Agenda
Wednesday, July 18
9am – 12:30pm

- Corporate Engagement
- Innovations & New Ventures Office
- Office of Foundation Relations
- Cybersecurity
- Data Management & Repository Services
- NU Clinical and Translational Sciences Institute (NUCATS)
- Institutional Animal Care & Use Committee
- Center for Comparative Medicine
- Research Misconduct & Compliance

Corporate Engagement
Annalise Robinson– Program Assistant
Corporate Engagement | What We Do

Find & Meet Industry Contacts
• Help faculty and staff find and meet industry contacts in R&D, tech scouting, corporate foundations, university relations and more

Background Information
• Provide background information on current relationships between companies and the entire university

Proposals
• Review proposals and supporting correspondence to formal and informal corporate grant-makers

Campus Visits
• Administer scheduling, space and provisions for campus visits by corporations

Managing relationships: on campus

Office of Sponsored Research, Gift and Record Services, Office of General Counsel (OGC)

Regulatory Support

Campus Engagement is NEVER linear

Faculty, Depts., Research Centers

Research

Northwestern Career Advancement, McCormick Career Development, Medill Career Services, Student Groups

Recruiting

Tech Transfer & Startups

INVO, Faculty, The Garage

Northwestern
Corporate Engagement | Who We Are

- Independent from:
  - Feinberg Corporate Relations
  - Kellogg Corporate Partnerships
  - Pritzker External Partnerships
Corporate Engagement | Pre-Award

- Identify Industry Funding Opportunities
  - If Research Funding – we work with ORD
  - If Program Funding – we send to all relevant parties
  - Ensure limited submissions coordination

- Help with Proposal Development
  - Help with common (and uncommon) deliverables
  - Indirect costs
  - Collaborate with OSR and ORD

Corporate Engagement | Post-Award

- Appropriate accounting for grants, awards, gifts
  - Checks, Wire Transfers, In-kind
  - Gift vs Grant
  - Coordination with OSR, OGC, ASRSP

- Relationship Management
  - Share appropriate information
  - Find new corporate connections for PIs and Administrators
Data available for CE priority companies

- Northwestern data for recent campus activity/stats
  - Giving
  - Relationship Managers
  - Recent Activity
  - Key Contacts
  - Senior Leaders

- External data
  - Information on new strategy/initiatives
  - Recent press releases
  - News on other school engagements

Information Needs?

Northwestern Relationship Managers

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeff Kominsky</td>
<td>Senior Director, Corporate Relations, Fondry</td>
</tr>
<tr>
<td>Jim Brier</td>
<td>Director, Corporate Engagement</td>
</tr>
<tr>
<td>Marcy Roberts</td>
<td>Senior Director of Corporate and Regional Engagement</td>
</tr>
</tbody>
</table>

On-Campus Recruiting Activity

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>NWCE CHANCE</td>
<td>17.15</td>
</tr>
<tr>
<td>NWCE CHANCE 2</td>
<td>17.16</td>
</tr>
</tbody>
</table>

Recent Activity

2018: April
- Laura Kernsman (Center for Entrepreneurship)
- Patrick O’Brien (Office of Corporate Engagement)
- Northwestern participation in the Launchpad Conference

2017: Fall
- NU National 100 (with NU alunos in the health care and technology sectors)
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- Northwestern participation in the UCEP Pan-American Conference and in the annual meeting of the organization.

- Shalee Wechsler, John Simon, Institute for Integrative Cancer Research,
- Integration of new strategy and initiatives
- Recent press releases
- News on other school engagements

Key Contacts

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</table>

Additional Senior Leaders

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joe Davis</td>
<td>Director, Corporate Relations</td>
</tr>
<tr>
<td>Tom Johnson</td>
<td>Director, Corporate Relations</td>
</tr>
<tr>
<td>Jane Smith</td>
<td>Director, Corporate Relations</td>
</tr>
<tr>
<td>John Doe</td>
<td>Director, Corporate Relations</td>
</tr>
</tbody>
</table>

What We Do: Examples of Highlighting NU Strengths & Faculty Research
Corporate Engagement | Relationship Management & Cultivation

**Alignment: Let’s Go Places Together**

**Northwestern Strengths**
- Multidimensional & Adaptive
- Powerful Collaborations
- Pioneering Innovation
- Meaningful Impact

**Toyota Smart Mobility**
- Interactive Intelligence
- Vehicle Enhancement
- Vehicle Connected Intelligence

Source: Toyota Pitch Deck

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**Northwestern | Multidimensional and Adaptive**

- Advancing global sustainability and energy solutions through transformational research, interdisciplinary education and public engagement
- Dozens of affiliated faculty from 5 different schools across the University
- Partnerships with several companies, active participation on executive council

**Research areas:**
- Creating sustainable cities and managing the risks of climate change
- Solar energy and fuels
- Catalysis and sustainable materials
- Nanotechnology for environmental remediation

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*Image* Northwestern University and Exelon Establish Partnership for Clean Energy Innovation

[Image: Northwestern | Multidimensional and Adaptive]
Partnering with You
Corporate Engagement | Next Steps

- Reach out to us to brainstorm companies or gather intel on corporate campus information
- Update NU Scholars with PI information
- Sign up for the Foundation Relations & Corporate Engagement RFP newsletter
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?
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

INVO | Our Activities

- Technology Transfer
  - IP Support (Consultation, Filing, Office Actions, etc.)
  - Technology Evaluations
  - Marketing Efforts

- Innovation & Entrepreneurship Programming
  - Workshops
  - Seminars
  - Mentoring
  - Internships
  - Coordination with Classes, etc.

- Funds
  - N.XT Fund ($10M)
  - NuSeeds Fund ($4M)

- Space
  - The Garage
  - Faculty Hub
  - University Memberships (mHub, 1871 & MATTER)
Technology Transfer

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

BAYH-DOLE ACT of 1980
Change in IP Ownership

PRE-BAYH-DOLE

<250 issued patents/year
30K university patents
5% led to new products

POST-BAYH-DOLE

5-6K issued patents/year (‘12-’14)
80K university patents (‘94-’14)
10-15% new products (‘12-’14)

Impact of Bayh-Dole on IP*

Significant Economic Impact of Bayh-Dole Act

5000 startup companies
>$500B GDP increase
3.8M US jobs

*AUTM US Licensing Activity Survey Highlights 2012-2014
INVO Staff

INVENTION MANAGEMENT TEAM

INVO | FY17 Stats

211 INVENTIONS DISCLOSED

529 PATENT APPLICATIONS

210 AGREEMENTS EXECUTED

$7.5 MILLION IN LICENSING REVENUES

185 PATENTS ISSUED

12 STARTUPS
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

Reasons to Disclose to INVO

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

Invention Disclosure Form

Definition of Inventorship vs Authorship*

Accuracy of Grant Information*
Invention Disclosure Form

- 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.
Invention Disclosure Form

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
   - 30 DAYS

2. INVENTION ASSESSMENT
   - 1 YEAR

3. PROVISIONAL PATENT APP
   - 3-5 YEARS

4. LICENSEE
   - Licensee on horizon?
   - Licensee willingness to pay?

5. INTERNATIONAL PATENT APP
   - Enabled application?
   - Identifiable market?
   - Non-problematic FTO?

6. US ISSUED PATENT

7. FOREIGN ISSUED PATENT

Northwestern
**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.

**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.

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)

Our Startup Playground
Northwestern Startups

NU Startup Funding & Acquisitions

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

$306M+  VC-Backed Startups

$2.72B+  Acquired 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
- Funding accuracy
  - 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

Ways to Learn More about INVO

WEBSITE: Visit www.invo.northwestern.edu
INVO NEWSLETTER: Sign up on our home page
SOCIAL MEDIA: Follow us on Twitter (@INVOatNU)
STUDENT OPPORTUNITIES: INVO Practicum Interns and N.XT Associates
THANK YOU

Sonia Kim, PhD  
sonia.kim@northwestern.edu

Andrea Minogue  
a-minogue@northwestern.edu

Office of Foundation Relations

Michelle Melin-Rogovin  
Senior Associate Director  
m-melin-rogovin@northwestern.edu
Office of Foundation Relations

The Office of Foundation Relations (OFR) is Northwestern University’s central office supporting faculty and staff who seek funding from private professional foundations. OFR manages relationships with foundations to advance University goals and priorities.

Organization Chart for Foundation Relations
Private Foundations & Why They Give

• Private foundations are mission-driven grant-making organizations that support exceptional projects and new initiatives that address specific societal problems and benefit the larger community.

• These national, professionally staffed foundations typically do not provide funding for core University needs.

• At Northwestern, foundation grants average $200,000.

  – “An institution is the lengthened shadow of one man.” – R.W. Emerson
  – “You’ve seen one foundation, you’ve seen one foundation.”

FY2017 Private Foundation Funding

• $59.6M in foundation commitments to Northwestern

• 311 proposals requesting a total of $193.9M

• 148 proposals awarded

• Top grant: $5M

• Assistance to every Northwestern School
OFR Services

http://www.northwestern.edu/foundationrelations/

- Coordinate strategic approaches to foundations
- Research foundations to identify potential funders
- Review proposals to craft persuasive arguments
- Provide materials for submission (IRS documents, financial statements, etc.)
- Partner with campus leaders and research administrators
- Track proposal submissions in development database
- Facilitate grant reporting
- Offer workshops on foundation grantseeking

Finding Private Foundation Funding

- RFP Listing on OFR Website:
  http://www.northwestern.edu/foundationrelations/finding-funders/request-for-proposals.html

- Databases:
  - Foundation Directory Online
  - Pivot (Community of Science)
  - SciVal
  http://www.northwestern.edu/foundationrelations/finding-funders/index.html

- Before contacting organizations listed in these databases, please contact OFR for advice and clearance
  - Restricted Foundations
  http://www.northwestern.edu/foundationrelations/finding-funders/restricted-foundations.html
Contact OFR

Please contact our office with any questions you may have about private foundations or whenever a faculty member you are working with is interested in seeking foundation funding.

foundationrelations@northwestern.edu
(847) 491-4590
Feinberg School of Medicine
Foundation Relations

Michelle Melin-Rogovin, Senior Associate Director
Foundation Relations
Feinberg School of Medicine
312-503-7072
m-melin-rogovin@northwestern.edu

FSM Foundation Relations Office

Funding Opportunity Analysis
- Analyze RFP blasts & ID candidates
- Meet with investigator to search for funding opportunities
- Coord. w/offices on campus & funders to receive notices

Research & Guidance
- Research foundation/s to provide best input on fit for funding idea
- Provide guidance to investigator on application strategy

Communication & Outreach
- Liaise with RA, department, school offices to ensure smooth coordination
- Can assist PI with communication with potential funder to answer questions during application process

Editing & Proofreading
- Analyze RFP requirements & deadlines with RA and PI
- Will read & provide technical edits and comments for PI

Progress Reports & Visits
- Assists with writing and review of progress report
- Participates in site visits
- Proactively interacts with foundations and associations
FSM Foundation Relations: Chicago-Based Expertise for Faculty & Staff

- Assistance for faculty who need customized searches for non-federal funding opportunities.
  - Philanthropic and corporate foundations, associations, other non-profit entities that provide grant funding for research and education
- Hold individual faculty meetings, and follow up by identifying funding announcements that are the best fit for each faculty member’s research.
- Review draft applications and provide technical and analytical edits; help faculty evaluate the responsiveness of their proposal to the foundation’s RFP prior to submission.
- Provide expert guidance to faculty and staff prior to the proposal submission process regarding non-federal funding opportunities.
- Liaise with OFR and other school and university offices to identify resources to help faculty and staff submit quality applications.

IT Security Policy Review
Feinberg School of Medicine
18 July 2018
Threats to FSM Research Data

- Disrupted research & delayed patient benefits
- Diverted resources to address data breaches, investigations & audits, & corrective action plan will distract from core research mission
- Public/Internal embarrassment, negative publicity, reputation, furious patients
- Fines, penalties, financial expenses / losses (future/renewed grants)
- Intellectual property theft
- Phishing victim (e.g., ransomware)
- Lack of security training/awareness

Phishing

- Attempts to get you to do something or tell the hacker something private which may also compromise you or your computer in some way.
- Do not click on links – check on actual destination by hovering cursor over link.
  
  - Avoid including sensitive information in email.
  - Do not open attachments unless you explicitly requested it.
  - Avoid propagating suspicious email by excessive forwarding.
  - Check with IT support if unsure.
  - Do not be curious!
FSM IT Security Policy Review

- Information Security & Access
- Data Security Plans
- Security Training
- Email Encryption
- Email Auto-forward
- File Sharing
- Device Security

Information Security & Access Policy

- September 22, 2016
- HIPAA/HITECH is the minimum standard for data handling
- De-identification must comply with the HIPAA Privacy rule
- Encryption is required (portable media, laptops, desktops, everything)
- Equipment, media, paper losses must be reported immediately
- Access to data must be maintained consistent with job role & approved IRB protocol
- Complex passwords are required
- Device security features are never to be disabled
- Research data on approved storage only (no Box.com, no Cloud)
- Use of commercial email systems are not permitted
- Data security plans are required
- Commercial vendors used in research require Dean's office approval
- No non-public NU data on personal devices
- Policy: http://www.feinberg.northwestern.edu/it/policies/information-security/fsm-policy-security.html
- Questions & support, FSMIT-policy@northwestern.edu
Data Security Plan Policy

- Effective May 5, 2015, updated April 21, 2017
- Required for research of principal investigators with FSM appointments.
  - Plans are required for all new clinical research studies
  - Plans are required for existing studies at continuing review/renewal
  - Submission form triggered via FSM appointment declaration in the RSS Operational Data form
- Study focused risk assessment (e.g., data origination and flow, storage, access, backup).
- Checklist items for recruitments data sources, cloud storage
- All plans submitted to review (4608 as of 12/31/17) and audit (1086 as of 12/31/17).
- Built-in process improvement and vendor management
- Improves safeguarding of the University data
- Policy, template and examples: http://www.feinberg.northwestern.edu/it/standards-policies/information-security/index.html
- Questions & support, FSMIT-policy@northwestern.edu

CITI Program: HIPAA and Information Security Training (FSM)

- CITI Training can be accessed by anyone with a Northwestern NetID.
- Four modules, 3 required and 1 optional:
  - Basics of Health Privacy (HIPAA) – Required
  - Health Privacy Issues for Researchers – Optional
- Accessing the course:
  Go to www.citiprogram.org. Select “Log In”. Then select “Log In Through My Institution”. Click on “Northwestern University”. Enter NetID/Password. Then “Add a Course.” Scroll to Question 5 and enroll in the HIPAA, Security and Privacy Training course. Upon completion of the training, a certificate of completion will be logged in the CITI system and available to print.
Email Encryption Policy

- Effective October 1, 2015.
- Email message and attachments are required to be sent encrypted when containing PHI or PII.

**Automatic Encryption** - Messages containing sensitive data sent from your @northwestern.edu e-mail address to or from recipients within Northwestern-affiliated domains are automatically encrypted and do not require additional effort. Northwestern-affiliated domains enabling automatic encryption:
  - northwestern.edu
  - lfh.org
  - nmff.org
  - cadencehealth.org
  - livingwellcrc.org
  - nmh.org
  - cdh.org
  - luriechildrens.org
  - northwesternmedicine.org
  - childrensmemorial.org
  - nm.org
  - sralab.org

**Manual Encryption** - Messages containing PHI or PII data sent from your @northwestern.edu e-mail address to non-Northwestern-affiliated environments will require manual encryption. Manually encrypted messages will be automatically quarantined.

**Forced Encryption** - Email messages will be automatically encrypted and quarantined if manual encryption is not used and PHI or PII is suspected.

- Policy: [http://www.feinberg.northwestern.edu/it/policies/email.html](http://www.feinberg.northwestern.edu/it/policies/email.html)
- Questions & support, FSMIT-policy@northwestern.edu

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Email Auto-forwarding Policy

- Effective October 1, 2015.
- Email message and attachments can be forwarded and/or auto-forwarded only within approved Northwestern-affiliated email systems. Current list published in policy.
  - northwestern.edu
  - lfh.org
  - nmff.org
  - cadencehealth.org
  - livingwellcrc.org
  - nmh.org
  - cdh.org
  - luriechildrens.org
  - northwesternmedicine.org
  - childrensmemorial.org
  - nm.org
  - sralab.org

**Forwarding or auto-forwarding email messages and attachments to public email systems such as gmail.com, yahoo.com, or hotmail.com is not allowed.** * The use of public email systems is not approved for any research purpose at Northwestern University, Feinberg School of Medicine.
- Email systems fsm.northwestern.edu, u.northwestern.edu and md.northwestern.edu are Google public email systems and are not part of approved Northwestern-affiliated email systems for the exchange of research data and other sensitive information.

- Policy: [http://www.feinberg.northwestern.edu/it/policies/email.html](http://www.feinberg.northwestern.edu/it/policies/email.html)
- Questions & support, FSMIT-policy@northwestern.edu

* Auto-forwarding will be disabled on the NU email system for FSM
FSM File Sharing Policy

<table>
<thead>
<tr>
<th>Data Type &amp; Examples</th>
<th>SharePoint</th>
<th>Vault (Research Only)</th>
<th>Northwestern Box</th>
<th>Northwestern File Servers</th>
<th>Google (Only Student Collaboration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public (e.g. calendar, course descriptions, maps, directory, approved census facts, audited financials)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Internal: Non-Sensitive (e.g. meeting agendas, project documents, team building event)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Internal: Sensitive (e.g. salary plans, employment data, budgets, donor information, IRR data, CTEC, patent information)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Legally/Contractually Restricted (e.g. PHI, SSA, PII, student records, medical records)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Policy (NUIT): http://www.it.northwestern.edu/file-sharing/overview.html
Questions & support, consultant@northwestern.edu

Policy (FSM): http://www.feinberg.northwestern.edu/it/services/storage-options.html
Questions & support, fsmhelp@northwestern.edu

Device Security Policy

- Effective April 15, 2016
- All devices: FSM IT managed & personal devices
- No non-public NU data on personal devices
- All devices must be encrypted and connection through only VPN
- Smartphones
  - Requires six-digit pin; and encryption enabled for Android devices
  - Limit of 30 days NU email
- Email synchronization to personal devices will be disabled on the NU email system for FSM
- Email synchronization via IMAP disabled
- Administrative rights will be phased-out
- Policy: http://www.feinberg.northwestern.edu/it/policies/information-security/index.html
- Questions & support, FSMIT-policy@northwestern.edu
Information Security Policy References

Health Insurance Portability and Accountability Act (HIPAA):
http://www.hhs.gov/hipaa/for-professionals/index.html

Health Information Technology for Economic and Clinical Health (HITECH)

Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule:
http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

FSM Information Technology:  http://www.feinberg.northwestern.edu/it/
FSM Email:  http://www.feinberg.northwestern.edu/it/policies/email.html
FSM Storage Options:  http://www.feinberg.northwestern.edu/it/services/storage-options.html
NU Storage Options:  http://www.it.northwestern.edu/file-sharing/overview.html
Incident Response Protocol:  http://www.it.northwestern.edu/policies/incident.html

NU Identity Management System (including passwords):  http://www.it.northwestern.edu/auth-svcs/nuvalidate.html
Service Provider Security Assessments:  http://www.it.northwestern.edu/about/departments/itms/cpo/assessment.html
NU Policies, Guidelines, and Practices:  http://www.it.northwestern.edu/policies/
Secure IT at Northwestern:  http://www.it.northwestern.edu/security/

Support & Resources (FSM)

• Central FSM IT Organization
  Carl Christensen, CIO
  Andrew Winter, Deputy CIO, Senior Director of Information Technology
  Carl Cammarata, Senior Director, Chief Information Security Officer
  Curtis Hanawalt, Director of Information Technology Customer Support
  Frank Schleicher, Director of Integrated Media Services
  FSM IT Steering Committee

• Central Support & Resources
  847-491-4357 or 1-HELP (from on campus)
  FSMHELP@northwestern.edu
  http://www.feinberg.northwestern.edu/it/index.html
Information Security Support & Resources

- **FSM**
  - 847-491-4357 or 1-HELP (from on campus)
  - FSMTPolicy@northwestern.edu
  - [http://www.feinberg.northwestern.edu/it/standards-policies/information-security/index.html](http://www.feinberg.northwestern.edu/it/standards-policies/information-security/index.html)
  - Carl Cammarata, Senior Director, Chief Information Security Officer, 312-503-2822
  - David Gundrum, Senior Information Security Analyst, 312-503-3869
  - Marvina Roebuck, Senior Information Security Analyst, 312-503-5735
  - Leon Tran, Information Security Analyst, 312-503-6140

- **University (Information & Systems Security/Compliance)**
  - 847-491-4357 or 1-HELP (from on campus)
  - security@northwestern.edu
  - Thomas Murphy, Senior Director, CSIO, 847-467-6422

Data Management & Repository Services

- University Libraries,
- Digital Scholarship Services
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

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**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

Arch
All Northwestern University
- Research papers
- Technical reports
- Documentation
- Presentations
- Case studies
- Datasets
- Posters
Managed by the Main Library
arch.library.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

Speeding transformative research discoveries to patients and the community
NUCATS is At Your Service!

- A centralized hub of resources available to your research team
- We provide **training, tools, and services** to support investigators across the full spectrum of clinical and transitional science research

Education & Professional Development

- **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
Clinical Research Support

• **Budget & Finance**: study budget preparation, billing and reconciliation
• **Regulatory Compliance**: assists with IRB process and FDA submissions
• **Recruitment & Retention**: research participant recruitment strategy development, creation & distribution of marketing materials
• **Study Coordination Support**: clinical research nurse and non-nurse coordinators for hire
• **Clinical Research Unit (CRU)**: at Lurie and NMH

Data Science, Informatics & Analytics

Secure, Web-based Applications
• **REDCap** (Research Electronic Data Capture): Data collection forms
• **Study Tracker**: Clinical trial management system
• **Recruit**: Research registry system

**Northwestern Medicine® Enterprise Data Warehouse (NMEDW)**
• **NMEDW**: Repository of research data on more than 6 million people
• **i2B2**: a free tool to determine the feasibility of conducting a clinical trial

**Biostatistics Collaboration Center (BCC)**
• Biostatistics
• Epidemiology
• Research Design
Community Engaged Research Support

• **Develops partnerships** between community, clinical, public health and policy sectors

• **Workshops**, seminars and programs on community and stakeholder engagement

• **Seed grants** for community-academic research teams

• **Consultations** for design and implementation of community engaged/based projects

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Innovation, Commercialization & Entrepreneurship

• Partnership with INVO

• Support for new drug and device development

• Expertise in technology commercialization and innovation

• Funding opportunities
Galter Health Sciences Library & Learning Center

Research Services
- Access to more than 8,600 e-journals, 3,000 e-books, and 300 databases
- Consultations
- Training and workshops
- Bioinformatics and biosciences support

Scholarly Services
- Preserving and sharing scholarly content with DigitalHub
- Impact measurement and evaluation
- NIH Public Access Policy
- Biosketch development

Stanley Manne Children’s Research Institute

- 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 Resources

NUCATS Studio Consultations:
• Gives investigators in the planning stages of a new program or center grant an opportunity to leverage 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 64 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

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: membership.nucats.northwestern.edu
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

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NUCATS
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312-503-1967
clare.mcfadden@northwestern.edu

http://www.nucats.northwestern.edu
Humans and animals have many comparable physiological processes. Genetically modified animals, usually mice, can be bred to increase these similarities with humans.

Basic research (compared to applied 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)
COMPONENTS OF AN ANIMAL CARE AND USE PROGRAM

INSTITUTIONAL LEADERSHIP

PI RESPONSIBILITY

Animal Welfare

DAILY ANIMAL CARE (CCM)

IACUC

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
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

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

TRAINING AND OCCUPATIONAL HEALTH

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

1. IACUC ONLINE TRAINING
   - Training materials must be completed by each individual listed on an Animal Study Protocol (ASP) on an extension prior to the document being submitted to the IACUC.
   - Contact Storm Roberts at 312-503-9183 or 312-503-9154 or by e-mail at s-roberts@northwestern.edu. Provide the spelling of your name and he or she will assign a Username and Password. You will then have a Northwestern University account in the AUARS learning library, which you will need to order to take classes. Only Northwestern affiliates can access the Auars Learning Library.

http://www.iacuc.northwestern.edu/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

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)
Federal Funding & IACUC Approval

• If a PI receives federal funding (e.g., an NIH grant), the institution is required to assess the grant application and animal study protocol, ensuring that they are congruent.

• Key points:
  – The full grant application needs to be attached to the electronic protocol in order to facilitate the grant-protocol congruency review.
  – It is strongly recommended that a PI begin work on the protocol when they are notified that their score is fundable.
  – Greater pressure to have IACUC approval more quickly.

Census

Animal Census (w/o Mice)

- Cats
- Dogs
- Gerbils
- Ground Squirrels
- Guinea Pigs
- Macaques
- Pigs
- Rabbits
- Rats
- Xenopus
- Zebrafish
A Numerical Summary

- So far in 2018, the IACUC has approved:
  - 129 new protocols
  - 1,020 amendments (i.e., changes/updates to active protocols).

- Currently 925 protocols are active.
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 than 24 hrs and USDA covered species are kept in the space for greater than 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

![Barcode Image]

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

![Paid Image]
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

CCM

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?
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](mailto:nu-ori@northwestern.edu) or 312-503-0054
- Contact your supervisor, department chair or dean
  - OR
- Contact [EthicsPoint](http://www.ethicspoint.com), either online or by phone

[http://www.researchintegrity.northwestern.edu/research-misconduct](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
lcampbell@northwestern.edu
847-467-4063

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

**Grant Management**
Office of Sponsored Research
Lynda Wolter, Executive Director
lwolter@northwestern.edu
312-503-7955
Controller’s Office
Mike Daniels, Director
m-daniels2@northwestern.edu
847-491-4710

**Research Misconduct**
Office for Research Integrity
Lauran Qualkenbush, Director
nu-ori@northwestern.edu
312-503-0054

**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

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
Penalties for Noncompliance

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

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

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**Recent Examples of the Impact of Noncompliance**

<table>
<thead>
<tr>
<th>Institution</th>
<th>Settlement Time Frame</th>
<th>Details</th>
</tr>
</thead>
<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
- Know when and where to ask for help
- Understand complex regulations
- When in doubt, ask
- We are all responsible

Questions?

What... Does this happen often?