Northwestern | RESEARCH
RESEARCH INTEGRITY

NEWS

Fall 2018 Vol. 6, Issue 1

Rebecca Crown Center, Evanston campus

IN THIS ISSUE

Institutional Responsibility for Research Compliance

Over the past 10 years, several high-profile instances of research misconduct and other serious research non-compliance have received substantial media attention. These have included questions and concerns about synthetic trachea transplantations and research performed by Paolo Macchiarini while employed at the Karolinska Institute (Berggren and Karabag 2018, Fountain 2014), Anil Potti's work on patients' responses to chemotherapy as predicted by certain gene expression signatures at Duke University (Kaiser 2015, Singer 2010), and Mani Pavuluri's research using lithium as a treatment for bipolar disorder in children at the University of Illinois at Chicago (Cohen 2018). These cases and others have sparked attention as they have impacted the medical treatment and potentially the health outcomes of the people who participated in these studies. However, they also have brought particular focus on an institution's role in maintaining oversight and accountability for the research it supports as well as the actions and decisions of its faculty and staff. In parallel, they have raised questions as to whether these institutions have the ability to put the interests of research participants and the public ahead of their own, and those of their faculty.

While the circumstances of each case vary, they have raised systemic institutional questions, including:

- Was enough training and guidance provided to the researchers?
- Did the research have appropriate institutional review board or other ethics review, as required for research with human participants?
- Were the reviews that did take place comprehensive, and did they follow the appropriate regulations and guidelines?
- When concerns were raised to compliance offices and others within the institution, did the appropriate reviews and due diligence take place?
- How robust is the vetting process when hiring new faculty and other researchers?

In each of these cases, there were likely several points along the way where issues could have been identified and addressed *before* they multiplied and compounded. An institution's willingness to acknowledge concerns and have appropriate measures in place to handle them as they arise is critical. Otherwise, if concerns are ignored or not properly reviewed, the institution could also be considered responsible and complicit.

In some instances, when concerns were raised, the processes the institutions had in place to ensure the highest level of research protections and integrity may have failed. As a result, each of the institutions involved faced repercussions, often with costs far beyond the actual misconduct that took place, for example: financial penalties and repayment of grants, additional oversight by outside agencies, or negative impacts to their reputations, which affects all members of the institution.

To maintain good research practices and ensure compliance across the board, faculty and research administration staff

continued on page 4

Research Compliance: Contacts and Resources

Given the many aspects of maintaining compliance in research, knowing where to go with any questions can help make things easier for everyone involved. The Office for Research and related offices can help address your questions about specific areas of compliance. You can also submit a question or concern anonymously via EthicsPoint online, or call the EthicsPoint hotline at 866-294-3545.

Type of Research Compliance Question & Who To Contact	
Human Research	
Examples of human research violations include the failure to: • obtain appropriate approval from the Institutional Review Board (IRB) • adhere to the IRB-approved research protocol • obtain informed consent and authorization from human research participants (or obtain an IRB-approved waiver of consent/authorization) • promptly report unanticipated risks involving subjects or others, including adverse reactions • follow the laws and policies relating to the conduct of research involving human subjects	**Institutional Review Board Office** Nathalia Henry, Executive Director nhenry@northwestern.edu 312-503-9338
Animal Research	
An animal research violation refers to any violation of laws or policies concerning the ethical care and use of animals in research.	**Institutional Animal Care and Use Committee Office** Mandy Kozlowski, Director m-kozlowski@northwestern.edu 312-503-0109
Research Safety	
Research Safety provides oversight, training, services and supplies to support laboratory-based research at Northwestern. Institutional oversight is required by federal, state and local laws. Areas of support include the safe use of potentially hazardous materials—biological, chemical or radiological including waste disposal and safe shipping of research samples. All research personnel must be registered with Research Safety and complete mandatory training.	**Research Safety** Michael B. Blayney, Executive Director michael.blayney@northwestern.edu 847-491-4387
Research Conduct	
Research misconduct is defined as fabrication, falsification, plagiarism, or other serious deviation from commonly accepted practices in the relevant scientific community for proposing, performing or reviewing research, or in reporting research results.	**Research Integrity** Lauran Qualkenbush, Director researchintegrity@northwestern.edu 312-503-0054
Conflict of Interest	
Northwestern's COI policy defines a conflict of interest as a situation in which an individual's financial, professional, or other personal considerations may affect (or have the appearance of affecting) his or her professional judgment in exercising a University duty or responsibility.	**Conflict of Interest Office** Kate Cosgrove Booth, Director nucoi@northwestern.edu 847-467-4515
Research Effort		
Research effort violations concern falsifying effort expended on projects.	**Controller's Office** Mike Daniels, Director m-daniels2@northwestern.edu 847-491-4710	**Office of Financial Operations** Jennifer Mitchell, Associate Executive Director for Research Financial Ops. jmitchell@northwestern.edu 847-467-2473
Grant Management		
Grant mismanagement includes the unallowable or questionable expenditures or cost transfers to government grants, contracts, or other agreements. It includes any expenditures or cost transfers that may be in violation of Uniform Guidance.	**Sponsored Research** Andrea Zakrzewski, Associate Director for Grants Management a-zakrzewski@northwestern.edu 847-467-3495	**Controller's Office** Mike Daniels, Director m-daniels2@northwestern.edu 847-491-4710
Export Controls		
Export controls are US laws and regulations that regulate the distribution of technology, services and information to foreign nationals and foreign countries for reasons including foreign policy and national security.		**Export Controls Compliance** Lane Campbell, Director lcampbell@northwestern.edu 847-467-4063

Did You Know?

In alignment with the NIH's single Institutional Review Board (IRB) mandate, all competing NIH grant applications for multi-site studies with NIH receipt dates on or after January 25, 2018 must include a plan describing the use of a single IRB for the study. For more information and resources, visit the Northwestern IRB's website. In addition, NIH has made changes to its clinical trial requirements, which affect applications with receipt dates on or after January 25, 2018.

In February 2018, the Core Facility Working Group at Northwestern announced "Publication Guidelines for Users of Core Facilities," which focuses on authorship and acknowledgement on manuscripts and grants.

The National Science Foundation announced the proposed implementation of its "Reporting Requirement Regarding Findings of Sexual Harrassment, Other Forms of Harassment, or Sexual Assault." Information on the proposed requirements is available here.

Introducing Corinna Raimondo

Photo by Roger Anderson, Research Communications

What is your title at Northwestern?

Senior Compliance Specialist

What does that mean?

I help facilitate research misconduct proceedings at the University.

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

That we are here for them, and we care

How long have you been at Northwestern?

5 years

What did you do before you came to Northwestern?

My PhD in Strasbourg, France

Where is your home town?

Genova, Italy

What is your favorite ice cream flavor?

Ice cream? Only gelato, fior di latte flavor, or dark chocolate, or lemon. Such a difficult choice!

What is your favorite thing to do outside of work?

Reading stories to my kids and pretending to be a superhero

What Chicago event are you most looking forward to experiencing?

Listening to the Chicago Symphony Orchestra, directed by Riccardo Muti

Notable Quote

"A single lie destroys a whole reputation of integrity."

— Baltasar Gracián, 17th century writer and philosopher

Research Compliance

continued from page 1

depend on each other, directly and indirectly. As part of an institution's responsibilities for research compliance, effective checks and balances need to be in place, with clear and open communication channels established from the top down. In taking this approach, key offices and personnel can be sufficiently prepared to address issues that are brought to their attention. Furthermore, within an integrated web of support and communication, concerns can be brought forward without fear of repercussions.

Northwestern's research-related policies and guidelines underscore the interdependencies between individual and institutional responsibilities. Ultimately, understanding and consistently following compliance policies and procedures helps to protect the research, the researchers, research subjects, the institution, and all involved. For additional resources to support good research practices, including roles, responsibilities, and the responsible conduct of research, visit researchintegrity.northwestern.edu/resources.

Register Now for October 2018 Research Administration Training

This four-session seminar is geared toward staff involved in research administration, and anyone who wants to learn more about Northwestern's research administration process, policies, procedures, and offices. Representatives from 20 offices will be presenting on topics such as pre- and post-award administration, research accounting, effort reporting, compliance, research development, working with industry, human and animal subjects research, research safety, core facilities, the research portal, and more. This is a great educational opportunity and an excellent chance to network with others in Northwestern's research community. The seminar is free, but registration is required.

October 16, 18, 23, and 25 (9:00 a.m. – 1:00 p.m.)
Chambers Hall, Ruan Conference Room (600 Foster St.)
Register via myHR Learn: learn.northwestern.edu

For more information, visit:
www.researchintegrity.northwestern.edu/research-administration-training-seminar

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 EthicsPoint online

RESEARCH INTEGRITY 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 | RESEARCH
RESEARCH INTEGRITY

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

Lauran Qualkenbush, *Director, Research Integrity Officer*
Krista Harnish, *Senior Compliance Specialist*
Samantha Hugghis, *Administrative Assistant III*
Corinna Raimondo, *Senior Compliance Specialist*
Michelle Stalilonis, *Senior Compliance Specialist*