services
  - Request a consultation
  - Apply for funding
  - Get the latest news about NUCATS

To join visit:
https://nucats.northwestern.edu/user/login
Cite and Acknowledge the CTSA

NUCATS Institute is funded in part by a CTSA grant from the NIH. Publications are the key metric that Congress, the NIH, and Northwestern use to demonstrate effective use of grant funding.

If NUCATS assists you with research please remember to cite the grant.

To learn more visit: nucats.northwestern.edu/about/ctsa-resources.html
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?
Northwestern INVO
Innovation and New Ventures Office

Sonia Kim, PhD
Managing Director
Marketing & Educational Programs

Nicole Janovick, PhD, JD
Invention Manager
TODAY’S GOALS

1. Who are we & what do we do at Northwestern?

2. How do faculty, post-docs, students, and staff engage with INVO?

3. What does the disclosure process look like? What should you know as someone who might support a potential inventor?

4. How can you learn more about what we do at INVO?
WHO ARE WE?

WHAT DO WE DO AT NORTHWESTERN?
INVO is the Innovation and New Ventures Office.

We are focused on activities that move technologies from the University to the public domain such as patent protection, licensing, and funding.
INVO Staff

INVENTION MANAGEMENT TEAM

Alicia Löffler, PhD  
Executive Director

Vara Prasad Josyula, PhD  
Chemistry, Therapeutics

Zach Brown, PhD  
Chemistry, Materials, BME

Arjan Quist, PhD  
Physical Sciences, Engineering

David Tiemeier, PhD  
Senior Director

Becky Crump, PhD  
Associate Director

Michael Moore, PhD  
Life Sciences

Dimitra Georganopoulou, PhD  
Life Sciences, Medical Devices

Gwendolyn Humphreys, PhD  
Life Sciences, Research Tools

Nicole Janovick, JD, PhD  
Life Sciences, Creative Works

Liuchun Yang, JD, PhD  
Nanotechnology

Sarah Kamper, PhD  
Chemistry
Tech transfer activities focus on moving technology from the University to the public domain

Why do we do this?

BAYH-DOLE ACT of 1980
Impact of Bayh-Dole*

PRE-BAYH-DOLE

<250 issued patent/year

30k university patents

5% led to new products

POST-BAYH-DOLE

5-6k issued patents/year ('12-'14)

80k issued patents ('94-'14)

10-15% new products ('12-'14)

2014 STATS

6363 issued patents

965 new commercial products

$28B net product sales

914 startups launched

Northwestern INVO
Innovation and New Ventures Office

*AUTM US Licensing Activity Survey Highlights 2012-2014
Impact of Bayh-Dole*

**PRE-BAYH-DOLE**
- <250 issued patent/year
- 30k university patents
- 5% led to new products

**POST-BAYH-DOLE**
- 5000 startup companies
- >$500B GDP increase
- 3.8M US jobs

*AUTM US Licensing Activity Survey Highlights 2012-2014
FY15 INVO Activities

- Invention Assessment: 211 disclosures
- Intellectual Property Prosecution: 417 patents filed
- Compliance & OSR Support: $594M research awards
- Technology Marketing: 692 available inventions
- License Negotiations: 121 agreements
- Translational Funding: $10M
- Commercialization Programs: 12 startups
- 138 patents issued
- 121 agreements
- 44 licenses & options
- N.XT
- NUSseeds

Northwestern INVO
Innovation and New Ventures Office
HOW DO FACULTY, POST-DOCS, STUDENTS AND OTHER NU STAFF ENGAGE WITH INVO?
Faculty Involvement

Invention Disclosure

Pre-Disclosure
Communication with INVO
Student & Post-Doc Involvement

Pre-Disclosure Communication with INVO
Northwestern Staff Involvement

Pre-Disclosure
Communication with INVO

- Invention Disclosure
- Invention Assessment
- Intellectual Property Prosecution
- Sponsored Research Compliance
- Technology Marketing
- License Negotiations
- Translational Funding
- Commercialization Programs
WHAT DOES THE DISCLOSURE PROCESS LOOK LIKE?

WHAT SHOULD YOU KNOW AS POTENTIAL INVENTORS?
Why disclose inventions to INVO?

1. EVALUATE COMMERCIAL POTENTIAL
   INVO can provide feedback on how to proceed in the commercialization process

2. PROTECT INTELLECTUAL PROPERTY
   If IP protection is appropriate, INVO can maximize IP protection if invention is disclosed in advance of public disclosure

3. FULFILL NORTHWESTERN’S RESPONSIBILITY TO REPORT TO RESEARCH SPONSORS
   INVO must report inventions to respective public and private research sponsors

4. IMPROVE MARKETING EFFORTS WITH INDUSTRY PARTNERS
   If INVO is aware of inventions, they can be properly recorded. This also helps with providing opportunities to industry
What is an INVENTION DISCLOSURE?

It is Northwestern’s record of an invention, the inventors involved, sponsorships, & other public disclosures and publications.

LIFE OF AN INVENTION

DISCLOSURE SUBMISSION ➔ INVENTION ASSESSMENT ➔ PROV PATENT APP* UTILITY PATENT APP* ➔ ISSUED PATENT*  
*if applicable
What is a PUBLIC DISCLOSURE and why does it matter?

1. PRINTED PUBLICATIONS (e.g. journal articles, book chapters)
   - Likely to be public disclosures
     - Posters/abstracts/proceedings
     - Oral disclosures such as conference presentations
   - Might be public disclosures…
     - Departmental seminars and thesis defense
     - Grant proposals

2. INVENTIONS USED BY PUBLIC (e.g. research materials and prototypes)
   If materials are provided only for testing and/or evaluation or for research purposes under written agreement, this may not be a disclosure

3. INVENTIONS ON SALE

4. INVENTIONS AVAILABLE TO THE PUBLIC
INVO encourages REGULAR DIALOGUE between faculty and respective Invention Managers

• Consider inviting us to a lab meeting where you will discuss research you’d like to disclose
• IMs can provide guidance regarding the timeline for disclosing and patent filing

WHEN IN DOUBT, CONTACT INVO.

PLAN TO SUBMIT YOUR DISCLOSURE
3-4 WEEKS PRIOR TO YOUR PUBLIC DISCLOSURE.
Forms

Disclosure Forms

- Invention
- Copyright - Includes but not limited to literary and artistic works
- Software - Includes but not limited to source code
- Research
Definition of Inventorship vs Authorship*  

Accuracy of Grant Information*
- Describe your invention in a less technical manner.

- What is the relevance to the public?

- Describe your invention in a more technical manner.

- This helps our team and outside counsel to understand how your invention is distinct from other inventions.
- Note work that is similar to yours and differentiate. Better to disclose information upfront.

<table>
<thead>
<tr>
<th>PUBLIC DISCLOSURE</th>
<th>DATE (MM/DD/YYYY or None)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Journal Article</td>
<td></td>
</tr>
<tr>
<td>Conference Abstract</td>
<td></td>
</tr>
<tr>
<td>Oral Presentation</td>
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<tr>
<td>Poster Presentation</td>
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<tr>
<td>Disclosure to Industry</td>
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<tr>
<td>Grant Proposal</td>
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<tr>
<td>Other</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>DATE AND PLACE WHERE DISCOVERY WAS MADE</th>
</tr>
</thead>
<tbody>
<tr>
<td>When was the idea conceived?</td>
</tr>
<tr>
<td>Where and how was it documented?</td>
</tr>
<tr>
<td>Was the idea reduced to practice?</td>
</tr>
<tr>
<td>If so, when?</td>
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</table>

<table>
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<tr>
<th>PRIOR ART</th>
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<tbody>
<tr>
<td>List all known related patents and/or publications:</td>
</tr>
</tbody>
</table>

| List known researchers who are active in this field: |

| How have others tried to solve the problem this invention overcomes? |

<table>
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<tr>
<th>COMMERCIALIZATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>What commercial problem does the invention solve? What is the unmet need?</td>
</tr>
</tbody>
</table>

| Who are potential licensees? (Please list companies with any known contacts or highlight relevant industries.) |
Provide COMPLETE contact information.*

- Name should be your LEGAL name—what’s on your passport and legal documents.

- For patent filing, we need to include the country where you have citizenship.

- Please inform us of any address changes for future correspondences & royalty checks.

- Electronic signature is acceptable.

---

**MATERIALS ASSOCIATED WITH INVENTION**

Did this invention use any Materials which were obtained with a Materials Transfer Agreement from a company or another institution? [ ] YES [ ] NO

If yes, please list the name of the company or institution

Did you transfer to any researcher outside Northwestern any new Materials (DNA, peptides, cell lines, vectors, catalysts, polymers, alloys, etc.) of this invention? [ ] YES [ ] NO

---

This disclosure is submitted pursuant to the Northwestern University Patent and Invention Policy and is subject to all the terms of that policy. [http://invnorthwestern.edu/policies/patent-invention-policy](http://invnorthwestern.edu/policies/patent-invention-policy)

If this invention is accepted by the Innovation and New Ventures Office at Northwestern University, I/we hereby agree to execute all necessary documents, assigning to Northwestern our rights in any patent application filed on this invention.
ALL INVENTIONS MUST MEET THE LEGAL REQUIREMENTS FOR PATENTABILITY:
NEW, USEFUL, AND NON-OBVIOUS

Why does INVO need to evaluate disclosures?

Not all inventions are eligible and/or ready for patenting.
Why does INVO need to evaluate disclosures?

- Not all inventions may be ready or able to be commercialized.
- There may not be a market for the potential product.
- There may be significant regulatory hurdles associated with the invention.

Cost of patenting: US is $25,000-30,000; other countries is $100,000

INVO’S DECISION NOT TO FILE DOES NOT REFLECT THE SCIENTIFIC MERIT OF THE INVENTION.
Common Evaluation Factors

**PATENTABILITY**
- Are there other papers or patent applications that describe inventions that may be similar to the disclosed invention?
- What potential claims can be pursued? Are they broad or narrow?
- Is there enough description or data collected to file the application?
- Are there others with patents in the space that may block use of a patent?

**COMMERCIAL POTENTIAL**
- Is there a market for the technology?
- What are the potential challenges of the market?
- Are there a lot of competitors? What are the benefits of this invention over others?
- What level of interest do those in industry or investors have?
- How close is the invention to a commercial product?
- How does this product fit with what is already available in the market?
Disclosure

Provisional Filing

Non-Provisional Filing and/or PCT Filing (International)

Office Action
Office Action
Office Action

Allowance

Issued Patent

60 days* 1 year 3-10+ years*
Potential Destinies of Disclosures

- Ready to Patent
- Waiting for Data
  - Released
  - Ready to Patent
SEND RELEVANT UPDATES TO IMs, SUCH AS FUTURE PUBLIC DISCLOSURES OR TECHNOLOGY DEVELOPMENT.

COMPLETE THE DISCLOSURE AS THOROUGHLY AS POSSIBLE.

BE AVAILABLE TO MEET WITH IM TO DISCUSS YOUR TECHNOLOGY.

RESPOND TO IMs AS QUICKLY AS POSSIBLE AS THEY MAY HAVE TIME-SENSITIVE QUESTIONS.
HOW CAN YOU LEARN MORE ABOUT WHAT WE DO AT INVO?
Ways to Learn More about INVO

• **VISIT OUR WEBSITE:** [www.invo.northwestern.edu](http://www.invo.northwestern.edu)

• **INVO NEWSLETTER:** Sign up on our home page

• **SOCIAL MEDIA:** Follow us on Twitter (@INVOatNU)

• **INVO PRACTICUM:** Graduate students and post-docs interested in IP landscape analysis and market analysis, exposure to marketing

• **I2C SUMMER FELLOWSHIP:** Graduate students interested in commercialization

• **CD2 FELLOWSHIP:** Engineers and Physicians interested in medical innovation
Sonia Kim, PhD
Managing Director, Marketing & Commercialization Education
sonia.kim@northwestern.edu

Nicole Janovick, PhD, JD
Invention Manager
nicole.janovick@northwestern.edu
Export Controls: What Are They and How Do They Impact Research?

Lane Campbell
Director, Office for Export Controls Compliance (OECC)
Overview and Background

• “Export Controls” are federal rules and regulations governing the shipment or transmission of items out of the U.S., including disclosures or transfers of technical data to foreign persons, whether in the U.S. or abroad.
Export Controls Timeline

1945-1991
1976
1985
2001
2006
2008
2010
Overview and Background

Export control concerns arise due to three primary reasons:

- The characteristics of the item itself (e.g. if it has military applications)
- The destination of the item (both the country and the individual or entity) – See Entity List
- The suspected end use of the item
Overview and Background

- Export controls are intended to address several concerns:
  - Protect U.S. national security
  - Implement U.S. foreign policy
  - Maintain a military and economic edge
Regulating Agencies

- Department of Commerce
- Department of State
- Department of Treasury
Restricted Parties

• The federal government publishes various lists which indicate certain parties (both individuals and companies) subject to restrictions.

• Primary lists include the Entity List, Specially Designated Nationals, Denied Persons, and Debarred Parties.

• Northwestern is now using screening software to conduct comprehensive and dynamic screening of restricted parties.
Embargoed Nations

- The U.S. has embargoes in place against several countries:
  - Cuba, Iran, the Sudan, Syria, and North Korea
  - Engagement with any of these countries requires a review of potential export control concerns
Export Controls Impact on Research

• “Deemed exports” involve the release of items subject to export controls to a foreign national.

  – The item is “deemed” to have been exported to the home country of the foreign national.

  – “Foreign national”: not a US citizen, a lawful permanent resident, or a “protected person.”
Fundamental Research Exclusion

Fundamental Research vs. Proprietary Research

Export Controls
Fundamental Research Exclusion

• The “Fundamental Research Exclusion” (“FRE”) was established in a memo signed by President Reagan

  – NSDD-189 Memo, issued in 1985

  – Characterizes “fundamental research”, “the results of which ordinarily are published and shared broadly within the scientific community.”

  – “It is the policy of [the federal government] that, to the maximum extent possible, the products of fundamental research remain unrestricted.”
Fundamental Research Exclusion

• The FRE is intended to control the flow of science, technology, and engineering information produced in federally-funded fundamental research at colleges, universities, and labs.

• Has subsequently been reaffirmed by 2 additional memos issued by the Department of Defense (DOD).
Fundamental Research Exclusion

- The FRE is destroyed when:
  - Sponsor is provided with the right to approve publications
  - Foreign nationals are restricted from participating in the research
  - “Side deals” are struck, wherein the researcher agrees to cooperate in some way with the sponsor to act inconsistent with “fundamental research”
Beyond the FRE

• The FRE does not apply to all university activities, e.g.:

  – All overseas physical shipments must be in compliance with export control regulations.

  – Anything provided under a non-disclosure agreement is potentially subject to controls.

  – Restricted parties and embargoes must always be considered when evaluating export control compliance concerns.
Consequences of non-compliance

- Failure to comply with export control regulations may have many consequences

- Criminal charges
- Monetary penalties
- Damage to reputation
- Loss of export control privileges
J. Reece Roth Case

- Professor Emeritus at the University of Tennessee who illegally exported sensitive technical information to China.

- Traveled to China with his laptop, which contained sensitive information.

- Shared information with foreign nationals, despite being put on notice by his employer and by the research contract.
In the News

• UMass Lowell was recently fined $100,000 for the unlicensed export of equipment to a company in Pakistan.
  – At the time, the company was listed on the Entity List.
  – The equipment was classified “EAR99.”

• Earlier this year, a former postdoc at the University of Michigan was criminally charged with exporting equipment to his home country of Iran.
  – The defendant faces up to 20 years in prison.
  – The violation involved the shipment of humanitarian items to an embargoed country.
The Role of OECC

• Established November 2012

• Intended to provide a central resource dedicated to export controls compliance.

• Coordinates with other offices to ensure that Northwestern is in compliance with the export control regulations.

• When in doubt, contact us.
Questions and Contact Information

OECC
Office for Export Controls Compliance
Northwestern University
633 Clark Street
Rebecca Crown Center,
North Tower 2nd Floor
Evanston, Illinois 60208

http://exports.northwestern.edu

Lane G. Campbell, JD, MBA
Director
lcampbell@northwestern.edu
Phone 847-467-4063
Conflict of Interest/Commitment

Conflict of Interest Office (NUCOI)

Kate Booth
Senior Compliance Specialist
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 in research
How Do We Handle COIs?

• 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
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
COI & COC at Northwestern

3 Disclosure Types:

- **Annual Faculty Disclosure** – completed once/year in February by faculty in eDisclosure

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

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

Researchers can meet research-related requirements simultaneously with annual disclosure requirements during the annual disclosure process each February. If no new interests/relationships arise during the year, annual disclosure alone is sufficient. If new interests/relationships arise outside of the annual disclosure process, researchers must update their disclosure within 30 days.
What Does a COI Look Like?

Not every disclosed interest/relationship 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
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](http://www.northwestern.edu/coi/policy/coi_by_sponsor.pdf)
Important Terms

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
# Important Terms

## Investigator

<table>
<thead>
<tr>
<th>Role on Project/Proposal Record</th>
<th>Investigator?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Personnel</td>
<td>YES - ALWAYS</td>
</tr>
<tr>
<td>Consultant</td>
<td></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>

Individuals in these categories may or may not be Investigators subject to COI requirements. If there is any question as to whether an individual is an Investigator, the PI must confirm the assignation of project role.

*Note: Department administrators or NUCOI may “deactivate” someone as an Investigator on a particular project in eDisclosure, with PI affirmation, if they are in this category and do not meet the definition of Investigator.*
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

## Investigator

<table>
<thead>
<tr>
<th>Role on IRB Study</th>
<th>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>
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.
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
Important Terms

**Significant Financial Interest (SFI)**

An external financial interest for an Investigator and their Immediate Family Member, when aggregated for the 12 months preceding disclosure date, from a single entity, consisting of one or more of the specific interests in the definition.
**Important Terms**

**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 Northwestern valued at / exceeding $5,000♦

*Excluding federal, state, or local government agencies, US 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 compensation, intellectual property interests, and sponsored/reimbursed travel.
Important Terms

Financial Conflict of Interest (FCOI)

An SFI that could directly or significantly affect the design, conduct, or reporting of research
Where To Disclose

Log-in link:

https://coi.northwestern.edu
Northwestern’s Process

Investigator names are entered into InfoEd in Personnel Section

**If a person is on their first research project at Northwestern, email NUCOI to set them up in eDisclosure.**

Investigator names are fed into eDisclosure every 20 minutes.

Compliance Checkpoint: Before submitting the grant, ALL investigators must have disclosed within the last year (365 days) and completed training within the last four years.

InfoEd Proposal Status of the project is updated to “JIT,” “Prepend,” or any “Award” status – this triggers NUCOI review of the project.

Compliance Checkpoint: Before opening the chartstring, ALL Investigators must have a status of “Review Complete.”
Key Compliance Points (Initial)

Investigators:
- ✓ Disclose SFIs
- ✓ Complete COI training

NUCOI & School Deans
- ✓ FCOI determination made
- ✓ FCOI managed, as applicable
- ✓ FCOI reported, as applicable

OSR & Departments
- Proposal Submission

OSR, ASRSP, & Departments
- Funding Released
Tools for Meeting Compliance Points

- COI Compliance Page in eDisclosure

- FDP Clearinghouse:
  http://sites.nationalacademies.org/PGA/fdp/PGA_070596
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 enters Award Workflow; OSR checks for COI determinations

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

Project Status

Investigator Statuses

Disclosed

Disclosed

Disclosed

Projects are not reviewed until the status is set to JIT, Prespend, or an Award status
A Note on Prespending

- Prior to drawing funds from the sponsor, a final COI determination must be on record for each Investigator named on the project, but *prespending* accounts can be opened prior to a final COI determination being made (i.e. when the COI review process is still underway)
  - Although prespending accounts can be opened before final COI determinations are reflected in *eDisclosure*, please note that each Investigator must have compliant training and disclosure dates on file prior to prespending accounts being opened
Investigators must:

- Disclose new SFIs within 30 days

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

- Complete COI training before engaging in research and every 4 years (or more frequently if required)
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**
- Verify compliance of disclosure & training dates prior to proposal submission / project initiation
- 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

Julia Campbell – Director
juliacampbell@northwestern.edu / 847.467.3938

Kate Cosgrove Booth – Sr. Compliance Specialist
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
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 Wednesday, 01/25 at 1:00pm in FSM – McGaw, Daniel Hale Williams Auditorium. If you have any questions or concerns, please do not hesitate to contact me.