



ORI Mission:

- Identifying compliance risks in our research practices and communicating those risks to the research community;
- Partnering with the research community in innovative and effective ways to minimize and manage research risks;
- Educating the research community with respect to appropriate business practices related to the conduct of research at Northwestern University; and
- Monitoring and correcting non-compliance in accordance with University and federal

Northwestern Hosts Grassroots Research Integrity Association

ORI Staff

Lauran Qualkenbush
Director
Research Integrity Officer

Beth Irwin
Research Training Manager

Yasmeen Khan
Administrative Assistant III

Michelle Stalilonis
Senior Compliance Analyst

The Association of Research Integrity Officers (ARIO) is a new grassroots organization, started by five US Research Integrity Officers (RIOs). This group is looking to address the lack of forums for RIOs in an effort to facilitate best practices, education, sharing and networking. RIOs are the institutional officials responsible for implementing federal regulations and institutional policies governing allegations of research misconduct. This September, Northwestern's ORI hosted the second annual ARIO meeting, a welcomed opportunity for RIOs, whose complicated work is often done in isolation, to discuss shared issues among peers as well dialogue with HHS ORI and NSF OIG, our federal oversight partners for research misconduct.

Organized with the support of the founding ARIO steering committee, which includes NU ORI's director, Lauran Qualkenbush, the conference was open to RIOs, general counsel, and staff who work with RIOs to handle research misconduct allegations. In attendance were approximately 90 national and international individuals, clearly demonstrating the need and interest for a professional community. Over the course of the three day event, a number of speakers presented on issues that contributed to current research misconduct regulatory and best practices discussions. Northwestern's own Teresa K. Woodruff, PhD, Director of NU's Women's Health Research Institute and Professor of Obstetrics and Gynecology, opened the conference with her keynote address, "Data Reproducibility and Research Integrity." Additional NU faculty members included Phil B. Fontanarosa, MD, MBA, Adjunct Professor of Emergency Medicine, Robert A. Lamb, PhD, Professor of Molecular Biosciences and George C. Schatz, PhD, Professor of Chemistry and Chemical & Biological Engineering, who spoke to their experience as editors of major scientific journals during a panel discussion titled "Balancing Interests: Journal's Perspective on Research Misconduct." Federal partners from HHS ORI and NSF OIG, RIOs from peer institutions as well as a European counterpart, all offered engaging discussions on a range of relevant topics. The full meeting agenda is accessible on the conference website (<http://www.research.northwestern.edu/ori/ario/>).

By hosting ARIO 2014, NU demonstrated its commitment to this grassroots association, which is vital to the work of RIOs nationwide. Given the limited practical guidance offered in the relevant federal regulations, the ARIO hopes to foster the formation of best practices for reviewing allegations of research misconduct and affect change on a national level. NU ORI is excited to be a leader in ARIO and will continue to support the RIO community by actively participating in both national and regional events in the coming years.

Did You Know?

The Conflict of Interest (COI) Office has a new one-page quick reference guide for investigators that emphasizes key aspects of the sponsored research COI disclosure processes. The short guide highlights critical process points, including: when disclosure is required; how disclosures are reviewed; and what happens if a COI is identified. Select [here](#) to view the guide or visit <http://www.northwestern.edu/coi/> for additional resources.

The Office for Sponsored Research (OSR) has launched its new website that greatly improves navigation to help you more easily access information about relevant policies and procedures, OSR staff contact information, educational resources, and electronic systems and forms. Visit the new site at: <http://osr.northwestern.edu/>

On 10/23/2014 the National Institutes of Health (NIH) released a revised definition of "clinical trial." The new definition will replace the current clinical trials definition in relevant NIH policies, guidance, and instructional materials and apply to completing grant applications/contract proposals that are submitted to NIH for the 1/25/2015 due date and/or subsequent dates. The new definition can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>



Introducing

Anne Grace....

1) What is your title at Northwestern?

Senior Contract & Grant Officer

2) What does that mean?

I'm responsible for negotiating and signing unfunded contracts, such as MTAs, on behalf of Northwestern University and its researchers.

3) What is one thing you want people to know about what you do here?

I'm trying to help them share data and materials as quickly as possible while still protecting the interests of the University and investigators.

4) How long have you been at Northwestern?

5 years

5) What did you do before you came to NU?

I was a postdoctoral fellow in Philadelphia working in an immunology lab and then a research administration fellow at Children's Hospital of Philadelphia.

6) Where is your home town?

Toledo, OH

7) What is your favorite part about the fall season?

Fall foods and football

8) What is your favorite thing to do outside of work?

Hanging out with my family and I like to cook

9) What is your favorite yearly Chicago event?

Beach Volleyball season because there is a team I play on called the Volley Llamas

Research Administration Upcoming Training

This four-session seminar is geared toward research administrators, staff involved in research administration and anyone who wants to learn about NU's research administration process, policies, and procedures. The seminar serves as an introduction to NU's research community and the extensive systems involved. It is a great networking and educational opportunity for staff new to research or experienced staff who would like a refresher in certain areas. Representatives from departments throughout NU will be on hand to present and answer questions.

The next seminar will next take place January 26th, 28th and February 2nd and 4th from 1:00 p.m. - 4:30 p.m. on the Chicago campus (McGaw, Daniel Hale Williams Auditorium). To register, email nu-ori@northwestern.edu

MTAs and DUAs: Making Smart and Beneficial Agreements

The exchange of data and materials is an important practice that commonly occurs between researchers at various institutions and agencies. Often it is through collaborations that advances in scientific research are made that lead to new insight and breakthroughs beneficial to society. While such types of partnerships are important, it is equally important to ensure they are done correctly to protect the researchers and research institutions.

Materials Transfer Agreements (MTAs) and Data Use Agreements (DUAs), which are vital administrative elements necessary for such protections, are legal contracts between research institutions that govern the transfer of proprietary research material and information. "This process is often initiated when outside investigators want to conduct research using Northwestern's material or data, or if one of our researchers similarly wishes to use material or data from another institution," explains Anne Grace, Senior Contract and Grant Officer in the Office for Sponsored Research (OSR)-Chicago. Both MTAs and DUAs essentially address the same key elements such as ownership, permitted use and further distribution, publication of results, possible inventions, compliance with applicable laws and liability. However, they differ slightly in the scope of what is covered. "Materials" can refer to biological materials (DNA, cell lines, tissues, animals, etc.), pharmaceutical drugs or compounds, chemicals, software, or other types of physical substances. DUAs vary depending on whether they are used to transfer non-human subject data, completely de-identified human subject data, or human subject data which includes Protected Health Information (PHI). IRB approval may be necessary when transferring human subject data or samples that contain PHI.

It is important to note that MTAs and DUAs are legal contracts between research institutions, not between individual scientists. Administrators seeking to expedite these agreements should send a draft of the agreement to the appropriate contact in OSR (listed below) since they are trained to understand the terms and negotiate as needed to protect the PI and NU. "It's important that OSR review and approve these agreements prior to having anyone sign them," explains Grace. "MTAs and DUAs should be submitted for review as soon as possible to avoid delaying the research project."

Requests for both inbound and outbound MTAs should be sent to mta@northwestern.edu regardless of whether you work on the Evanston or Chicago campus, and should include a completed inbound or outbound MTA [form](#) which is located on OSR's newly updated website. Requests for inbound and outbound DUAs can similarly be sent to mta@northwestern.edu for research conducted on the Chicago campus, while all Evanston campus DUA requests should be sent to Michael Rynties at Michael.Rynties@northwestern.edu. Requests for all MTAs and DUAs may soon be made using the Electronic Sponsored Projects Request (ESPR) application.

Contact your OSR office should you have any questions.

	DUAs	MTAs
Evanston	Michael.Rynties@northwestern.edu	312-503-0884 Mta@northwestern.edu
Chicago	312-503-0884 Mta@northwestern.edu	

Quote Corner

Good design begins with honesty, asks tough questions, comes from collaboration and from trusting your intuition.
-Freeman Thomas





EthicsPoint is a third party vendor that allows you to confidentially raise ethical concerns, ask questions, and/or report activities that may involve misconduct or violations of Northwestern University policy. For more information visit the website at:

www.northwestern.edu/ethics



Office for Research Integrity

750 N Lake Shore Drive
Rubloff, 7th floor
Chicago, IL 60611

PHONE:
(312) 503-0054

FAX:
(312) 503-0902

E-MAIL:
nu-ori@northwestern.edu



NORTHWESTERN
UNIVERSITY

Lawsuit Serves as Essential Compliance Reminder

“Learning would be exceedingly laborious, not to mention hazardous, if people had to rely solely on the effects of their own actions to inform them what to do.” – Albert Bandura, Social Learning Theory.

Though the importance of effective effort reporting has been a focal point of discussion at NU for quite some time, one can't help but find the above quotation exceedingly applicable in light of the recent lawsuit against Columbia University. The October 28th settlement, in the sum of \$9 million, resolved a civil lawsuit by the U.S. government accusing Columbia of submitting false claims for its International Center for AIDS Care and Treatment Programs. Specifically, despite the obligation to track employees' efforts, it was determined that multiple grants were falsely charged for work not dedicated to the funded projects.

This case serves as a reminder that mindfulness of, and compliance with, regulations is extremely important for all of us, whatever role you may play in the research community. Best practices encourage everyone to complete essential training and understand the most current policies/procedures. Visit the following link for detailed information about research related policies and procedures at NU: <http://www.research.northwestern.edu/policies/index.html>

New Electronic IRB Submissions System and Tools

The Institutional Review Board (IRB) Office has been working on a major revitalization project focused on improving the proficiency, quality, and effectiveness of its oversight of human research conducted by the NU research community. Essential to this project has been adopting new IRB Office processes and review procedures and creating helpful tools to improve consistency of review across all IRB meetings, in addition to more timely communications between the IRB Office and research community.

A significant update central to how research will be conducted involves the eIRB+ system. Launched on November 10, 2014, this new electronic system upgrade is geared towards streamlining the submission process and overall experience for researchers. Some of the benefits include a significantly shorter application, limited duplicate entry, no selection of the specific IRB review path, and allowance of concurrent modifications (study team and other changes). This also reinforces IRB's goal to make procedures consistent and transparent by focusing on regulatory requirements, providing functional SOP's for IRB staff, and worksheets/checklists for both IRB staff and IRB members.

The IRB Office provides a multi-tiered training and outreach program, with regular Brown Bag sessions, presentations at the Office for Research's quarterly Research Administration Training Seminars, as well as *ad hoc* training, catering to individual department's training needs/requests. Anyone unable to attend one of the eIRB+ training sessions can contact irbtraining@northwestern.edu to identify other training opportunities.

Stay tuned for an announcement about the series of eIRB+ tutorial videos that are currently in production and will cover the essentials for using the new IRB system.