Resources for Faculty Transitions

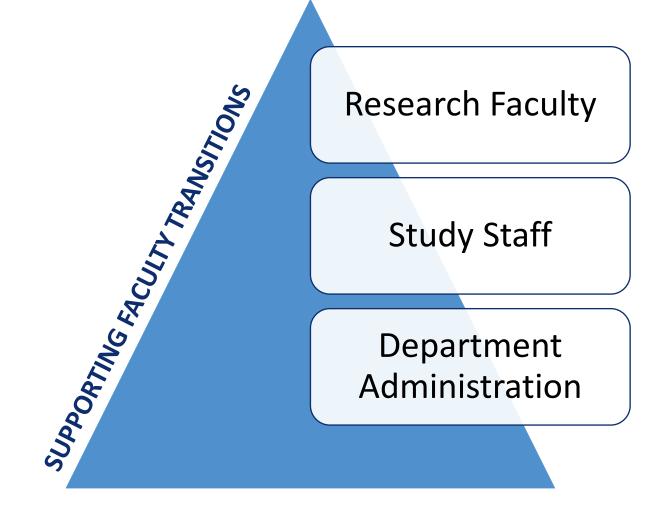
PRESENTED BY:

- Yasmeen Khan, Institutional Review Board (IRB) Office
- Katie Hammond, Northwestern University Clinical & Translational Sciences Institute (NUCATS)
- Emily Updegraff, Conflict of Interest
- Mary Kate Clifford, Export Controls & International Compliance

Unified HRPP Collaboration

- Novel Human Participant Protection Program (HRPP) collaboration on researcher on-boarding and off-boarding processes to ensure the seamless transition of research work to and from Northwestern University.
- This project brought together units from across the institution to jumpstart the on-boarding process for researchers new to Northwestern and avoid administrative delays.
- The project also has an off-boarding component that ensures investigators efficiently and compliantly transition away from Northwestern University.

Partnership Between:



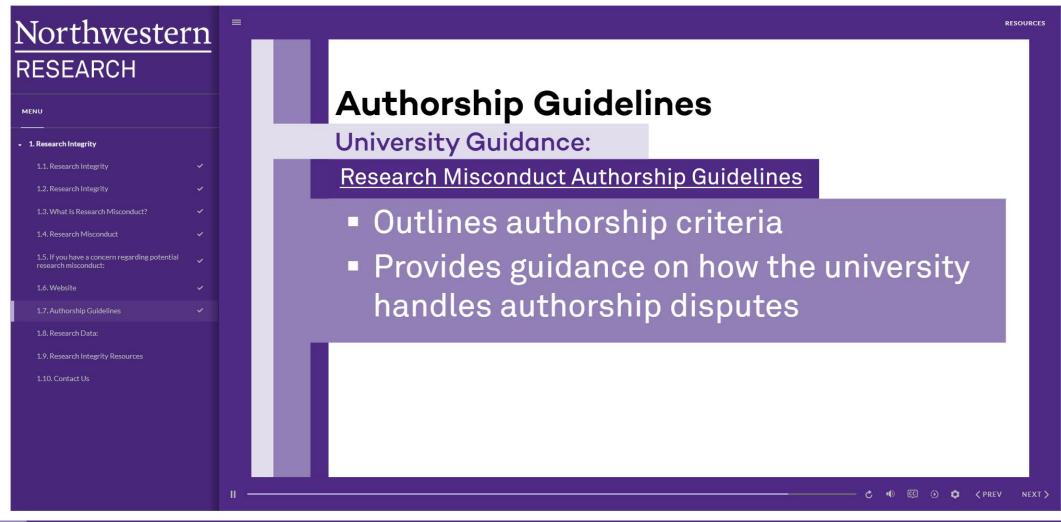
MyHR Learn: Researcher Onboarding & Offboarding

Departments and Units

Accounting Services for Innovation & New Ventures Institutional Animal Care and Institutional Review Board (IRB) **Research and Sponsored Use Committee (IACUC)** Office (INVO) Programs (ASRSP) **Core Facilities Center for Comparative Export Controls & International Conflict of Interest (COI)** Medicine (CCM) Compliance (ECIC) (CORES) **Northwestern University Northwestern Libraries (NWL)** Information Security (IS) **Clinical and Translational Corporate Engagement Sciences (NUCATS) Office of Foundation Relations Research Development** Office for Research Integrity Office for Research Safety

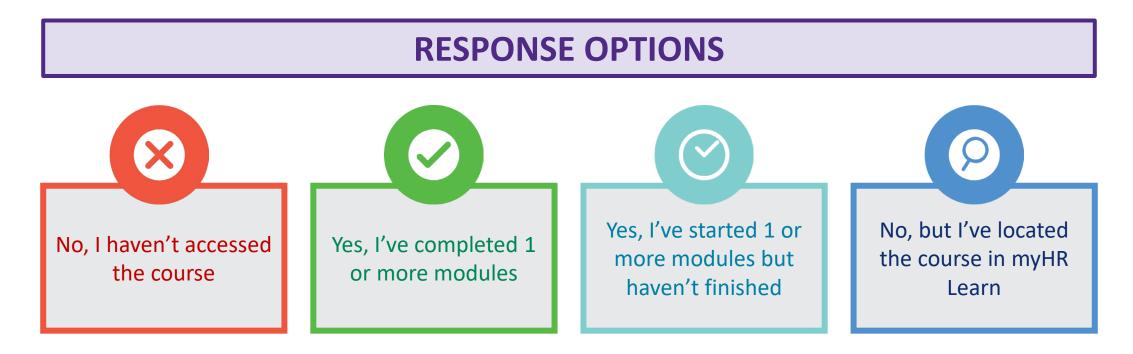


myHR Learn Course: Researcher Onboarding/Offboarding



QUESTION:

Have you accessed or completed any part of the Researcher Onboarding or Offboarding course in myHR Learn?





Onboarding Module Overview

NUCATS Overview

- NUCATS supports investigators across the entirety of the translational research spectrum. Our mission is to accelerate YOUR clinical and translational research discoveries to improve human health. This support takes many forms, from research team development and pilot funding to careerdevelopment awards and grant-writing.
- As one of 60+ members of the Clinical and Translational Science Award Consortium, the NUCATS Institute can connect your study team with local, regional, and national institutions to provide critical services and resources to assist clinical and translational research

1.03 Franks

NUCATS Centers & Programs

- Our centers and programs allow us to develop, demonstrate and disseminate scalable solutions in clinical and translational science and meet our scientists' urgent needs
- For contact information by center, please visit our Contact Us page.

Clinical Research Resources

The <u>Center for Clinical Research</u> (CCR) works closely with study teams to provide central support services, reduce investigator burden, and share best practices. CCR seeks to maximize quality and efficiency of all programs and quickly resolve issues when they arise.

Service Units within CCR:

- NMH Clinical Research Unit (CRU) & Core Lab
- Ambulatory services clinic
- Outpatient & Inpatient Mobile RN Services
- CCR Regulatory Unit
- Initial IRB approval, ongoing trial maintenance, e-regulatory binder establishment and ongoing compliance.
- CCR Finance Uni
- Industry Clinical Trial Budgets, Contract Review & Execution with NU Sponsored Research, Study Invoicing & Reconciliation



NUCATS Resource Request Form



NUCATS Resource Directory

Northwestern | RESEARCH

Education & Career Development

The <u>Center for Education & Career Development</u> (<u>CECD</u>) trains the translational research workforce through more than a dozen programs, allowing early career faculty, postdoctoral fellows, scholars, trainees, and clinical research professionals to advance Northwestern's research enterprise.

Requests & Resources

- Investigator Development
- Research Staff Development
- **Good Clinical Practice Training**
- Science Immersion Program
- NIH Diversity Supplement Guidance

NIH Training Grant Awards

- K12 Multidisciplinary Career Development Program: designed to train a diverse workforce of investigators to drive future innovation and implement effective clinical and translational research.
- T32 E-TRAIN Program: seeks to prepare postdoctoral trainees for research careers through mentored research while they develop strategies to anticipate and overcome scientific and operational barriers

Other Consultation and Learning Resources

- Trial Innovation Network (TIN)
- NUCATS On-Demand
- Clinical Research Coordinator (CRC) Resources
- ClinicalTrials.Gov Support & Resources

Northwestern | RESEARCE

Support Services & Courses

Grant Writing Support & Funding

Research Navigation Support at NUCATS

- Requesting a NUCATS Letter of Support
- Requesting University-wide "Facilities and Other Resources" document
- NUCATS Studios and First-Submission Grant Consultations

Need Help?



Pilot & Voucher Funding

NUCATS connects scientists to a wide variety of funding opportunities to meet the special needs of each stage of the clinical and translational research continuum.

Research Navigation Support at NUCATS

- Translational Science Pilot Awards (up to \$30,000)
- Voucher Awards (up to \$2,500)
- NMEDW (up to \$1,000)



Northwestern | RESEARCH

Northwestern | RESEARCH

NUCATS Institute Course Offerings

Course Offerings:	
Master of Science in Clinical Investigation	Taking Responsibility for the Responsible Conduct of Research
Succeeding with Your K Award	Navigating the Research Enterprise
Developing & Enhancing Mentoring Relationships	Mentor Training Certificate Program
Kellogg Leadership & Management Strategies for Clinical Investigators	NU Clinical & Translational Investigation Accelerator
Science and the City: Diverse Pathways from Student to Scientist	CRC Basic Training (Live & Asynchronous)

NUCATS Marketing & Communications

Northwestern | RESEARCH

Trial Innovation Network & NUCATS

- The Trial Innovation Network (TIN) links NUCATS with the 60+ nationwide CTSAs through two dedicated Innovation Centers. NUCATS and the TIN helps bolster and expand investigator networks for developing multisite clinical trials—aiding locally, regionally, and nationally.
- The TIN Trial Innovation and Recruitment Centers can provide many no cost network resources to aid your research – from idea concept through the lifecycle of multisite translational trials.
- Resource examples include consult support for protocol development, study operations enhancement, budget guidance, community engagement studios, multisite recruitment planning and tools, EHR based resources, and much more.
- For contact information, visit our NUCATS TIN Contact page.



publications, and more.

Communications Support

Campus-wide Emails

- Chicago Transit Authority Advertising
- News articles on pathbreaking discoveries

Our weekly NUCATS Minute email provides

timely information about events, trainings,

pathbreaking research, NUCATS members,

grants, resources, services, and more,

Our monthly newsletter highlights

Find us on Social

Twitter: @NUCATS Institute
 LinkedIn: NUCATS Institute



Contact Us

Roger Anderson
 Director of Marketing and Communications
 Roger-Anderson@northwestern.edu

Northwestern | RESEARCH

Northwestern Conflict of Interest

What is a Conflict of Interest?

A conflict of interest is a situation in which an individual's outside financial interests and/or activities affect, or appear to affect, their professional judgement in exercising their Northwestern responsibilities.

What do new faculty need to do?

- Become familiar with the Policy on COI and COC and the Policy on COI in Research
- 2. Disclose outside financial interests and activities through eDisclosure
 - a) Disclosure is required annually and within 30 days of acquiring a new financial interest
 - b) Disclosure is required before submitting a proposal or joining an IRB protocol

https://coi.northwestern.edu/

e-Disc Sure

How Can Units Help?

1. In September, contact NUCOI with a list of new hires. Send midyear updates if possible.

2. Share the Disclosing for Resources page with faculty:

https://www.northwestern.edu/coi/disclosing/disclosing-for-research.html

Northwestern

EXPORT CONTROLS & INTERNATIONAL COMPLIANCE

Do you (or anyone you supervise):

- ☐ Conduct **sponsored** research
- □ Execute or arrange NDAs/MTAs and other agreements with certain restrictions
- ☐ Host international visitors
- □ Collaborate with international partners
- ☐ Travel abroad for work (conference/teach/research)
- □ Ship items internationally (or send data to parties abroad)
- ☐ File patents outside the United States
- ☐ Receive compensation (monetary or in kind) from foreign sources
- □ Work with individuals, including students or organizations located in a **comprehensively OFAC-sanctioned country** (Cuba, Iran, North Korea, Syria, or certain areas in Ukraine)
- Work with individuals, including students or organizations located in a military end-use country (Belarus, Burma, Cambodia, China, Nicaragua, Russia, and Venezuela)

Yes?...

You may then be impacted by export controls and research security regulations.

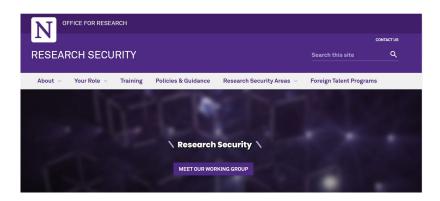
IF YOU HAVE SPECIFIC QUESTIONS ABOUT INTERNATIONAL EXPORT OR RESEARCH SECURITY, PLEASE REACH OUT TO OUR TEAM.

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	International Shipping/ Hand Carrying	International Travel	International Collaborations	Purchase of Controlled Items	
WHO/ HOW?	 To whom are you sending or hand carrying the items? What will the recipient do with the items? 	 Who are you meeting or working with? Who is funding (travel, honorarium)? How can you protect your data and device? 	 What organization or company is the collaborator affiliated with? Is the collaborator in or from a high-risk country? Research Visitor – use recommendation form Unpaid Interns – follow NU's process 	How will the item be used?Who will be working on or with the items?	
WHAT/ WHY?	 Biological, chemical, or hazardous materials (e.g.,: virus, toxin, bacteria, GMO) Critical technology area (e.g.,: IC, supercomputer, quantum, biotech) High-tech or encryption equipment (e.g.,: camera, scanner, software) Military / Space item 	 Purpose of trip? Business? (e.g.,: Research, Conference, Meetings) Personal? Clean laptop Required for OFAC countries Highly recommended for MEU; Feinberg requires any country 	 What is the nature of the collaboration? Are they affiliated with a restricted entity? Award requirements/restrictions? Talent program considerations Compensation (monetary or in kind)? Agreements or contracts? Is the person you are working with associated with a foreign talent recruitment program (is it malign?) Is your activity considered a foreign talent recruitment program? Could the activity or collaboration increase your federal risk profile? 	 Is it controlled? Substances? Equipment? Software? Technology? Materials? Does it have an end-user statement? Is it marked export controlled? 	
WHERE?	What is the final destination? Any shipment or hand carry to a high-risk country (OFAC and MEU)	High Risk Countries ✓ OFAC ✓ Military end use	Where is the collaborator physically located? Any collaboration with a high-risk country (OFAC and MEU)	How will you secure the item? Will they remain in the U.S.?	

Resources and FAQs to assist you:

- International Collaborations
- Disclosure guidance
- <u>Improper Foreign Influence</u>
- Federal Agency Risk Reviews
- Foreign Talent Program Guidance
- Restricted Party Screening Denied Entity
- International Travel Guidance
- OFAC Guidance (Cuba, Iran, North Korea Syria, and parts of Ukraine)
- OFAC and Iran
- International Shipping

Research Security Website



exportcontrols@northwestern.edu

Brief video – 8 minutes!



Export Controls Website



Northwestern

INSTITUTIONAL REVIEW BOARD OFFICE

Onboarding – Key Sections

What training courses are required by Northwestern to conduct research?



How to register with eIRB+?



Does my research qualify as human research at Northwestern?



How can I transfer my research to Northwestern?



Onboarding

Key Concepts

Investigator Manual

elRB+

Is the Study
Human
Research?

Human Research
Protections
Training

PI Eligibility

Prepare & Submit a Human Research Study

Reliance Planning

Educational Tools

Offboarding – Key Sections

Close the Study

Submit CR in eIRB+
Only for non-exempt human research

Transfer Researcher
Oversight

Transfer research oversight to another faculty researcher at Northwestern

Document Retention Responsibilities

Retention of research records is transferred to the faculty member's department

Key Takeaways

Key Takeaways

QUICK, TARGETED TRAINING:

New Researcher Onboarding and Offboarding courses provide concise, action-oriented guidance.

KNOW YOUR RESOURCES & CONTACTS:

Each HRPP office shared key tools and contact information to support researcher transitions.

PROACTIVE IS KEY:

Early planning helps prevent disruptions, delays, and potential non-compliance.

PREVENT COMPLIANCE GAPS:

How to prevent common oversights during transitions that could lead to non-compliance.

CONSISTENCY ACROSS THE INSTITUTION:

The new training ensures a standardized, university-wide approach to onboarding and offboarding researchers.

WE'RE IN THIS TOGETHER:

Supporting researcher transitions is a shared responsibility.

QUESTIONS?