Research Administration Training Seminar

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

Agenda – Day One
- Research Roles and Responsibilities
- Policies and Procedures overview
- Institutional Review Board (IRB)
- Institutional Animal Care & Use Committee (IACUC)
- Innovation & New Ventures Office (INVO)
- Center for Comparative Medicine (CCM)
- Institute for Northwestern University Clinical and Translational Sciences (NUCATS)
- Data Security
- Office for Research Development

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: Why?

• To better understand our role at the University
• To protect the research:
   Data
   Participants
   Funding
   Integrity of the research
   The public’s trust
• Recipient of federal funds:
   Northwestern received $676.5 million in sponsored research funding in FY 2017
   Northwestern ranked 16 in NIH and 45 in NSF research funding to universities in FY 2016
• Mandatory regulations and policies:
  Ensuring compliance remains a priority for the federal government and Northwestern University

Introduction
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

Michelle Stallonis
Senior Compliance Specialist
Office for Research Integrity
Research Administration Roles

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

Central Unit
Principal Investigator

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 University’s 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

http://researchroles.northwestern.edu
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

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

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

Core Facilities Administration Responsibilities

- 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.
  - Electron and confocal microscopes
  - Functional MRI facilities
- Core Facilities are recharge centers, operating under a fee-for-service model, with the mission of enabling research at Northwestern

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

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
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

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

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

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

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

ORI Responsibilities

- Promote research integrity and the responsible conduct of research
- Help researchers navigate the complex research compliance and administrative arenas
- Serve as a confidential source for reporting research related concerns
- Facilitate review of alleged research misconduct
- Coordinate quarterly research administration training seminars
- Track compliance with NSF RCR training requirements
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 faculty, and learn about core research facilities at Northwestern
- View collaboration networks among researchers within Northwestern and with external scholars.

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

Roles & Responsibilities

Northwestern | Research

OR Administration

- Administrative Services
- Financial Administration
- Research IT Strategy and Operations
- Research Communications
- Office for Research Strategic Planning and Coordination
- University Research Center Administration

https://research.northwestern.edu/research-offices

Other Related Northwestern Offices

- President
- Provost
- Vice President for Research
- Executive Vice President
- Vice President of Finance and Treasurer
- Executive Director for Research Financial Operations
- Accounting Services for Research and Sponsored Projects (ASRSP)
- Cost Studies

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

Roles & Responsibilities

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

Roles & Responsibilities

Research Centers

- Northwestern President
- Northwestern Provost
- Office for Research
- Respective School Dean
- University Research Centers
- School Based Research Centers

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

Roles & Responsibilities

Policies & Procedures

Michelle Stallonis
Senior Compliance Specialist
Office for Research Integrity

Regulatory Pyramid

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


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/PDA_054588

Policies & Procedures
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?

Networking/Break

IRB Role in Research

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

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

NU IRB Facts
- >10,000 Submissions a Year
- 6 IRB Review Boards (2 Campuses)
- Avg. 655 Studies Reviewed at Panel each Year
- 60% Biomedical and 40% Social Behavioral

Three administrative areas:
- IRB
- Human Research
- Compliance
- Training and Education

Northwestern IRB Affiliated Partners
- Northwestern Medicine (NMHC, NMH)
- Shirley Ryan AbilityLab
- Lurie Children’s Hospital
- Research Privacy Board

Why do we need IRB?

Protecting Human Research Participants
- Timeline of Events
- Willowbrook Hepatitis Study
- Humphrey “Tea Room Trade” study
- Stanford Prison Study
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.

IRB Ethical Responsibilities

Belmont Report (1979): 3 Ethical Principles

1. Respect for Persons
2. Beneficence
3. Justice

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-510)
- HRP 310 WORKSHEET Human Research Determination
IRB Review Categories

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Description</th>
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<tbody>
<tr>
<td>Exempt</td>
<td>Minimal risk, Belmont Principles still apply, Does not apply to FDA regulated research unless it falls under Emergency Use.</td>
</tr>
<tr>
<td>Expedited</td>
<td>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.</td>
</tr>
<tr>
<td>Full Board</td>
<td>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)</td>
</tr>
</tbody>
</table>

.111 Regulatory Criteria

- Participant Selection
- Vulnerable Populations
- Voluntary Consent
- Benefits
- Risks
- Research Design

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.

Speaking “IRB”

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
Quick Quiz: Which study meets the definition of research with human participants?

A. A researcher plans to conduct a linguistic study of comments posted on a local public blog.
B. A developmental psychologist proposes videotaping interactions between groups of toddlers and their caregivers to determine which intervention methods most effectively manage aggression.
C. A researcher proposes asking the director of a local free clinic about the number of patients in the last two years with newly diagnosed HIV/AIDS.
D. A university designs an in-house study to improve the mentoring of women students in engineering with the proposed outcome consisting of a report of recommendations for the department.

Which are the ethical pros and cons of:

Recruitment of participants using:
1. Paper flyers or posters posted on bulletin boards
2. Email solicitation
3. Craigslist
4. Facebook

General Contact Information

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

- Main number (BioMedical): 312-503-9338
- General IRB queries: irb@northwestern.edu
- eIRB assistance/queries: eirb@northwestern.edu
- Compliance queries/issues: irbcompliance@northwestern.edu
- Social and Behavioral IRB: 847-467-1723

Questions?

Research: Basic vs. Applied

- 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)

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.
Key Functions of the IACUC

Animal Subject Protection

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

Key Actions:

- 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

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...

Getting Started

Requirements for Personnel

- Training and Occupational Health

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
- Application is assigned to Designated or Full Committee review
- Application may require clarification or modification
- Application is approved
- Revised application is returned to the IACUC for re-review
- Application is returned to the PI for revisions and resubmission
- Process continues until Reviewers are satisfied

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)

June 2017 Census

- So far in 2017, the IACUC has approved 210 new protocols.
- Currently 862 protocols are active.
- This quarter, the IACUC approved over 619 amendments (i.e., changes/updates) to active protocols.

Questions?

You are also welcome to contact the IACUC Office:
Phone: (312) 503-9339
Email: acuc@northwestern.edu

Innovations & New Ventures at Northwestern
TODAY’S GOALS

1. Who are we & what do we do at Northwestern?
2. What does the invention disclosure process look like?
3. What should research administrators know about INVO?
4. How can you learn more about what we do at INVO?

Our Mission

To catalyze the translation of Northwestern innovations to benefit the public

- Become a source of impactful innovations and products that improve lives
- Become a magnet for entrepreneurial talent

Our Activities

- Technology Transfer
  - IP Support (Consultations, Filing, Office Actions, etc.)
  - Technology Evaluations
- Funds
  - N.XT Fund ($10M)
  - NuSeeds Fund ($4M)
- Space
  - The Garage
  - Faculty R&D
- University Memberships (mHub, 1871 & MATTER)
- N.XT Fund ($10M)

Areas of Innovation

- computer science
- life sciences
- nanotechnology
- engineering
- physical sciences
- therapeutics
- research tools
- advanced materials
- manufacturing
- nanotechnology
- biotechnology
- computer science
- medical devices
- chemistry
- electronics

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

BAYH-DOLE ACT of 1980

Change in IP Ownership

BAYH-DOLE ACT
Impact of Bayh-Dole on IP*

<table>
<thead>
<tr>
<th>PRE-BAYH-DOLE</th>
<th>POST-BAYH-DOLE</th>
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<tr>
<td>&lt;250 issued patents</td>
<td>5-6k issued patents/year ('12-'14)</td>
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<tr>
<td>30k university patents</td>
<td>80k university patents ('94-'14)</td>
</tr>
<tr>
<td>5% led to new products</td>
<td>10-15% new products ('12-'14)</td>
</tr>
<tr>
<td>1980</td>
<td>2014</td>
</tr>
</tbody>
</table>

Significant Economic Impact of Bayh-Dole Act

- 5000 startup companies
- >$500B GDP increase
- 3.8M U.S. jobs
- $500 billion GDP increase
- 5,000 new startup companies

Impact of Bayh-Dole on IP*

1. **PROTECT 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 NU’S RESPONSIBILITY TO REPORT TO RESEARCH SPONSORS**
   - INVO must report all inventions to respective public and private research sponsors.

4. **IMPROVE MARKETING WITH INDUSTRY PARTNERS**
   - INVO can help provide industry with insight into available technologies and the research that is taking place at the university.

The Invention Disclosure

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

Inventors should plan to submit their invention disclosure 3-4 weeks prior to a public disclosure:
- Posters/abstracts/proceedings
- Journal articles, book chapters
- Conference presentations
- Some departmental seminars & thesis defenses
- Some grant proposals

**DISCLOSING AN INVENTION TO INVO DOES NOT PROTECT AN INVENTION. A PATENT APPLICATION MUST BE SUBMITTED TO THE USPTO.**
Definition of Inventorship vs Authorship

- Accuracy of Grant Information

Describe the invention in a less technical manner.
- What is the relevance to the public?
- Describe the invention in a more technical manner.
- This helps our team and outside counsel to understand how this invention is distinct from other inventions.
- Note work that is similar and differentiate. Better to disclose information upfront.

Provide COMPLETE contact information.
- Name should be a LEGAL name—what’s on a passport and legal documents.
- For patent filing, we need to include the country of citizenship.
- Please inform us of any address changes for future correspondences & royalty checks.
- Electronic signature is acceptable.

Life of a Patented Technology

1. Disclosure Submission
2. Patent Application
3. Patent Issuance
4. License
5. Foreign Issuance

Important Take-Homes

- Complete the disclosure as thoroughly as possible
- Be available to meet with IM to discuss your technology
- Respond to IM as quickly as possible as they may have time-sensitive questions
- Send relevant updates to IM, such as future public disclosures or technology development
1. Explore Additional Sponsored Research Opportunities
   INVO coordinates with other offices to review IP stipulations. Ideally, several weeks are needed to review these agreements.

2. License Technology to Existing Company
   INVO helps identify and negotiate license agreements. If there’s interest, IMs contact faculty to discuss.

3. Create University Startup
   INVO has Startup Guide online.

---

Northwestern Licensees (Past & Present)

Northwestern Startups

Recent Issues for Discussion

Pre-Award
- Commercialization Plan or IP Provisions – Reach out to INVO/Invention Manager early

Disclosures – Key Items
- Employee ID to identify personnel @ NU – our system is linked to myHR
- Corrections result in costly fees to NU – each one can be hundreds of $.
- When possible, include grant Project Award Summary as an attachment to disclosure

Agency Requests
- If you are ever asked from an agency about reporting, please reach out to INVO early.
- iEdison Reporting – INVO takes care of this. Please reach out to INVO/Invention Manager if asked by agency.
- Foundation/Private funding compliance – INVO takes care of this. Please reach out to INVO if asked by agency.

Northwestern | INVO

Commercializing Technologies

1. Explore Additional Sponsored Research Opportunities
   INVO coordinates with other offices to review IP stipulations. Ideally, several weeks are needed to review these agreements.

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Our Startup Playground

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Current Investments

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NU Startup Funding & Acquisitions

$56M* SBIR/STTR Funded Active Startups (2006-2016)

$306M* VC-Backed Startups

$2.72B* Acquired Startups
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 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.
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

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.

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

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**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

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**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

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**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

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**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
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 Shirley Ryan AbilityLab
- Our goal is to promote Northwestern’s culture of collaboration, innovation and translation through team-building, education, and training to empower the multidisciplinary translational research teams of tomorrow
- We provide training, tools, and services to support investigators across the full spectrum of clinical and transitional science research

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 approximately 800 studies in 2016

Center for Translational Innovation
Accelerates drug and device development 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
  - NMEDW: Repository of clinical and research data from Northwestern Medicine
  - i2b2: a 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

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
- Trial Innovation Network (TIN):
  - A network of 84 other CTSA that helps execute Multi-center clinical trial or study better, faster, and more cost-efficiently through leveraging the skills and expertise at other networks

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

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

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Information & Systems Security/Compliance
Feinberg School of Medicine
Research Computing Services

Information = Asset

- Budgets
- Invoices, receipts, payments, planning, forecasting
- HR Data
- Compensation, pension, benefits, performance
- Contracts
- Terms & conditions, nondisclosure, service agreements
- Research
- IP, patents, consent agreements, patient records
- Personal
- SSNs, credit cards, DoB, medical/health records, certificates

“If it’s worth collecting, it’s worth protecting”
Threat Landscape

- Highly automated
- Indiscriminate and targeted attacks
- 24 X 7 – never takes a vacation, never takes a holiday
- Medical records now more "valuable" than financial (e.g., credit cards)

https://cybermap.kaspersky.com

Simple Steps to Security

Configuration Management
- Replace default passwords with longer/stronger

Change Management
- Control changes to your environment

Patch Management
- Keep systems & applications current

Endpoint/User Management
- Encryption, Anti-malware, Anti-virus
- Phishing: Be aware, don’t click on links

"It just has to be 'good enough'..."

Process Improvements

Feinberg School of Medicine
- Encryption: Computers, Mobile Devices and Email
- Email: Auto-forwarding, commercial email not permitted
- Personal devices: No non-public NU data, Device Security Policy
- Information Security Data Security Plans
- Research Use of EDV Data
- Hardware, Software, Data Storage Standards
- Information Security & Access Policy

http://www.feinberg.northwestern.edu/standards-policies/

References

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Office of Research Development

October 3, 2017
Office for Research

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

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

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

Research Program Development

Large Interdisciplinary Proposal Development

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

Project Management Support

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

Research Administration Support

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

Large Interdisciplinary Proposal Development: Seed Funding

NU-Interdisciplinary Program 1-2-3

- I1: $1,000 for a workshop; rolling submission
- I2: $15,000 for expenses pertinent to the submission of a large proposal; rolling submission
- I3: $120,000/year for up to 2 years for promoting effective team assembly, developing track record of collaboration, generating preliminary data and submitting a large/center proposal to an external sponsor; annual due date

http://www.research.northwestern.edu/interdisciplinary123/

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

ORD LINC Series

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

Past Events: “Microbiome” and “Internet of Things”

New Weekly Funding Opportunity Alert (ORD INSIGHT)

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

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

- Funding Opportunities
  - FOAs screened weekly for eligibility and relevance to NU research
  - FOA summary is hyperlinked to Pivot database listing
  - “Limited Submission” funding opportunities
  - Divided into 6 research areas: Biomedical & Life Sciences; Engineering & Computer Science; Learning Sciences; Media, Arts & Humanities; Physical Sciences; Social Sciences & Law
Ongoing "curated" list by research area in Pivot database

I. Facilitating Interdisciplinary Research Programs

II. Supporting the Pursuit of Funding Opportunities

III. Promoting the Submission of Outstanding Proposals

IV. Guiding Early Career Investigators

Promote the Submission of Outstanding Proposals

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

Limited Submission

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

https://ord.northwestern.edu/limited-submissions
Northwestern’s Limited Submission (LS) Process

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

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

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

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

Limited Submission: Outcomes
- Packard Science and Engineering Fellows
  - National awardee each year 2007-11, 2013
  - of an annual total of 16 fellows from 50 Universities
- Pew Biomedical Scholars
  - of an annual total of 21 scholars nationally
Guiding Early Career Investigators

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

Guiding Early Career Investigators: ORD Presents

- NSF CAREER Workshop (5/3/17)
- Introduction to Funding Opportunities
- Early Career Funding Opportunities
- Broader Impacts Fair

Please contact ORD if you…

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

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ORD-NU
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Follow Us on Social Media

https://ord.northwestern.edu/
Thank you!

Questions??

Day 1 is Complete!

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

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

The next session is on Thursday, 10/5 at 9:00am in Chambers Hall – Lower Level Classroom. If you have any questions or concerns, please do not hesitate to contact me.

Administrative Business