Northwestern | OFFICE FOR RESEARCH INTEGRITY

NEWS

Fall 2015. Volume 4, Issue 1

IN THIS ISSUE

PI Transfer Dispute

When a PI transfers institutions, there are many processes involved to ensure effective continuity of research studies. Typically these moves are straightforward, particularly when institutions have clear procedures in place to provide support to the transitioning PI. However, Alzheimer's researcher Dr. Paul Aisen experienced his recent move from the University of California San Diego (UCSD) to the University of Southern California (USC) as anything but straightforward. In fact, his case represents perhaps the worst case scenario for researchers and universities alike.

When Dr. Aisen left his position at UCSD in June 2015, some 30 colleagues followed him to USC, and he attempted to transfer a $100 million-plus prestigious Alzheimer's Disease Cooperative Study (ADCS) that he directed. The study, which had been headquartered at UCSD, is in fact an umbrella term for a related group of several studies funded by the NIH National Institute on Aging, and also funded by corporate grants from companies such as Eli Lilly & Co. While NIH has not transferred the federal grant funding the study to USC, UCSD has lost control over much of the non-federal funding from private sponsors, such as Lilly. One of these privately funded studies is an ongoing three-year trial testing the efficacy of solanezumab, a much anticipated Alzheimer's drug, when administered to people at risk for the disease before symptoms emerge.

There is now ongoing litigation between UCSD and USC over control of the ADCS, with both sides offering dramatically opposing interpretations of Dr. Aisen's departure and the status of the cooperative study he directed. UCSD has held the study contract from the NIH since the study began in 1991, with Dr. Aisen becoming director when he moved there from Georgetown University in 2007. Since awards are given to an institution rather than the PI, UCSD holds that it is the rightful custodian of the award and alleges that Dr. Aisen broke his commitment to the university by attempting to illegally move control of the Alzheimer's research program, research awards, and study data to USC. UCSD is seeking access to the research data, monetary compensation given the loss of contracts, and punitive damages from Dr. Aisen, some of his staff, and USC. The countersuit from USC claims that UCSD, Dr. William Mobley, and Dr. David Brenner, dean of UCSD School of Medicine "set out to destroy Dr. Aisen's reputation in academia" and violated Dr. Aisen's academic freedom and reputation. Dr. Aisen and USC have further argued that UCSD no longer had the technical expertise needed to administer the program since many researchers responsible for the study, such as all the members of the informatics team, also transferred to USC. Litigation is still ongoing.

This case magnifies both the PI's and institution's interests in retaining control of a massive research project when a PI transfers to a new institution. The research community will be watching the Aisen case unfold to better understand the landscape of how projects, employment, and collaborations will be affected when a PI transitions to a new institution.

Research Related Onboarding and Check-Out Procedures for PIs

Northwestern University has two excellent resources to support departments when PI's are joining or leaving the University. The Onboarding Procedures for PIs and Checkout Procedures for PIs highlight key policies, procedures and contacts in the various research related offices, to support appropriate grant transfers and effective communication during both processes. These documents have been recently updated and will be reviewed and updated at least annually to ensure accuracy. Departments can use these documents as a guide to identify the key research issues to be addressed for new or departing PIs and to supplement any department-specific procedures.

In particular, PIs new to the University should work closely with the department and Human Resources to ensure appropriate employment forms and access are established prior to arrival. PIs should also work closely with the Office for Sponsored Research (OSR) in order to ensure that their awards are transferred and appropriately equipped and staffed. Conversely, PIs with active awards transferring from the University must first notify OSR and the sponsor to discuss the PI's potential future role on the award and whether the award should be transferred to the PI's new institution.

Northwestern's research related offices are committed to ensuring a smooth transition for new and departing PIs and these documents are an effort to streamline the processes. Each section contains the key subject matter expert to contact who can assist the PI and department in navigating the complicated steps, so that the transition to and from the University is seamless.

National Academy of Sciences Panel Recommends Streamlining

In 2015, the National Academy of Sciences convened a panel, at the request of the US Congress, to review concerns of ever-increasing regulatory burdens on research institutions and investigators. While regulations are necessary to ensure responsible oversight, there are worries that compliance has had the unanticipated consequence of significantly encroaching on investigators' time; time that could better be spent on their core research and education missions.

The panel reviewed and considered regulations across the research enterprise, ranging from proposal preparation and the conduct of research to the final accounting of research funds. Its recommendations focused on efforts to streamline and harmonize the current regulations and rules across all federal agencies. Several areas where the panel saw room for improvement included:

-The implementation of uniform grant proposal and progress reporting documents;

-The creation of a central database for information regarding investigators;

-The implementation of a federal-wide financial conflict of interest policy;

-Review of the feasibility of a consistent approach to animal care and use in research across agencies;

-Work with agencies to harmonize regulations and definitions pertaining to human subjects protections;

-Work to risk-stratify human subjects protections to reduce the regulatory burden for minimal risk studies; and

-Provide the FDA with authority to develop a waiver or modify the requirements for informed consent in minimal-risk research.

In addition to these recommendations, the panel also encouraged the formation of a Research Policy Board. This Board would be a government-academic partnership that would serve as the "primary policy forum for discussions relating to the regulation of federally funded research programs in academic research institutions." It would also be responsible for working with research institutions to develop policies and sanctions to hold institutions accountable when they deviate from accepted norms in the research community.

Finally, the panel recommended reviewing the roles and responsibilities of the agency-specific offices of the Inspectors General in order to determine their role in partnering with and advising research institutions on "economy, efficiency, and effectiveness" within the research enterprise.

The 142 page report, released in September, echoes concerns and recommendations previously raised by the National Science Foundation, the President's Council of Advisors on Science and Technology, the Association of American Universities and the Council on Governmental Relations, and the Federation of American Societies for Experimental Biology, among others. While these previous reports failed to gain much traction, it is hoped that with Congress considering other legislation this session regarding research policy, medical innovation, and higher education, these recommendations will be enacted where appropriate and feasible.

Stay tuned for part 2 of the committee's report which should be issued in early 2016 and address additional items in its charge, such as export controls and dual-use research concern.

QUOTE CORNER

Every right implies a responsibility; Every opportunity, an obligation, every possession, a duty.

John D. Rockefeller

Did You Know?

A new Human Research Protection Program Compliance policy has recently been released. This new policy establishes the framework for the University's Human Research Protection Program and provides information on how to report allegations of noncompliance in research involving human participants. If you have questions regarding the policy, please contact the IRB Office at (312) 503-9338, or email irbcompliance@northwestern.edu.

The Office for Sponsored Research (OSR) has a standard research agreement that can be provided to collaborators before formal negotiations occur. The agreement offers standard terms that Northwestern can endorse and helps expedite negotiations. Be sure to use the most current version, located on OSR's website.

The National Science Foundation recently issued an updated Proposals & Award Policies & Procedure Guide (PAPPG) which is effective for all proposals due on or after Monday, January 25, 2016. Refer to page 2 of the Guide for a summary of the significant changes.

Introducing Krista Harnish

1) What is your title at Northwestern?
I am a Senior Compliance Specialist in the Office for Research Integrity.

2) What does that mean?
I help facilitate research misconduct investigations at the University.

3) What is one thing you want people to know about what you do here?
That our office is here to help faculty and researchers protect the integrity and reputation of all research conducted here.

4) How long have you been at Northwestern?
I've been here just about 4 years. Prior to joining ORI, I was a Manager of Research Administration in Feinberg.

5) What did you do before you came to NU?
I worked at Lurie Children's Hospital as an Assistant Director of Grants & Contracts in the Office of Sponsored Programs.

6) Where is your home town?
Middletown, New Jersey

7) What is your favorite ice cream flavor?
Mint Chocolate Chip

8) What is your favorite thing to do outside of work?
Gardening and spending time with my two basset hounds

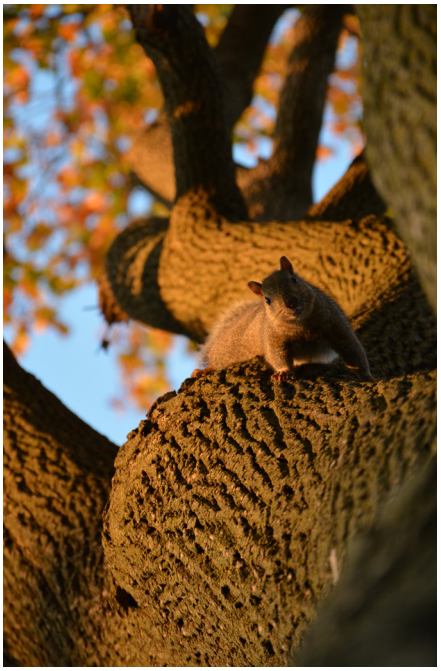
9) What is your favorite yearly Chicago event?
Movies in the Park

Research Administration Training Seminar

This four-session seminar is geared toward research administrators, staff involved in research administration, and anyone who wants to learn about Northwestern's research administration process, policies, and procedures. The seminar serves as an introduction to Northwestern's research enterprise 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 offices throughout Northwestern will be on hand to present and answer questions.

The next seminar will take place January 19th, 21st, 26th and 28th, on the Chicago campus from 1:00-4:30pm (Daniel Hale Williams Auditorium, McGaw Pavilion).

Registration can now be completed through Northwestern University's new training management system, Learn@Northwestern. Simply log-in using your NetID and password, then use the search tool in the top right-hand corner to find the Research Administration Training Seminar class. When you select "enroll," you will be registered for all four days of the seminar. If you experience difficulties registering or have any questions, please email bethirwin@northwestern.edu for support.



Updates to NSF RCR Requirements for Graduate Students and Postdoctoral Researchers

Training in the responsible conduct of research (RCR) promotes awareness of complex research issues and ethical dilemmas that researchers may face throughout their career. It is also recognized by many as an essential piece in a researcher's professional development. Aside from the educational value RCR training offers, it is also an important requirement mandated by several federal agencies. Recently, through the Vice President for Research, changes have been implemented with respect to graduate students and postdoctoral researchers supported by the National Science Foundation (NSF) in an effort to ensure 100% compliance with the NSF RCR requirements.

Graduate students and postdoctoral researchers currently supported by NSF awards must complete their RCR training within one year after salaries are first charged to the account. Salary costs for individuals who have not completed the required training within the year are unallowable and must be removed from the award and charged to a non-sponsored account. NSF RCR training is satisfied by completing a minimum of four hours of instructor-led training, with additional online requirements depending on school/departmental policies. It is a PI's responsibility to ensure RCR training of their trainees is completed in a timely and compliant fashion.

ORI supports the schools/departments in the process of tracking RCR training compliance for NSF funded researchers with monthly reports now generated by Learn@Northwestern, the University's training management system, and sent to school administrators. ORI's website identifies current RCR requirements and course options by audience. The site also clearly highlights NSF as well as National Institutes of Health (NIH) regulations that detail RCR training requirements.

While each school/department has RCR contacts and individuals to support RCR training compliance, ORI's Research Training Manager, Beth Irwin, is always available to help navigate RCR-related questions or concerns.

ethics•point integrity at work

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 here.

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.

Northwestern | OFFICE FOR RESEARCH INTEGRITY

750 N Lake Shore Drive
Rubloff, 7th floor
Chicago, IL 60611
phone 312.503.0054
nu-ori@northwestern.edu

Lauran Qualkenbush, *Director, Research Integrity Officer*
Krista Harnish, *Senior Compliance Specialist*
Beth Irwin, *Research Training Manager*
Yasmeen Khan, *Administrative Assistant III*
Michelle Stalilonis, *Senior Compliance Specialist*