



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 guidelines.

ORI Staff

Lauran Qualkenbush
Director
Research Integrity Officer

Beth Irwin
Research Training Manager

Yasmeen Khan
Administrative Assistant III

Michelle Stallonis
Senior Compliance Analyst



Choose Your Own Research (Mis)Adventure

Training for protecting research subjects and avoiding research misconduct just got a lot more interesting! A new interactive video was recently released by the U.S. Department of Health and Human Services' Office of Research Integrity (ORI) and Office for Human Research Protections (OHRP), aimed at teaching improved methods for conducting clinical research.

The Research Clinic, a web-based interactive training video, allows the viewer to assume the role of one of four characters and determine the outcome of the storyline by selecting decision-making choices for each playable character. The character options are:

- A principal investigator (PI), a busy oncologist who must balance doing what she thinks is best for her patients and her research;
- A clinical research coordinator, an overworked nurse who works for the PI who pressures her to falsify data and violate study protocols;
- A research assistant who has difficulties obtaining informed consent and following research protocols; and
- An Institutional Review Board (IRB) chair who is tasked with ensuring that research subjects and the integrity of the research enterprise are protected while dealing with a culture resistant to change.

Given the range of varying outcomes, this engaging video can be used to illustrate how to avoid violating human subjects' protections and avoid research misconduct. By highlighting typical scenarios involving falsification, fabrication, plagiarism, problems with informed consent, participant enrollment and IRB review/approval, the video provides knowledgeable solutions to help researchers avoid missteps.

The Research Clinic video is available free on the ORI and OHRP websites and can be used as a great teaching/educational resource:

<http://www.ori.hhs.gov/TheResearchClinic>

Did You Know?

Did you know that the National Science Foundation recently issued an updated Grant Proposal Guide (GPG) which must be used for proposals submitted/due on or after February 24, 2014? The revised GPG can be found online at:

<http://www.nsf.gov/pubs/policydocs/pappguide/sf14001/gpgprint.pdf>

Did you know that Contracted Services paperwork (for payments to an individual) is the only type of Online Voucher that needs original paperwork sent to ASRSP for approval? Online voucher polices are located at:

http://www.northwestern.edu/asrsp/docs/Online_Voucher_Policies_03232011.pdf

Did you know that NUCATS offers several resources for investigators, research staff and students to strengthen your knowledge and professional development in the field of clinical and translational research? Explore these research training opportunities at:

<http://www.nucats.northwestern.edu/advice-consultation/i-need/research-training.html>



Introducing Mandy Kozlowski....

1) What is your title at Northwestern?
PAM Coordinator in the IACUC Office

2) What does that mean?

Once an investigator has an approved protocol, I work with the research team to ensure that they remain compliant with their protocol, NU policies and procedures and external regulatory bodies. The PAM program performs a very vital function of ensuring that research at NU is conducted appropriately which helps to protect the institution's assurance and accreditation.

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

I'm here to support the researchers, helping them perform their research in an ethical manner, while also keeping the welfare of the animals a priority.

4) How long have you been at Northwestern?

I have been at NU for 3 years.

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

I was a vet tech for a large animal veterinary practice and then joined the world of research as an IACUC Coordinator at Children's Memorial Hospital.

6) Where is your home town?

Cedar Lake, IN

7) What is your favorite flavor of ice cream?

Moose Tracks

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

I love to ride horses and there is nothing better than a vacation via horseback!

9) What is your favorite yearly Chicago event?

The air and water show

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 June 9th, 11th, 16th, and 18th from 9:00 a.m.-12:30 p.m. on the Chicago campus (FSM-McGaw). To register, email bethirwin@northwestern.edu.

Introducing PAM: IACUC's Post-Approval Monitoring System

The post-approval monitoring program, known to many as PAM, is yet another example of great efforts taken to improve the integrity of research conducted at Northwestern University. One of the first of its kind in the country, this cutting edge electronic program was specifically designed to support the PAM process and has served as a model to many other institutions. PAM is a program through which the Institutional Animal Care and Use Committee (IACUC) can ensure and document program integrity, compliance with regulations and guidelines, and adherence to protocols.

Though PAM can serve as the 'eyes and ears' of the IACUC, a major goal is to work with, and in support of, research staff members and to confirm accurate and consistent protocol performance in a collegial, unobtrusive manner.

PAM is grounded in various regulations requiring timely review and quality performance standards, such as: USDA: 2.31 IACUC Functions, Public Health Service (PHS), The 'Guide for the Care and Use of Laboratory Animals,' and U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research and Training. All active Animal Study Protocols (ASP) involving the use of animals may be subject to this randomly selected review, occurring at least once every year, though protocols involving less invasive procedures will be monitored at the discretion of the IACUC and veterinary personnel. Examples of areas that are reviewed include: protocol and personnel; study procedures; anesthesia; surgery; post-surgical care; euthanasia; record keeping; and the laboratory used for animal procedures.

In general, the PAM Coordinator or designee will schedule monitoring sessions with the PI in advance and conduct the review using IACUC approved PAM checklists for visits. During each session, the PAM Team will compare procedures conducted in the laboratory with those listed in the approved protocols. Any discrepancies will be discussed with the PI and other research personnel before leaving the laboratory, with issues that pose an immediate threat to animal welfare immediately referred to the Attending Veterinarian for resolution. Following the visit, the PAM Coordinator will send a draft report to the PI, allowing an opportunity for response, before the final report is prepared and presented to the IACUC Senior Staff. The PAM Coordinator will follow-up on any issues that require protocol modifications, orientation of new personnel or training, and supporting the laboratory in corrective actions when necessary.

Compliance with regulations and program integrity is of the utmost importance to IACUC. The PAM processes will continue to evolve to ensure current best practice standards are supported.

More information regarding the PAM program and/or related documents are located at: <http://www.research.northwestern.edu/opr/acuc/post-approval/>

Quote Corner

"To give real service you must add something which cannot be bought or measured with money, and that is sincerity and integrity."

-Douglas Adams





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

Training for NIH's Transition to Subaccounts

Accurate award management and fiscal oversight are essential to maintaining scientific integrity and public trust in the administration of federal funds. To facilitate this mission, all operating divisions within The Department of Health and Human Services (HHS), including the National Institutes of Health (NIH), are making modifications that will affect how grant funds are managed. One notable change involves a shift from pooled account payments to subaccount payments.

Unlike the customary method of accessing funds through a single pooled account to draw down cash and pay for research expenses, the new subaccount system will require grantees to draw funds from award-specific accounts using the HHS Payment Management System (PMS). This new system will ultimately allow grantees and the NIH to better understand how much money is available for distinct research projects.

Information sessions on both campuses (detailed below), have been scheduled to further clarify how this transition to subaccounts will impact NU's aims and responsibilities. Representatives from Accounting Services for Research and Sponsored Projects (ASRSP), Effort Reporting and the Office for Sponsored Research (OSR) will discuss in more detail the impact this will have at NU, an implementation timeline, and compare/contrast how NU is currently paid by HHS with the changes in place.

Evanston Campus: Tuesday, May 13, 12:00-1:00pm, Chambers Hall, 600 Foster Street, Lower Level, Ruan Conference Center

Chicago Campus: Thursday, May 15, 12:00-1:00pm, Arkes Pavilion, 676 N Saint Clair, 6th floor, Surgery Training Room

More information about the PMS subaccount can be found online at:
<https://grants.nih.gov/grants/payment/faqs.htm>

Annual Reporting of Research Misconduct

Federal regulations state that Northwestern University is required to protect federal funds from misuse by safeguarding the integrity of federally sponsored work by responding to and reporting allegations of potential research misconduct. Misconduct includes fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results.

All institutions which receive or apply for Public Health & Sciences (PHS) support, research-training or research-related grant or cooperative agreements must have an annual assurance with the Federal Office of Research Integrity (ORI) on file.

This assurance means an institution promises that (1) it has required policies and procedures in place for dealing with allegations of research misconduct; (2) it has provided ORI with contact information for its assurance official; and (3) it will submit an annual report to ORI, identifying activity from the previous year that involved federal funds and resulted in allegations of potential research misconduct. This report also indicates which allegations moved forward to the formal inquiry or investigation process and what was formally reported to federal ORI.

As Northwestern's Research Integrity Officer (RIO), Lauran Qualkenbush is responsible for the annual assurance with federal ORI. Any questions related to this process or potential research misconduct concerns should be discussed with her.

More information regarding research misconduct and the annual report system can be found at: <http://ori.hhs.gov/>