Responsible Conduct in Research: Research Misconduct

Tulane University Office of Research Compliance

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Objectives

To understand and review:

- The reasons why research oversight developed
- Tulane Research Misconduct policies and procedures
- Case studies on research misconduct allegations
Background

- Prior to World War II, little public funding of research existed.
- Today, public funds support 1/3 of all research and development in the United States and half of all basic research.
- As public funding for research has grown, interest by the public, through its elected officials, has resulted in increased regulation and oversight of research.
According to the Federal Office of Research Integrity, in general terms, Responsible Conduct in Research ("RCR") is simply good citizenship applied to professional life.

Researchers who conduct and report their work honestly, accurately, efficiently, and objectively can achieve RCR.
Sources of Rules for RCR

- Professional “self-regulation”
- Government regulation
- Institutional Policies
- Personal Responsibility
When the public perceives problems with research, the result, through elected officials, is regulation.

Research institutions (such as universities) are required by law to have policies that cover aspects of research for which the institution receives federal funding.

Why is government regulation of research needed?
Government Regulation – why is it needed?

- Tuskegee Syphilis Study (1932-1972):
  - No informed consent
  - Participants not informed of all known dangers.
  - Participants not given a cure, even when the cure was widely known and easily available.
Government Regulation

- Research oversight required of Tulane University by federal regulation:
  - Institutional Animal Care and Use Committee ("IACUC") for the welfare of laboratory animals: [http://tulane.edu/asvpr/iacuc/hsc/sops.cfm](http://tulane.edu/asvpr/iacuc/hsc/sops.cfm)
  - Research Misconduct (today's topic):
Research Misconduct

• The federal Research Misconduct Policy requires Tulane, as a recipient of funding, to:
  ◦ Define Research Misconduct
  ◦ Outline procedures for reporting and investigating allegations of Research Misconduct
  ◦ Provide protection for whistleblowers and persons accused of Research Misconduct

Source: Federal Research Misconduct Policy
http://ori.dhhs.gov/policies/fed_research_misconduct.shtml
Tulane Research Misconduct Policy

• Located in Faculty Handbook, Sec. III(H)(3)
• Defines Research Misconduct as:
  ◦ Falsification of data – ranging from fabrication to deceptive, selective reporting, including the purposeful omission of conflicting data with the intent to falsify results;
  ◦ Plagiarism – representation of another's work as one's own;
  ◦ Violation of Federal Regulations – material failure to comply with federal requirements that uniquely relate to the conduct of research.
Tulane Research Misconduct Policy
– the process

• Complainant reports allegation to respondent’s Dean, or to Research Compliance Officer, who will report allegation to Dean.

• Complainant can request to remain anonymous.

• University must protect complainant who has made an allegation in good faith, even if the allegation is not sustained.
Tulane Research Misconduct Policy - Inquiry

- Dean makes the initial determination as to whether the allegation is one of research misconduct.
- If yes, then Dean begins an “Inquiry.” Dean may conduct the Inquiry or appoint an ad hoc Inquiry Committee.
Tulane Research Misconduct Policy - Inquiry

- Inquiry committee gathers and reviews all factual information to determine if reasonable cause for an Investigation exists.
- Dean makes the final determination as to whether or not a reasonable cause for Investigation exists.
- If “no,” complainant can renew complaint.
- If “yes” or complaint renewed, next step is Investigation.
Tulane Research Misconduct Policy - Investigation

- Investigation is conducted by the Grievance Committee of the respondent's school.
- Respondent is notified of Investigation and can request a hearing before the Grievance Committee.
- Investigation should conclude within 180 days.
Tulane Research Misconduct Policy - Investigation

- Grievance Committee drafts a report with findings.
- Respondent can comment on report
- Committee must consider comments in making a determination of research misconduct and recommended disciplinary action, if any.
- Provost can accept or reject recommendations of Committee.
Tulane Research Misconduct Policy
– Disciplinary Actions

- Letter of reprimand;
- Removal from the particular project;
- Special monitoring of future work;
- If a student, suspension or expulsion;
- If a staff member, termination of employment;
- If a faulty member, referral to the Senate Committee on Faculty Tenure, Freedom, and Responsibility (FTFR) for dismissal proceedings against the faculty member.
Tulane Research Misconduct Policy

- Respondent can appeal recommendations of Committee and Provost’s decision to the FTFR.
- FTFR submits recommendation to Provost, who makes final determination regarding nature and severity of disciplinary action.
Tulane Research Misconduct Policy

- ASVPR notifies sponsoring agencies if there is a finding of research misconduct.
- Provost may choose to notify:
  - Co-authors, co-investigators, collaborators;
  - Professional societies and licensing boards;
  - Editors of journals in which fraudulent research was published;
  - Editors of journals or other publications, other institutions, sponsoring agencies, and funding sources with which the individual has been affiliated; and
  - Where appropriate, criminal authorities.
Federal Research Misconduct Policy – disciplinary actions by sponsors

- Letter of reprimand
- Restrict expenditures under award
- Suspension or termination of award
- Require correction of research record
- Prohibition of individual as federal agency reviewer, advisor, or consultant
- Debarment of individual and/or institution
Research Misconduct: case study 1

- Informed Consent documents for a research study contained multiple places for a participant to sign. Audit of study revealed that on some of the signed informed consents, signatures on one part of the form did not match signatures on another part of form (i.e., some signatures looked to be forged).

- Research Misconduct?
Research Misconduct: case study 1

- Informed Consent documents for a research study contained multiple places for a participant to sign. Audit of study revealed that on some of the signed informed consents, signatures on one part of the form did not match signatures on another part of form (i.e., some signatures looked to be forged).
- Research Misconduct?
- No
- Why not?
Research Misconduct: case study 1

- Even though this was a noncompliance with federal regulations regarding obtaining informed consent, it was determined not to be “material failure” to comply with federal regulations, nor did it constitute falsification of data or plagiarism.

- The matter was reported to appropriate federal agency as noncompliance but not as research misconduct.
Research Misconduct: case study II

- Co-investigator working on a project alleges that principle investigator created a hostile working environment and did not comply with reporting requirements of the grant.
- Research Misconduct?
Research Misconduct: case study II

- Co-investigator working on a project alleges that principle investigator created a hostile working environment and did not comply with reporting requirements of the grant.
- Research Misconduct?
  - No
- Why not?
Research Misconduct: case study II

- The hostile working environment determined to be an employment issue.
- The failure to comply with reporting requirements was determined not to be a “material failure” to comply with federal regulations, nor did it constitute falsification of data or plagiarism.
Research Misconduct: case study III

- Respondent falsified data in 17 grant applications to the NIH and fabricated data in 10 publications.
- Research Misconduct?
Research Misconduct: case study III

- Respondent falsified data in 17 grant applications to the NIH and fabricated data in 10 publications.
- Research Misconduct?
- Yes
Research Misconduct: case study III

- Banned forever from receiving public research money
- Retraction or correction of 10 scientific papers
- Ordered to serve 1 year and 1 day in federal prison.
- Agreed to repay $180,000.00 to NIH plus $16,000 to the complainant for attorney’s fees.
Other examples of Research Misconduct per federal guidance

- Failure to report research misconduct
- Obstructing investigations or retaliation against complainant.

- Final note: the responsibility to avoid committing research misconduct is the minimum standard for RCR.
Questions?

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