Objectives

To better understand:

- The reasons why development of research oversight requirements occurred
- Laws & regulations applicable to research misconduct
- Tulane’s research misconduct policies and procedures
- Case studies on research misconduct allegations
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.
Background (continued)

- According to the Federal Office of Research Integrity (“ORI”), 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?

- People imprisoned by Nazis during Holocaust were forced to participate in human experiments – no informed consent.
- Total deaths uncertain, but death toll was very high. For example, experiments on twins resulted in 1,300 deaths out of 1,500 forced to participate.
- Other experiments: freezing, malaria, mustard gas, sterilization, high altitude.
- Led to passage of Nuremberg Code: guidance on informed consent, minimization of risk and harm, and freedom to withdraw.
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 by federal regulations:
  - 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)
Tulane’s Research Misconduct Policies:

1. Tulane Research Misconduct Policy (primary policy): Applicable to all allegations of research misconduct except when research is funded by National Science Foundation (“NSF”) or Public Health Service (“PHS”):

2. Tulane Research Misconduct Policy for NSF-Funded Research:
   http://tulane.edu/asvpr/research-compliance.cfm

3. Tulane Research Misconduct Policy for PHS-Funded Research:
   http://tulane.edu/asvpr/research-compliance.cfm

The three policies mostly mirror each other.
Tulane Research Misconduct Policy (primary 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; or
  - Violation of Federal Regulations – material failure to comply with federal requirements that uniquely relate to the conduct of research.
Complainant reports allegation to respondent’s Dean, or to Research Compliance Officer, (“RCO”) who will report allegation to Dean.

- RCO has duty to consult confidentially with persons uncertain about whether to submit a research misconduct allegation

- Complainant can request to remain anonymous.
Tulane Research Misconduct Policy – the process (continued)

- University must protect complainant who has made an allegation in good faith, even if the allegation is not sustained.
- Respondent (person accused of misconduct) has due process rights, and the identification of respondent must be kept confidential throughout process.
4 Stages of the process:
1. Inquiry
2. Investigation
3. Formal Finding
4. Appropriate Disposition.
Tulane Research Misconduct Policy - Inquiry

• Dean makes the initial determination as to whether the allegation falls under the definition of research misconduct.

• If yes, then Dean begins an “Inquiry.” Dean may conduct the Inquiry or appoint an ad hoc Inquiry Committee.

• Respondent must be informed of the allegation at the outset of Inquiry and of the right to seek advice of counsel.
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 - Inquiry

- For NSF/PHS funded research, TU must inform NSF/PHS of the allegation at the inquiry stage if:
  - Immediate health hazard exists;
  - Immediate need to protect federal funds or equipment, the person making allegation, or the respondent;
  - It is probable that allegation will be made public; or
  - Indication that criminal violation occurred.
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.
- If NSF/PHS funded research, must notify NSF/PHS of investigation
Tulane Research Misconduct Policy
– Formal Finding

- 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
- Provost notifies complainant and respondent of findings.
Tulane Research Misconduct Policy
– Disposition

- Examples of disciplinary actions include:
  - Letter of reprimand;
  - Removal from the particular project;
  - Special monitoring of future work;
  - Suspension or expulsion (students);
  - Termination of employment; (staff)

- If dismissal of a faulty member recommended, matter is referred to the Senate Committee on Faculty Tenure, Freedom, and Responsibility (“FTFR”) for dismissal proceedings.
Tulane Research Misconduct Policy

– Disposition

• 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

– Disposition

- 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.
Tulane Research Misconduct Policy
– Disposition

- For NSF/PHS sponsored research, Tulane shall make all reasonable and practical efforts to protect or restore the reputation of a respondent when no finding of research misconduct is made.
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
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 appeared to be forged). Was this 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 the appropriate federal agency as serious noncompliance but not as research misconduct.
Co-investigator working on a project alleged that principle investigator created a hostile working environment and did not comply with reporting requirements of the grant. Was this Research Misconduct?

No. Why not?
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 published a paper reporting that he could produce nuclear fusion without heat with a tabletop fusion process and that the experiment had been independently verified.
- Federal funds spent on numerous unsuccessful attempts to replicate respondent’s work. Research Misconduct?
- Yes.
Research Misconduct: case study III

• In 2006, Purdue decided not to proceed to an investigation of charges of research misconduct against Dr. Taleyarkahn; however, Purdue did proceed after pressure from a Congressional panel investigating use of federal funds in attempts to reproduce the results.
• Found guilty of research misconduct for falsification of the research record.
• Stripped of named professorship and forbidden to serve as a major professor to graduate students for three years.
Research Misconduct: case study IV

• Following a 5 years long research misconduct investigation, respondent admitted to falsifying data in 17 grant applications to the NIH and fabricating data in 10 publications over a period of 10 years. Was this Research Misconduct?

• Yes
Research Misconduct: case study IV

- 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 University of Vermont plus $16,000 to the complainant for attorney’s fees.
Other examples of Research Misconduct per NSF/PHS policy:

- Failure to report research misconduct
- Obstructing investigations or retaliation against complainant.
Examples of falsified clinical data: ORI 2007-2009

- Substituting one subject’s record for another
- Altering dates and results for required eligibility tests
- Backdating patient records to fit study protocol
- Falsifying patient’s test results
Examples of falsified clinical data: ORI 2007-2009

- Selective suppression of results or reporting data from a sub-set of patients only
- Falsely reporting a larger number of research subjects or falsifying outcome of statistical tests
- Selective “omitting” of data
- Using bloods/tissues from one subject to represent two or more additional subjects
Examples of falsified clinical data: ORI 2007-2009

- Falsifying interview results (interviews were not conducted)
- Representing animal data as if it were from humans
- Falsifying images in presentations and published reports
Lessons Learned from ORI Cases

- Any person involved in clinical research may be responsible for research misconduct, regardless of rank or duties on the project.
- The majority of respondents have held technical positions (not doctoral degree holders).
- Respondents may have had excessive work loads or time pressure – or pressure to increase enrollment.
Lessons Learned from ORI Cases

- There are many different motivations for research misconduct:
  - Financial (enrollment or accrual bonuses)
  - Professional advancement (papers, grants, tenure, job promotion/change)
  - Personal
  - Misguided altruism
Uncovering Research Misconduct

- Research Misconduct commonly discovered by:
  - Routine data audit
  - Whistleblower
  - Staff member

- The responsibility to avoid committing research misconduct is the minimum standard for Responsible Conduct in Research.
Questions?

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