Agenda
Tuesday, May 1
9am – 12pm

- Institutional Review Board
- Institutional Animal Care & Use Committee
- Center for Comparative Medicine
- Core Facilities Administration
- Office for Research Safety
- Data Management & Repository Services
- Research Misconduct & Compliance
- Wrap-Up (Check Your Knowledge)

Northwestern University
Institutional Review Board (IRB)

Kathleen E. Murphy, PhD, CIP
Manager, social and Behavioral IRB
What is an IRB?

An Institutional Review Board (IRB) is a committee established to review and approve research involving humans. The purpose of the IRB is to ensure that all human research be conducted in accordance with all federal, institutional, and ethical guidelines. The sole mission of the IRB is the protection of humans who participate in research.

The structure of the NU IRB
NU IRB Facts

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

Three administrative areas:

- IRB
- Human Research
- Training and Education
- Compliance
Why do we need IRB?
IRB is required by federal regulation but even without that it is a moral responsibility. We need IRB because:
• No one can be objective about their own work
• People underestimate the risks involved with areas they are very familiar
• People overestimate the benefit of things that are important to them.

More importantly, society trusts researchers to do the right thing. Trust is the highest honor and obligation in research.

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

Timeline of Events:
- 1940: Adoption of Universal Declaration of Human Rights
- 1973: National Research Act
- 1974: Establishment of the National Commission for the Protection of Human Subjects
- 1991: Publication of the Common Rule

Source: NIH Office of Extramural Research-Training Modules
Day-to-day IRB

When Does the IRB Get Involved?

When it is Human Research.

It’s Research when there is a systematic investigation intended to develop or contribute to generalizable knowledge.

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.
Factors that inform the IRB review:

- Codes of Ethics
- Standards of practice
- Academic / Professional Values
- Cultural values, norms and other local considerations
- Standards
- CFR, FDA, FERPA, HIPAA, MHDDCA
- International Country Codes

Ethical decision making

Moral Virtue

IRB Ethical Responsibilities

Belmont Report (1979): 3 Ethical Principles

1. Respect for Persons
2. Beneficence
3. Justice
## IRB Review Categories

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

**Speaking “IRB”**
What the IRB is looking for:

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

NU IRB Submission Process

- 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
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

CHICAGO:
Biomedical Research Panels A, B, C, D, Q
Arthur Rubloff Building, 7th Floor
750 N. Lake Shore Dr.
Chicago, IL 60611
Phone: (312) 503-9338
irb@northwestern.edu

Evanston:
Social and Behavioral Research Panel E
Chambers Hall, 2nd Floor
600 Foster St.
Evanston, IL 60208
Phone: 847-467-1767
sbsirb@northwestern.edu

QUESTIONS?
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 Office of Laboratory Animal Welfare (OLAW)
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.*

**Our Mission**

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

Animal Subject Protection

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

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

IACUC
Before Protocol Approval…

**Getting Started**

**REQUIREMENTS FOR PERSONNEL**

1. All personnel working with animals must be listed on an approved protocol.
2. All principal investigators and research staff handling and housing for animals are required to take the basic IACUC Online Training and Occupational Health Safety Program (OHSP); enrollment. Please see below.

**TRAINING AND OCCUPATIONAL HEALTH**

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

1. **IACUC ONLINE TRAINING**
   - An training module must be completed by each individual listed on an Animal Study Protocol (ASP) or an amendment prior to the document being submitted to the IACUC.
   - Contact: IACUC at 312-5000 within 312-5000 (office) or by email at iacuc@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 AMURS Learning Library, which you will need to access the courses in AMURS Learning Library.
   - Login for training at [www.iacuc.northwestern.edu/training.html](http://www.iacuc.northwestern.edu/training.html). Click on “Open Training Center” or “Deregister Animals” in the upper right corner and update your IACUC.

**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

- PI submits the study application to the IACUC
- Application reviewed by IACUC coordinator for completeness
- Application is assigned to Designated or Full Committee review
- Application may require clarification or modification
- Application is approved
- If necessary, Application is returned to the PI for revisions and resubmission
- 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 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)
A Numerical Summary

- So far in 2018, the IACUC has approved 60 new protocols.
- Currently 891 protocols are active.
- In the 1st quarter of 2018, the IACUC approved over 569 amendments (i.e., 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)
Center for Comparative Medicine: Facts for you to know!

- What is ‘Comparative Medicine’?
  - 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

- 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 Center for Comparative Medicine is a core service, teaching and training unit dedicated to supporting humane animal care and use in research and education at Northwestern University. We provide quality animal care, and promote animal welfare and regulatory compliance through efficient operations and positive collaborations with faculty, students and staff

We Care for the Animals that Care for Us All
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

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
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 then 24 hrs and USDA covered species are kept in the space for greater then 12 hrs.

How is CCM Organized?

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

- Attending veterinarian is a mandatory member of the IACUC
  - CCM veterinarians review ASPs and provide guidance to researchers
- Provide training 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 animal
- Treat animal health problems

Husbandry Staff

- Comprised of Animal Care Technicians (ACTs), Cage Wash Technicians, Group Leaders, Supervisors, & Managers
- 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. Coordinate the movement of research animals within and out of the facilities.

- **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 Office

- Prepare monthly invoices to bill laboratories

- 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

https://ccm.northwestern.edu/
Online Resources

• Online training provides easy access to important information
  – AALAS Learning Library
  – Can be viewed as often as one wishes, in a quick but secure fashion
  – Especially convenient for research personnel on the Evanston Campus
  – Great resource for new PIs and their staff

• 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
  – Blood Collection
  – Tail Biopsy
  – Administration of Special Feed or Fluid
  – Weighing of Animals

Questions?
Core Facilities Administration

Sasha Mechetner
Administrative Assistant
Office for Research
aleksandra.mechetner@northwestern.edu

What does CFA do?

- Core Facilities Administration provides financial support, administrative oversight, professional development, assessment and communication of shared research resources to advance the research mission of Northwestern University.
  - Institutional Policies and Procedures
  - Federal Regulations and Compliance
  - Annual Report Review
  - Program Review
  - Inter-Institutional Activities (OAI, Cores at Argonne, SHyNE)
  - Marketing and Communications (business consulting, support services, website, brochure)
What are Core Facilities?

- **Core Facilities** are centralized research laboratories with state-of-the-art (expensive) equipment
- "Recharge Centers" operating under a fee-for-service model, with the mission of enabling research at Northwestern
  - **Department Core Facilities** serve researchers in a single department, earning revenue less than $30K/year
  - **University Core Facilities** serve researchers in multiple departments, earning revenue greater than $30K/year
  - **Clinical Core Facilities** serve the research needs of researchers/clinicians engaged in clinical research studies
- **Cores provide centralized services to researchers:**
  - Genomics/Proteomics/Animal Model services
  - Synthesis and characterization of biomolecules (small molecules, peptides, proteins)
How are Core Facilities Supported?

• Central Oversight of University Core Facilities
  • Administrative and Financial Services (NUcore)
  • Rigorous Evaluation of Annual Reports (Awards)
  • Policies and Regulations (Federal, University)
  • Professional Development Opportunities

• Annual Financial Support
  • OR (approx. $2M/yr)
  • Centers, Schools, Departments (approx. $2M/yr)

• Construction and Improvements of Space for Core Facilities

How are Core Facilities Supported? (cont’d)

• Office for Research Equipment Grants: two competitive rounds per year, support equipment purchases up to $100K, ReLODE loan program up to $500K (10 yr. to pay back)

• Office for Research Operating Support: requested via the Annual Report, supports expenses not allowable on recharge, facility growth, unexpected expenses

• FSM Dean’s Office Support: competitive, single round per year, provides subsidies for cores serving FSM researchers

• Voucher Program: when a PI donates new equipment to a core facility, they are eligible for a voucher to use the equipment
Additional Support of Core Facilities

- Schools and Departments provide operating subsidies or annual deficit coverage to core facilities
- Core-specific grants reduce the operating costs (NIH RHLCCC grant and other P30’s, NSF MRSEC grant)
- External users charged a higher rates - especially commercial users that can help a core facility balance its budget (some transactions may be taxable!)

How can I learn more about Core Facilities?

- Visit our website: http://facilities.research.northwestern.edu/
- **Internal Opportunities**
  - Core Facility Listserv Quarterly Brown Bags
  - Kellogg Course: Leadership and Management in Core Facilities
  - Quarterly NUCore Tech Talks
- **External Opportunities**
  - National: ABRF (Association of Biomolecular Resource Facilities)
  - Regional: MWACD (Midwest chapter of ABRF)
Contact us with questions!

Phil Hockberger  
Assistant VP for Research

Andrew Ott  
Director of Core Facilities

Steve Matz  
Director of Facilities and Planning

Aaron Rosen  
Senior Financial Analyst

Sasha Mechetner  
Administrative Assistant

Cindi Mason  
Manager, Research Safety Training
safety-training@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

Why does Northwestern need ORS?

• Identify hazards

• Control risks

• Manage compliance
Regulatory Agencies

Consequences of Noncompliance

- Employee exposure to hazards
- Fines
- Loss of funding
- Legal consequences
ORS Programs

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

Biological Safety

Dr. Andrea Hall, Biological Safety Officer

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

Dr. Mark Bachrach, Chemical Hygiene Officer

Programs:
• Laboratory Safety Reviews
• 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 (Jose Macatangay)
• Training and Audits
• Radioactive material use authorization
• RAM inventory, accountability, receiving/shipping
• X-ray
• Irradiator Security

Laser Safety (TJ Whittenhall)
• Training and Audits
• Laser use authorization
• Laser Inventory
Emergency Response

- Hazmat response
- Spill kits
- Incident reporting

Hazardous Waste Disposal

Heritage Environmental Services

- Chemical waste
- Biological waste
- Radioactive waste

http://researchsafety.northwestern.edu/hazardous-waste/hazardous-waste-disposal-guide
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

**NSIS: Principal Investigators**

**Principal Investigators:** If you are new to the University and need to create an NSIS profile send an email to nsis_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 setup.
NSIS: Safety Evaluation

Safety Evaluation Summary

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

Training

https://learn.northwestern.edu
NSIS: Lab Workers

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

Procurement and Payment Services
• Purchasing, compressed gases, dry ice and liquid nitrogen

University Police
• Personal safety, security threats and breaches

http://researchsafety.northwestern.edu

Visitors and Volunteers

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

http://www.researchsafety.northwestern.edu/training/laboratory-visitors-volunteers
What Now?

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

http://www.researchsafety.northwestern.edu

Questions?
Data Management & Data Sharing

Makes your data easily accessible by you and others
Can save you time and perhaps money
Data sharing increases recognition of your work
Helps with reproducibility of your published results
Helps further new discoveries and research
Preserves data for long-term access and prevents loss of data
Federal and other funding agencies require data management plans and data sharing
Journals require deposit of data underlying the articles in public repositories
Help Guide

Resources for...
- Data Management Plans
- Funding Agency Policies
- Data repositories
- Data Citation
- Metadata

Contact Cunera Buys for assistance: c-buys@northwestern.edu

libguides.northwestern.edu/datamanagement

DMP Tool

Login with NetID
Generates Data Management Plans
Templates from federal agencies and private foundations
Saves your plans for reuse and adaption
Export as PDF, DOCX

dmptool.org
Research & Data Repository Services

Northwestern’s research and data repositories are built for sharing and preserving research and scholarly outputs.

Compliant with public access requirements from funding agencies and publishers.

All works receive a Digital Object Identifier (DOI) for citation and persistent linking.

Copyright is retained by the author. The author grants Northwestern University a non-exclusive license to preserve and provide online access to the content.

Visibility options include Public Access, Northwestern University (end-users need to login with NetID), or Embargo (i.e. set a future release date).

Deposited content becomes part of the library’s digital preservation program.

DigitalHub

Northwestern Medicine only

- Research papers
- Technical reports
- Documentation
- Presentations
- Case studies
- Datasets
- Posters

Managed by the Galter Library

digitalhub.northwestern.edu

digitalhub@northwestern.edu
Arch
All Northwestern University
- Research papers
- Technical reports
- Documentation
- Presentations
- Case studies
- Datasets
- Posters

Managed by the Main Library

digitalscholarship@northwestern.edu

Self-deposit Process

- Go to arch.library.northwestern.edu
- Log in with your NetID
- Describe your work
- Upload files
- Select visibility setting
- Agree to Deposit Agreement
- Save to the repository
Example: Dataset

Faculty member in Chemical and Biological Engineering wants to provide access to the underlying data in support of his publication:

- Digital Object Identifier (DOI)
- Cited in journal article
- Publicly available

Contact Chris Diaz for assistance with any deposit: chris-diaz@northwestern.edu

Data Management & Repository Services
University Libraries, Digital Scholarship Services

Cunera Buys
Data Management Librarian
c-buys@northwestern.edu

Chris Diaz
Digital Publishing Librarian
chris-diaz@northwestern.edu
Research Misconduct & Compliance

Michelle Stalilonis
Senior Compliance Specialist
Office for Research Integrity
m-stalilonis@northwestern.edu

What is Research Misconduct?

- Fabrication
- Falsification
- Plagiarism

http://www.researchintegrity.northwestern.edu/research-misconduct
Research Misconduct

**Fabrication** is making up data or results and recording or reporting them.

**Falsification** is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

**Plagiarism** is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

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Reporting a concern

If you have a concern regarding potential research misconduct:

- Contact the Office for Research Integrity at nu-ori@northwestern.edu or 312-503-0054
- Contact your supervisor, department chair or dean
  OR
- Contact EthicsPoint, either online or by phone

http://www.researchintegrity.northwestern.edu/research-misconduct
To ask a question, receive guidance, or report a violation, contact a representative from the list below.

**Export Controls**  
Office of Export Controls Compliance  
Lane Campbell, Director  
kcampbel@northwestern.edu  
847-467-4063

**Falsification of Research Effort**  
Controller’s Office  
Mike Daniels, Director  
m-daniels2@northwestern.edu  
847-491-4710

**Research Misconduct**  
Office for Research Integrity  
Laurie Qualkenbush, Director  
tu-ori@northwestern.edu  
312-503-0354

**Grant Management**  
Office of Sponsored Research  
Lynda Wolter, Executive Director  
lwolter@northwestern.edu  
312-503-7959

**Research on Human Subjects**  
Institutional Review Board  
Nathalia Henry, Executive Director  
nhenry@northwestern.edu  
312-503-9338

**Research on Animals**  
Institutional Animal Care and Use Committee  
Mandy Kozlowski, Director  
m-kozlowski@northwestern.edu  
312-503-0109

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**EthicsPoint: A Compliance Hotline**

- Compliance Office manages the University’s EthicsPoint hotline
- Any suspected problems will be reviewed according to University procedures
- Policy prohibits retaliatory action against those reporting
- Anonymous
EthicsPoint: A Compliance Hotline

- Report potential misconduct or violations of policy
- File a report online, or call the hotline at 866-294-3545

http://www.northwestern.edu/ethics
Penalties for Noncompliance

Institutional:
- Fines and penalties
- Exceptional status
- Funding reduction

Personal:
- Termination
- Disciplinary action
- Criminal/civil sanctions
- Suspension and debarment
- Professional integrity compromised

Recent Examples of the Impact of Noncompliance

<table>
<thead>
<tr>
<th>Institution</th>
<th>Settlement Time Frame</th>
<th>Details</th>
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<tbody>
<tr>
<td>Northwestern University</td>
<td>February 2003</td>
<td>$5.5 million penalty for overstating effort reporting on federal sponsored projects</td>
</tr>
<tr>
<td>University of Connecticut</td>
<td>January 2006</td>
<td>$2.5 million penalty for overstating anticipated expenses, overcharging the government, and billing for items not covered by grants, Cost sharing issues</td>
</tr>
<tr>
<td>Cornell University's Weill Medical College</td>
<td>Fall 2007</td>
<td>$2.6 million settlement for a PI failing to disclose on grant applications to the NIH the full extent of various active research projects</td>
</tr>
<tr>
<td>Yale University</td>
<td>December 2008</td>
<td>$7.6 million settlement for inadequate documentation of cost transfers and summer salary charges wrongly charged to federal grants</td>
</tr>
<tr>
<td>Dartmouth College</td>
<td>October 2010</td>
<td>$275,000 settlement and $604,000 in contract funds returned to the government for contract pricing and cost recovery issues, lack of compliance with Federal Acquisition Regulation (FAR), and Conflict of Interest issues.</td>
</tr>
</tbody>
</table>
Research Data: Ownership, Retention and Access


- Defines “research data”
- Defines University and PI responsibilities
- Transfer to data when researcher leaves institution
- Data retained for minimum of **3 years** after the last financial report for the project has been submitted, unless longer periods are required
How can you ensure compliance?

- Identify resources
- Understand complex regulations
- Know when and where to ask for help
- When in doubt, ask

We are all responsible

Questions?

Why... Does this happen often?