
Responsible Conduct of Research: Academic Ethics and Integrity

By taking early and firm control of Responsible Conduct of Research issues, you can be proactive instead of reactive.

I. Universe of Potentially Applicable Federal Regulations includes:

Public Health Service (PHS) units involved in compliance include:

- the Office of Research Integrity (ORI),
- Office of Human Research Protection (OHRP),
- Office of Laboratory Animal Welfare (OLAW) / IACUC,
- National Institutes of Health (NIH), and
- the Food and Drug Administration (FDA).

USDA –“research misconduct” is defined the same way for all federal departments and agencies

- Individual AGENCIES within the Department may have additional research misconduct policies or procedures, so long as they are consistent with the Department’s regulations
- Includes an obligation that institutions inform investigators about these regulations

Environmental Protection Agency – [EPA Order 3120.5](#)

Other non-PHS agencies with additional / separate regulations include:

- [National Science Foundation](#) (Office of Inspector General)
- Department of Education
- National Endowment for the Humanities
- Department of Transportation

More regulations every day, so the universe of applicable rules is not static.

II. Guiding Documents for Responding to Allegations of RM

- The University of Tennessee [Policy on Misconduct in Research and Service](#) (2005)
 - watch out for rogue versions
 - currently under revision
- [Public Health Service \(PHS\) Regulations](#) cover funded research from any of the 11 Public Health Service agencies, including National Institutes of Health (NIH)
- [FI0125 – Conflict of Interests](#)
 - includes management and enforcement

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- Focus on Section 6(f): “Having a financial interest . . . In an outside venture that would reasonably appear to be affected by any research conducted by the covered individual.”
- Financial interest = equity interest exceeding 5%/\$10k + IP rights
- [FI0225 – Code of Business Ethics for Sponsored Projects](#)
 - “Employees are expected to assume personal responsibility and accountability for reading and understanding UT fiscal policies, US laws and regulations, sponsor guidelines, and award document provisions that are applicable to their sponsored activity.”
 - “Employees in a supervisory capacity are expected to encourage and require compliance from subordinates and coworkers.”
 - “Compliance is adhering to the letter and the spirit of the law or rule.”
- [UTIA Compliance Checklist for Faculty Members](#)

III. Defining Research Misconduct (FFP)

UT Policy

Misconduct means **fabrication, falsification, plagiarism**, or other serious unethical or illegal deviations from accepted practices in proposing, conducting, or reporting the results of research and service activities. It does not include honest error or honest differences in interpretations or judgments of data.

PHS Regulations

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- (a) **Fabrication** is making up data or results and recording or reporting them.
- (b) **Falsification** is 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.
- (c) **Plagiarism** is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.
- (d) Research misconduct does not include honest error or differences of opinion.

IV. Possible sanctions: investigator

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- Retraction of published articles / retraction of manuscripts
- University sanctions include termination for cause. Sanctions short of termination may be imposed when deemed appropriate by the Chancellor.
- Governmental sanctions include
 - Complete debarment from all federally-funded projects for a period of time (usually 1, 2, or 3 years)
 - Required supervision of research processes
 - Required certification by University officials before submitting grant proposals
 - Required sign-off by University mentor before submitting abstracts or manuscripts for review or publication
 - Exclusion from review panels and service to PHS agencies

V. Possible sanctions: institution

- Loss of institutional eligibility for federally funded research
- Loss of private funding to both the individual researcher and institution
- Diminished credibility in future RM cases

VI. HOW TO BE PROACTIVE

- ✓ Be part of a great institution that provides the tools you need to be proactive about research integrity.
- ✓ Gather information about applicable government regulations.
- ✓ Read the research contracts.
- ✓ Know your RIO.

TO DO:

- Refresh your understanding of RCR issues:
 - IRB / IACUC regulations – both have relatively recent revisions
 - Minimum training requirements for you/your staff vs. PREFERRED training standards

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- Financial conflicts of interest – manageable vs. unmanageable conflicts; new NIH regulations
- Data management practices
- Clarify mentor/trainee responsibilities
- Discuss supervision of data – help your manager help you
- Careful transition to an independent researcher – key pitfalls related to times of transition
- Identify pitfalls in collaborative research
- Review applicable authorship and publication issues (ORI guidance, discussion with colleagues, contact with publisher)
- Review University and government policies regarding equipment, travel, computers (especially laptops), multiple-funding sources, etc.
- ORI-Introduction to the Responsible Conduct of Research (<http://www.ori.dhhs.gov/sites/default/files/rcrintro.pdf>)
- CITI – Collaborative Institutional Training Initiative – through Research Office (contact Jane Burns at 974-7375 or janeburns@utk.edu) – training modules in 7 languages

VII. Advice from the Compliance Side

1. Make friends in the University's Research offices – these people know the rules and how to get things done.
2. Get opinions in writing. Ask more than one person. If it seems too good to be true, it probably is.
3. Ask the opinions of your RIO, trusted advisors, and ORI/NSF early and often.
4. Consider the time it will take to respond to *questions* about your research integrity – stay away from the gray areas.

General principle: The most expensive cab ride is cheaper than the least expensive DUI lawyer.

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5. If you need to do something that you find difficult or questionable, get administrative buy-in on the front end. Administrators can then get input from our office, VC-Research, Chancellors, etc.
6. Scary cases involve good (or formerly good) researchers at high quality institutions, e.g. in 2011 include:
 - Michigan Medical School post doc and a tenured faculty member
 - St. Jude post doc
 - UVA medical resident
 - Kansas high level lab director
 - Pittsburg graduate student
 - SUNY full professor and Chair of Neuroscience & Physiology
 - Duke post doc
7. Collaborators can drag you down despite the best of intentions: know what you are joining when you sign on as a co-author.
 - Read the pieces of the article you didn't write. If something seems odd, raise the issue or get out.
 - Make sure you understand the science in the parts you didn't write.
 - Identify in writing any limits to your familiarity or input.
8. **Become an expert at RCR, not at the compliance process.**