Where Human Research Meets Integrity: What You Need to Know

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OFFICE FOR RESEARCH

RESEARCH INTEGRITY

ORI fosters research integrity and promotes the responsible conduct of research through the facilitation of the review of alleged research misconduct.

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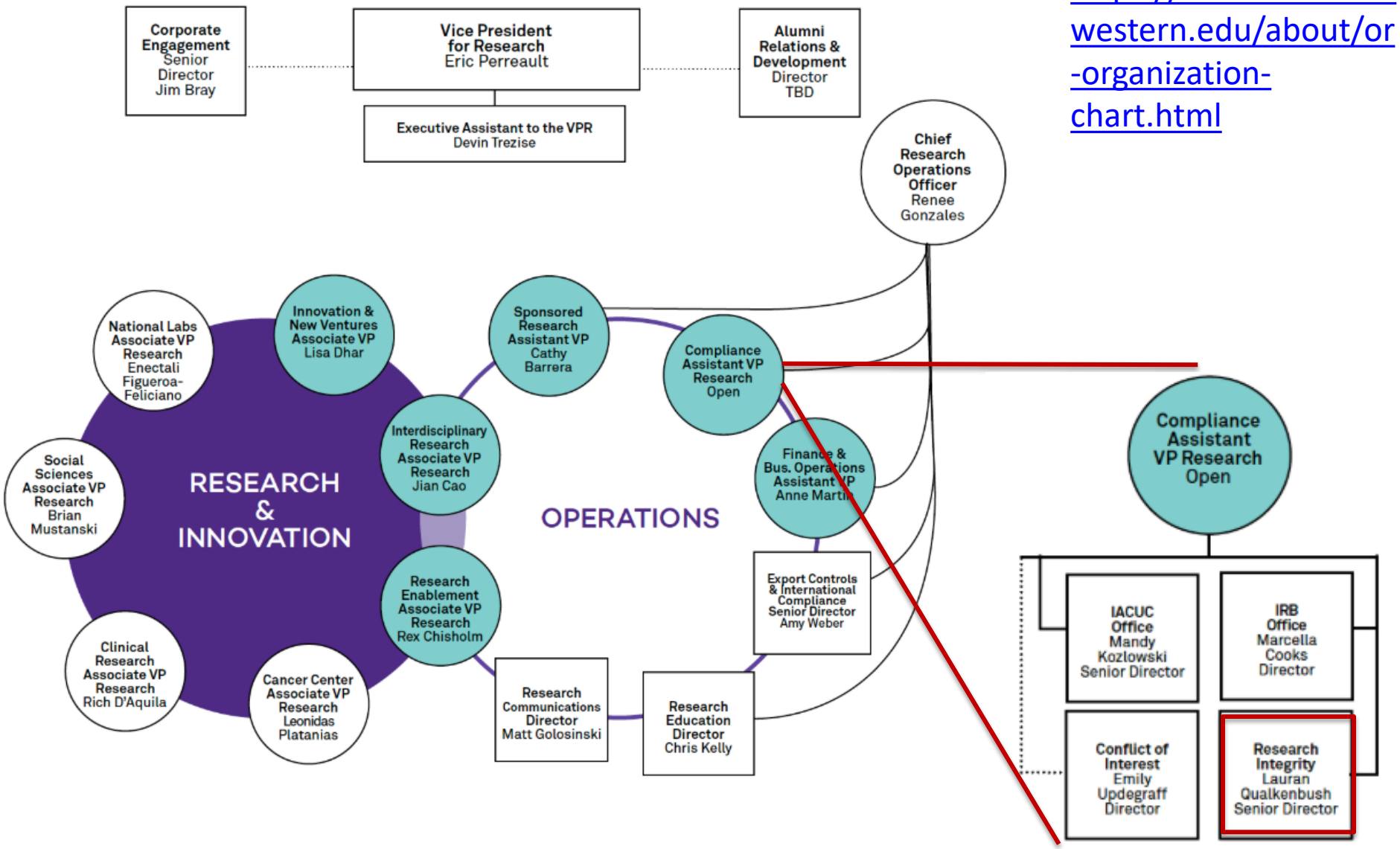
https://research.northwestern.edu/about/or-organization-chart.html



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

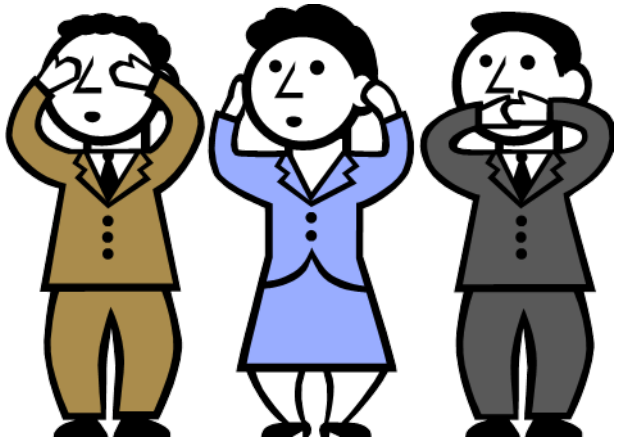
Research misconduct is defined as fabrication, falsification, plagiarism, or other serious deviation from commonly accepted practices in the relevant scientific community in proposing, performing or reviewing research, or in reporting research results.

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 the results of procedures

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 (clinical trial participant 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
  - Is the evidence specific and credible to warrant a 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

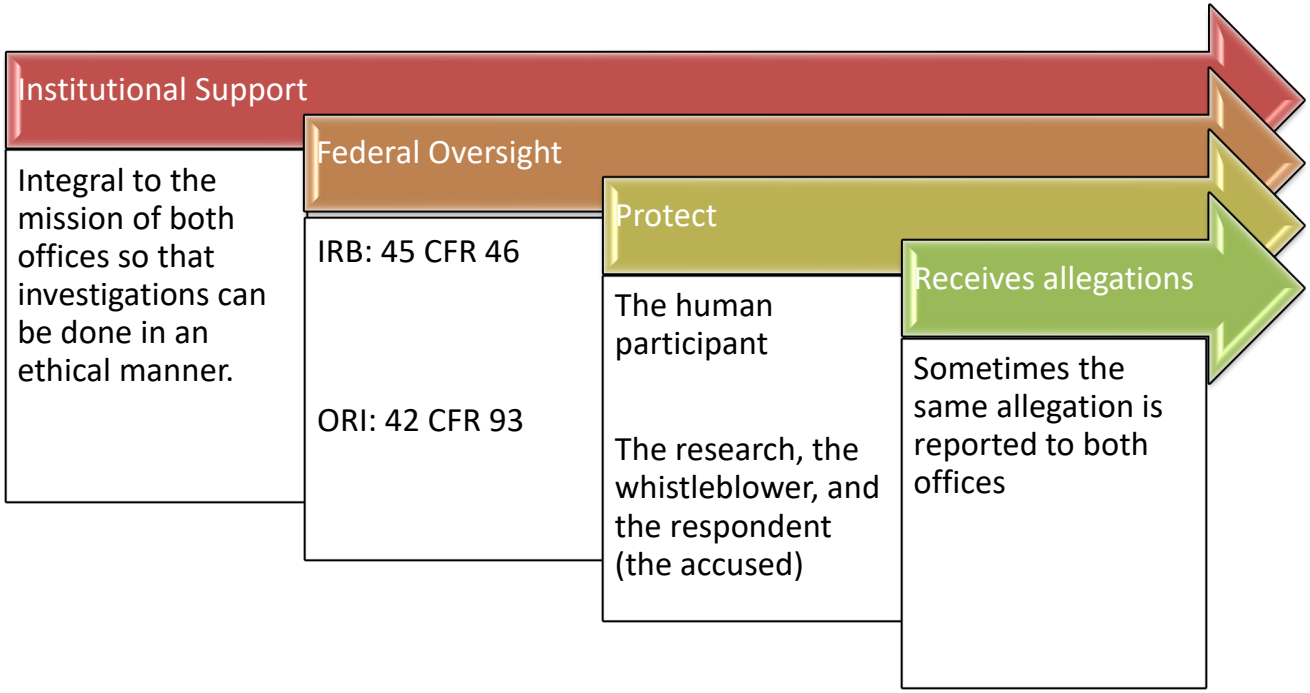
What's New?

New University Policy!
https://researchintegrity.northwestern.edu/research-misconduct/

New Federal Regulations!
42 CFR 93

Use of AI, Pub Peer, Super Sleuths, Social Media/Internet

How are ORI and the IRB the same?



Slides reused from Yates, Stalilonis presentation, 2013 IRB member retreat, reviewed and updated by 2023 IRB compliance team

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

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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

Slides reused from Yates, Stalilonis presentation, 2013 IRB member retreat, reviewed and updated by 2023 IRB compliance team

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

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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

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Why do we care?

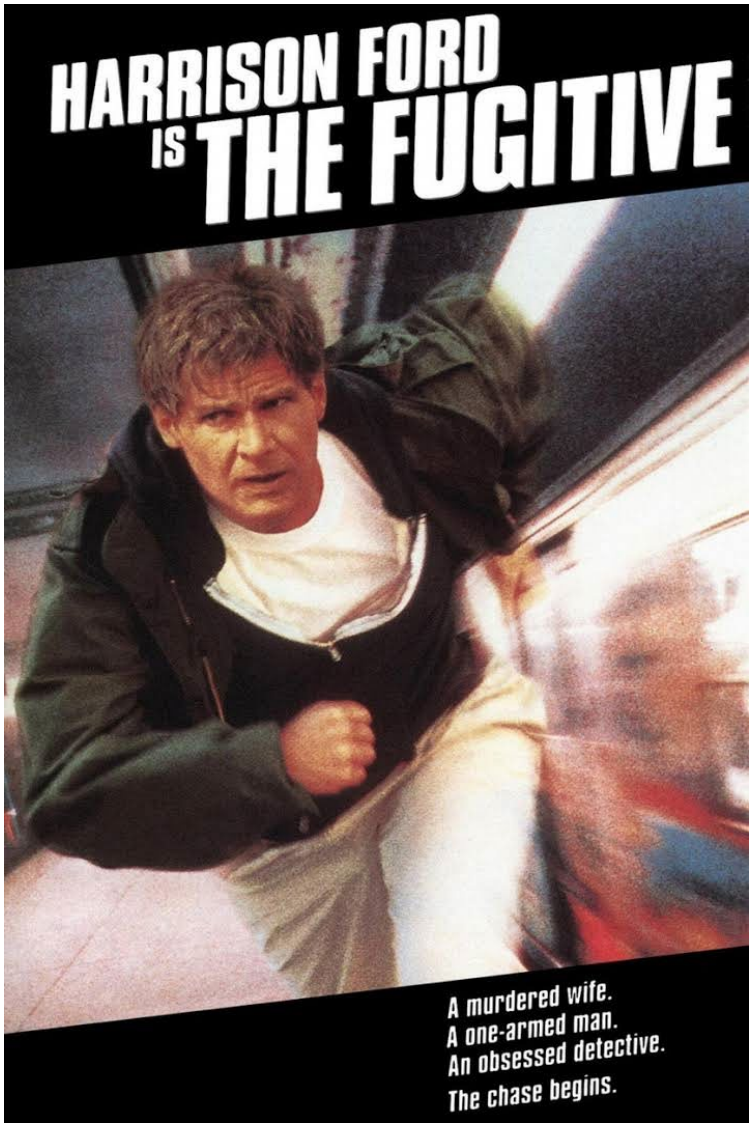
- It is wrong
- Compromises integrity of research
- Jeopardizes public trust
- Costs of misconduct

Thorny Issues

- Are allegations brought in “good faith?”
- Preventing retaliation
- Protecting confidentiality
- Restoring respondent’s reputation
- Power differentials

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.

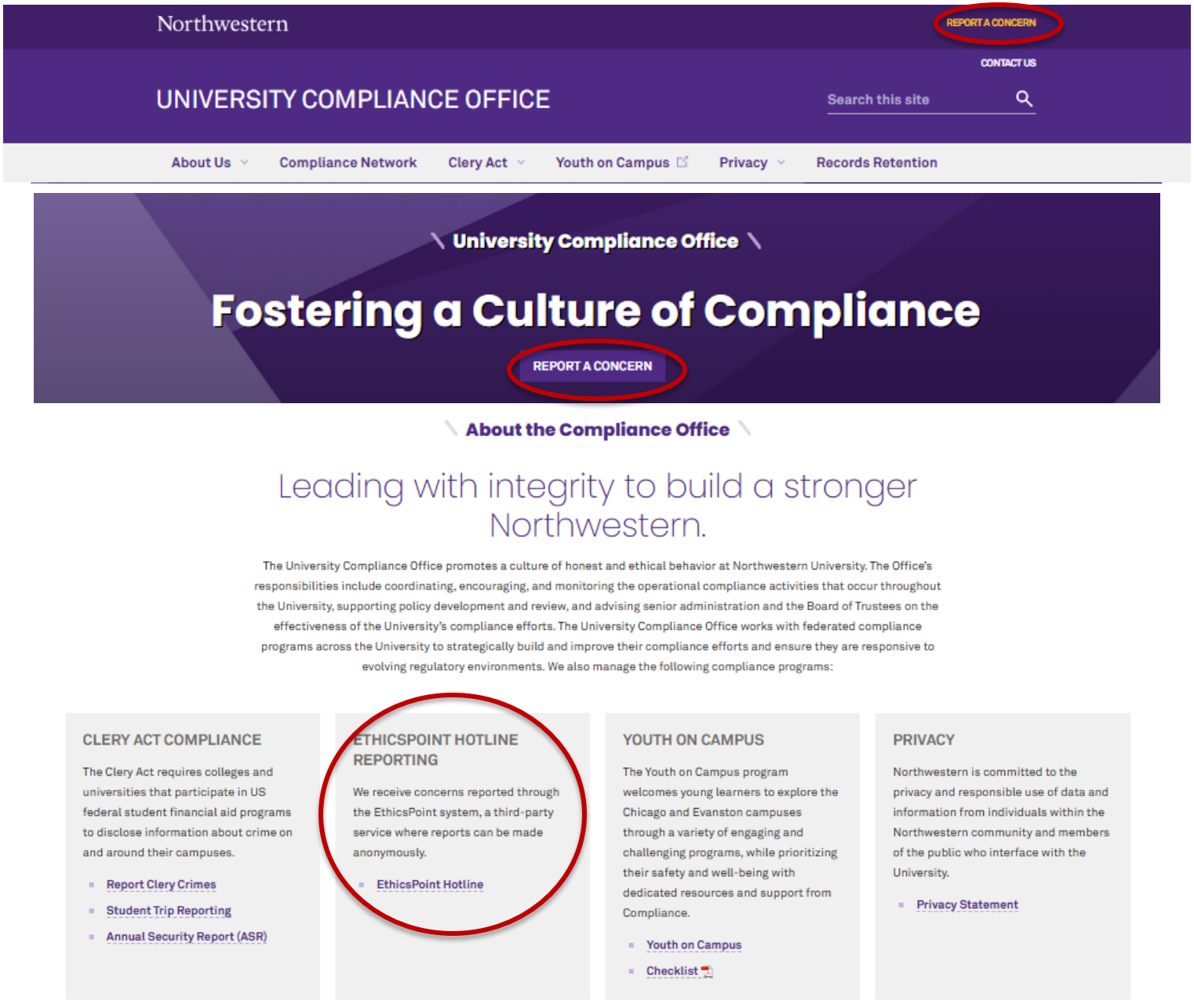
Who is non-compliant and why?

People who believe the rules do not apply to them

People under pressure:

- Competitive environment
- Personal pressures
- Pressured by others

Untrained, unqualified, unsupervised


Northwestern
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University Compliance Office
Fostering a Culture of Compliance
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About the Compliance Office
Leading with integrity to build a stronger Northwestern.
The University Compliance Office promotes a culture of honest and ethical behavior at Northwestern University. 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 University Compliance Office works with federated compliance programs across the University to strategically build and improve their compliance efforts and ensure they are responsive to evolving regulatory environments. We also manage the following compliance programs:
CLERY ACT COMPLIANCE
The Clery Act requires colleges and universities that participate in US federal student financial aid programs to disclose information about crime on and around their campuses.
Report Clery Crimes
Student Trip Reporting
Annual Security Report (ASR)
ETHICSPOINT HOTLINE REPORTING
We receive concerns reported through the EthicsPoint system, a third-party service where reports can be made anonymously.
EthicsPoint Hotline
YOUTH ON CAMPUS
The Youth on Campus program welcomes young learners to explore the Chicago and Evanston campuses through a variety of engaging and challenging programs, while prioritizing their safety and well-being with dedicated resources and support from Compliance.
Youth on Campus
Checklist
PRIVACY
Northwestern is committed to the privacy and responsible use of data and information from individuals within the Northwestern community and members of the public who interface with the University.
Privacy Statement

How can *you* ensure compliance?

- Everyone involved in research is responsible
  - Ensuring compliance
  - Reporting suspected noncompliance or misconduct
- Understand that regulations and compliance are complex
- Talk to your PI, department chairs, trusted faculty
- Identify resources - ORI
- Know when and where to ask for help
- When in doubt, ask
- ****Keep clear, organized records****

Call Anytime with Any Questions

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