

Where Human Research Meets Integrity: What You Need to Know

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ORI fosters research integrity and promotes the responsible conduct of research through

- coordination of training and
- facilitation of the review of alleged research misconduct.



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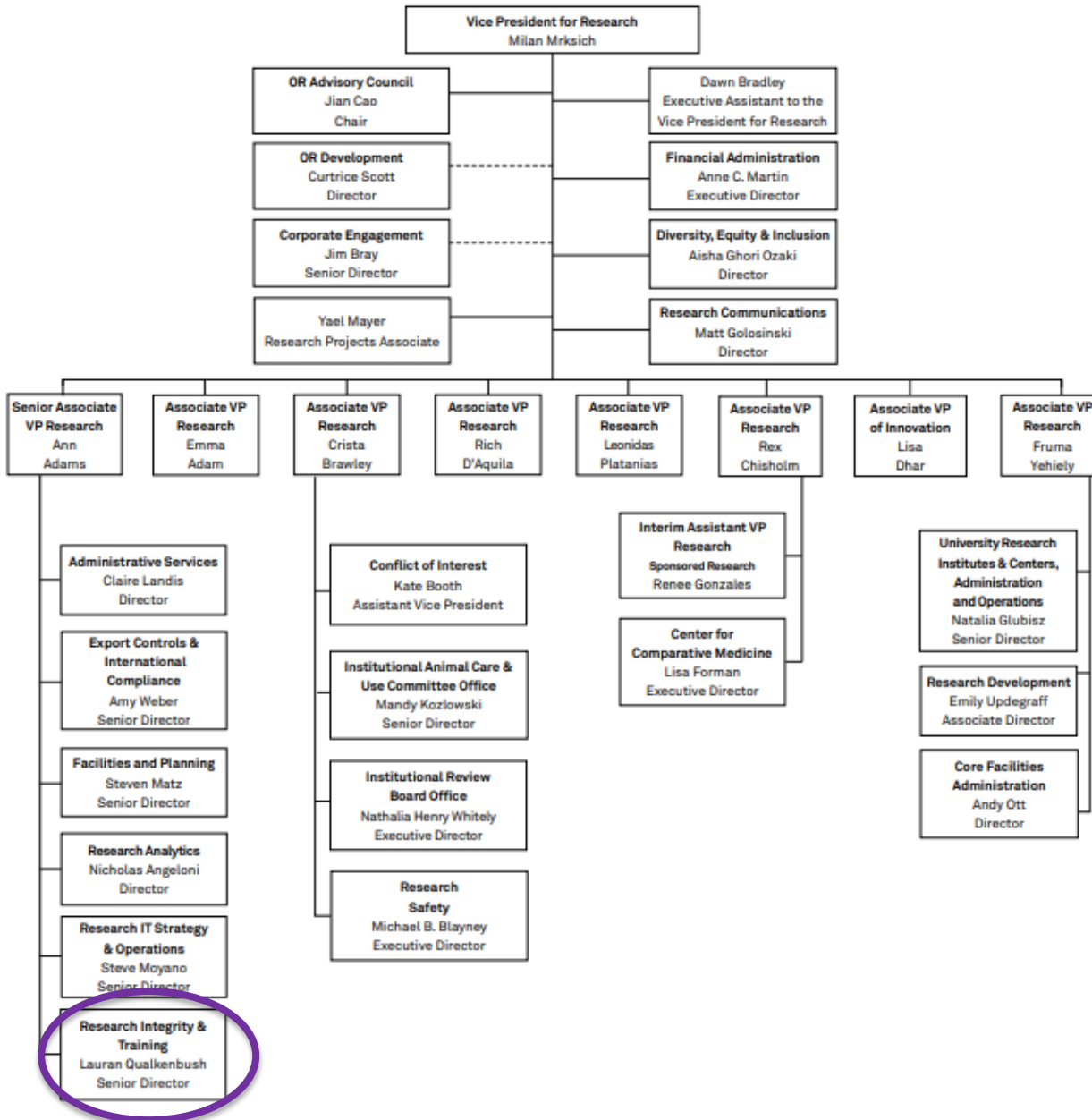
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Office for Research Organization Chart 2023

<https://research.northwestern.edu/about/team/or-organization-chart.html>



Research Misconduct

Research Non-compliance

- Not following the approved protocol
- Not following IRB/IACUC approved procedures
- Not complying with institutional policies
- Fiscal misappropriation or inappropriate grant management
- Not following SOPs
- Research misconduct
- May require federal or other reporting
 - Sponsor, FDA, OHRP, USDA, federal ORI, NSF OIG

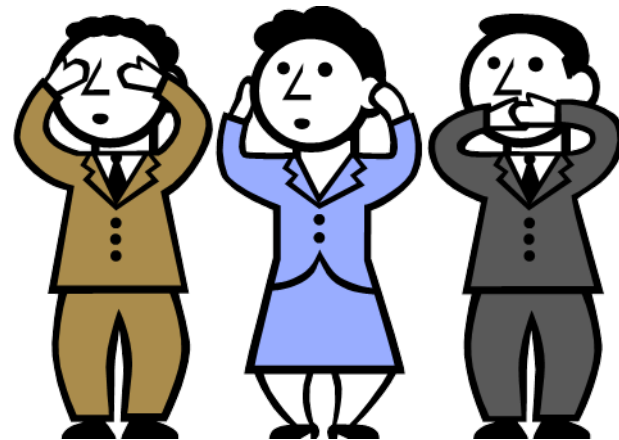
Research Misconduct

Fabrication & Falsification

- Making up data or results and recording or reporting them
 - Creating records of experiments or procedures that were never performed
- Manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record
 - Omitting data points
 - Falsely reporting that certain experiments or procedures had been performed

Plagiarism

- Appropriation of another person's ideas, processes, results or words without giving appropriate credit



42 CFR Part 93 and 45 CFR 689

<http://ori.hhs.gov/assessing-res-misconduct-alleg>

Research Misconduct Defined

Northwestern University definition includes:

- **Other serious deviations** from accepted practices including but not limited to:
 - Abusing confidentiality
 - Stealing, destroying, or damaging the research property of others with the intent to alter the research record; and
 - Directing, encouraging, or knowingly allowing others to engage in fabrication, falsification or plagiarism

Research Misconduct Defined

- Does not have to be formally published
 - Could include proposals, draft manuscripts, non-published/shared research records
- Does not include:
 - honest error
 - differences of opinion
 - authorship disputes
- Mandatory reporting to federal ORI or NSF OIG for federally funded projects

Northwestern's *Procedures for Reviewing Alleged Research Misconduct*

- Initial assessment of allegation(s)
- Inquiry Committee
 - Does the evidence warrant full investigation?
- Investigation Committee
 - Did research misconduct take place?
 - Intentional, knowing or reckless
 - Preponderance of the evidence
 - Significant departure from the expected practices of the relevant research community
 - Who committed research misconduct?
- Institutional decision
- Federal reporting and oversight review

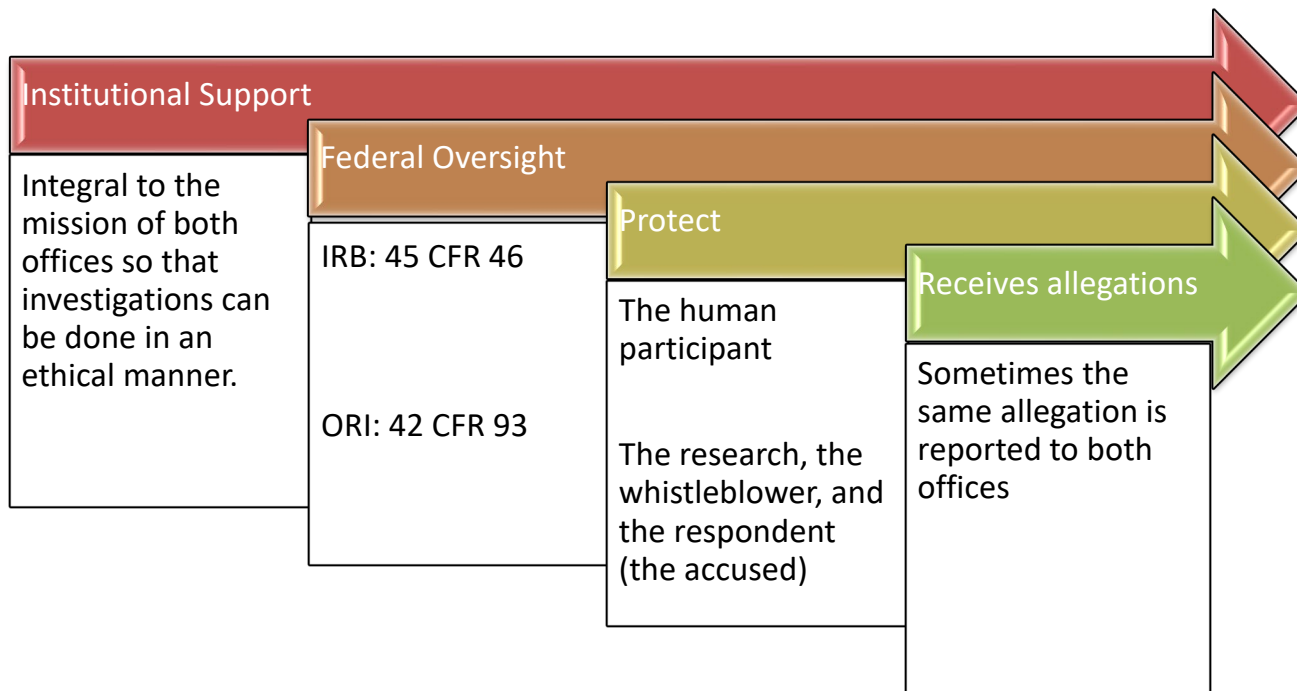
Research Misconduct Consequences

- Recognition on federal websites and publications

https://ori.hhs.gov/content/case_summary

- Suspension or termination of grants
- Debarment
- Prohibition from service on PHS advisory committees, peer review committee, or as consultants
- Criminal charges, fines, penalties and/or imprisonment

How are ORI and the IRB the same?



How are the IRB and ORI different?

ORI

- Formal process
- Standard of proof (preponderance of evidence)
- Confidential process
- Timing (sequestration)=swift
- Timing (process)=federally regulated, but thorough
- Federal Sanctions: Respondent

IRB

- Informal process
- No standard of proof
- Human participants, IRBs, and Institutional Officials have a right to know
- Timing (not federally mandated, but “prompt reporting” encouraged)
- Federal sanctions: Institution

Red flags for follow-up review by IRB and ORI



IRB

- Failure to report events that meet [IRB Reporting criteria](#)
- Multiple or recurring protocol deviations
- Investigational product dispensation issues
- Failure to use IRB-approved versions of informed consent forms, or improper documentation of informed consent
- Conducting research or implementing changes to the research without prior IRB approval

IRB and ORI

- Forging an investigator's signature
- Forging consent forms
- Failing to obtain informed consent
- Enrolling subjects who fail to meet eligibility criteria
- Altering eligibility criteria
- Medical records or other records contradict enrollment criteria
- Changing research records to reflect desired data and results
- Altering dates on screening logs for prospective subjects
- Noting consistent or repeating values

A research subject participated in an IRB approved study, but was later found not to meet the eligibility criteria because the results of the safety tests were altered. Who will need to be notified?

1. IRB
2. ORI
3. Both

A researcher's study protocol stated he was going to perform a retrospective review of 200 subjects. However, he published an article stating that (under the same IRB approval) he conducted a prospective review of 300 subjects.

The IRB reviewed the study data and determined that the researcher actually did conduct a prospective review of 300 subjects.

Who is this an issue for?

1. IRB
2. ORI
3. Both

Why do we care?

It is wrong

Compromises integrity of
research

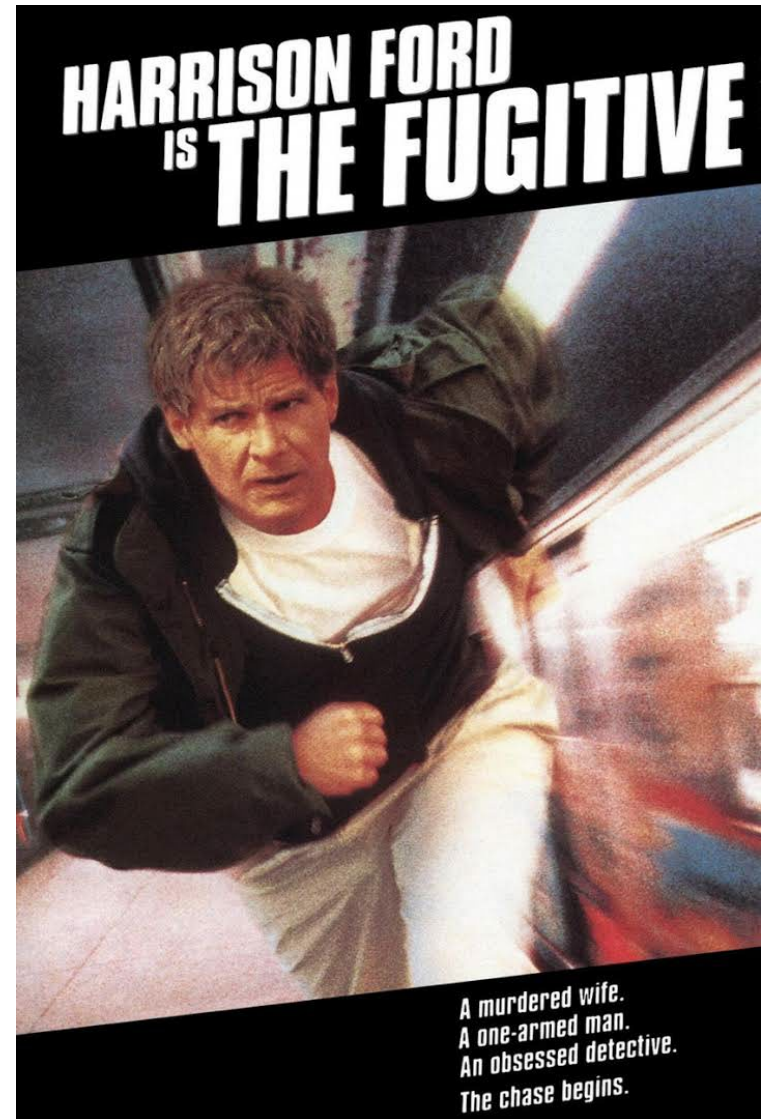
Jeopardizes public trust

Costs of misconduct



Dr. Charles Nichols

Arranged for the murder of his friend and colleague, Dr. Richard Kimble, in order to prevent him from exposing that Nichols' new drug, Provasic, causes liver damage.





Andrew Wakefield, M.D.

- 1998 published the infamous, now discredited study linking MMR vaccine to autism in Lancet.
- The study was found to have ethical concerns regarding recruitment, research that was misrepresented and Wakefield failed to disclose he was funded by vaccine manufacturers.



Anil Potti, M.D.

- Former Duke cancer researcher who altered research data used to design clinical trials and to determine which drug participants received.

Who is non-compliant and why?

People who believe the rules do not apply to them

People under pressure:

- Competitive environment
 - Personal pressures
 - Pressured by others

Untrained, unqualified, unsupervised



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Compliance

HOME > COMPLIANCE

Compliance FAQ

Key Compliance Areas & Contacts

Report a Concern

Compliance

About Us

Northwestern's central Compliance Office helps the University to promote a culture of honest and ethical behavior as well as to identify and manage risk. The Office's responsibilities include coordinating, encouraging and monitoring the operational compliance activities that occur throughout the University, supporting policy development and review, and advising senior administration and the Board of Trustees on the effectiveness of the University's compliance efforts. The Compliance Office works with

Related Links

- [EthicsPoint](#)
- [University Policies](#)
- [University Police](#)
- [Office of the General Counsel](#)
- [Standards for Business Conduct](#)

Responsible Conduct of Research (RCR) Training



RCR Training

[RCR Web-based Training: Getting Started](#)[RCR Instructor-Led Training](#)Research Administration
Training

Responsible Conduct of Research (RCR) Training

The goal of Responsible Conduct of Research (RCR) training is for anyone involved in research to perform the most ethical research possible. Northwestern has in place a number of policies that clearly demonstrate our commitment to research integrity. Collectively, these apply to all members of Northwestern's research enterprise: students/trainees, staff, and faculty.

The **National Science Foundation (NSF)** mandates that, at the time of proposal submission, institutions must have a plan in place to provide appropriate RCR training and oversight for any student (graduate or undergraduate) or postdoctoral fellow supported by NSF. The **National Institutes for Health (NIH)** also requires RCR training.

- [Federal RCR Training Requirements](#) – Information on the NSF and NIH requirements

In an effort to standardize the RCR training required for NSF trainees, Northwestern developed the plan below that went into effect on September 1, 2015.

- [Northwestern's NSF RCR Training Plan](#) 

Introduction to Research Administration at Northwestern



RESEARCH INTEGRITY

Research Misconduct **Training** Reporting Concerns News & Events

Training

HOME > TRAINING **RESEARCH ADMINISTRATION TRAINING**

RCR Training

Research Administration Training

Online Training: Overview & Registration

Online Training: Curriculum Guide

Online Training: FAQs

<https://researchintegrity.northwestern.edu/training/research-administration-training/index.html>

Description:

This training program is geared towards research administrators and any staff involved in research administration.



It provides an introductory overview of the Office for Research and related offices, research roles and responsibilities, regulatory fundamentals, research compliance, and key concepts essential to research administration.



Staff from 20 units/offices introduce you to their offices, the services they provide, who to contact, tips and best practices, and additional training opportunities.

Audience:

This training is ideal if you are:

- New to the profession of research administration
- Experienced in research administration but new to Northwestern
- Experienced in your role but would like a refresher in certain areas

Availability:

This training program can be completed either in-person or online:

- In-person, classroom-based training: In-person training is on hold as of March 2020, per COVID-19 safety guidelines.
- **Online training: Available now!**

Questions?

Please contact us at researchintegrity@northwestern.edu or (312) 503-0054 with any questions. We also invite you to join our [mailing list](#) for announcements and updates.

Related Training:

Visit the Office for Research's [Research Tools](#) for additional research-related training opportunities and resources.

Call Anytime with Any Questions

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www.northwestern.edu/research/ori