



Federal and UD Research Misconduct and Investigation Policies

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Federal Policy on Research Misconduct*

Research misconduct is defined as *fabrication*, *falsification*, or *plagiarism* in *proposing*, *performing*, or *reviewing research*, or in *reporting research results*.

* US Office of Science and Technology Policy.
<www.ostp.gov/html/001207_3.html>



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Fabrication

- **Fabrication** is the description of experiments not actually performed, the invention of data not actually collected, and/or the reporting of these experiments and results.



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Falsification (Cooking and Trimming)

- **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.
- **Cooking** is retaining and reporting only the data that fits the theory and discarding others.
- **Trimming** is the smoothing of irregularities to make the data look more accurate and precise than they really are.



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Plagiarism

- **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.



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Federal Policy on Research Misconduct Excludes “Honest” Error

“Research misconduct does not include **honest error** or **differences in opinion**.”

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UD Statement on “Honest Error” Exclusion

Research misconduct “does not include **honest error or honest differences in interpretations or judgments or in reporting research results.**”

UD Policy for Responding to Allegations of Research Misconduct, September 2007

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“A finding of research misconduct requires that:

- There be a significant departure from accepted of the scientific practices of the relevant research community; and
- The misconduct be committed intentionally, or knowingly, or recklessly in disregard of accepted practices; and
- The allegation be proven by a preponderance of evidence.”

http://www.ostp.gov/cs/federal_policy_on_research_misconduct

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UD Policy on Research Misconduct

- It is the policy of the University of Delaware to abide by the OSTP policy in **all University research**. Any intentional distortion of research data or intentional distortions of information or conclusions derived from research data constitutes misconduct in research and is prohibited by University Policy.

<http://www.udel.edu/research/preparing/misconduct.html>

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Continued...

- The University of Delaware has the ethical responsibility to prevent misconduct in research, the legal responsibility to inquire into all allegations of research misconduct and to report and investigate all instances where a reasonable presumption of misconduct is established by inquiry.

UD Policy for Responding to Allegations of Research Misconduct. September 2007

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Continued

- The University, the State, suppliers of grant accounts, clients of consultation services, and the public all have the right to expect and demand unbiased and factual information from University personnel. In the long run, University personnel benefit individually and collectively from the maintenance of high ethical standards. An atmosphere of intellectual honesty enhances the research process and need not inhibit productivity and creativity. Establishing and maintaining such an atmosphere is a responsibility that must be accepted by all University personnel.

UD Policy for Responding to Allegations of Research Misconduct. September 2007


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UD Policy for Responding to Allegations of Research Misconduct

- Complaint
- Assessment
- Inquiry
- Investigation
- Administrative Actions

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General Rules for Misconduct Investigations



- Due Process
- Confidentiality
- Appropriate Expertise
- Protection of Complainant (Whistleblower)
- Protection of Respondent
- Protection of Evidence
- Protection of the University
- Meet or Exceed Federal Requirements

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Complaint and Assessment




- Complaint Received by the Research Integrity Officer
 - From individual whistleblower
 - From funding agency (☹)
 - From other institutional sources
- Assessment by Research Integrity Officer
 - Credible
 - Specific
 - Jurisdictional (☹)
 - Research Misconduct?

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Inquiry Process




- Purpose: initial review of the available evidence to determine whether to conduct a misconduct investigation.
- Must examine evidence
- May interview Complainant and Respondent
- Rapid Response
- Reports to Research Integrity Officer

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Investigation Process




- Within 30 days of completion of Inquiry, if warranted
- “...explore details, examine evidence in depth, and to determine whether misconduct has been committed, by whom, and to what extent.”
- May broaden scope of investigation
- Weighs seriousness
- May recommend appropriate sanctions

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Administrative Actions by Deciding Official




- Accept or Reject Investigation Report
- Determines whether misconduct has occurred
- May return report to Investigation Committee for further action
- Takes action on behalf of University
- Is required to notify other legal authorities, licensing boards, professional societies, collaborators, editors of journals
- Transmits report and findings to federal agencies (☹)

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Penalties



- Monitoring
- Debarment (Temporary or Permanent)
- Remedial Procedures
 - Compensation to University or Support Agency
 - Academic penalties
- Publicity (Federal Record)
- Firing

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Scott E. Monte, Huntington Memorial Hospital, Pasadena, CA: Based on the findings of an investigation conducted by Huntington Memorial Hospital (HMH) and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Scott E. Monte, L.V.N., former Clinical Research Associate, HMH, **engaged in scientific misconduct by knowingly and intentionally falsifying and fabricating clinical research records** in HMH cancer prevention and treatment protocols supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards U10 CA69651, U10 CA12027, U10 CA32012, and U10 CA86004.

Specifically, Mr. Monte **knowingly and intentionally**:

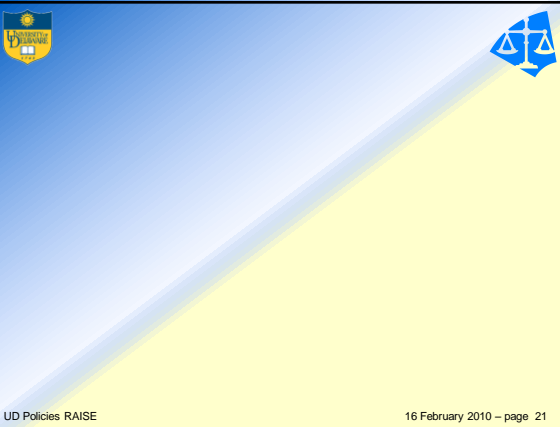
- (1) Entered falsified and fabricated laboratory data or physical examination results on five (5) research protocol case report forms (CRFs);
- (2) Falsified a gynecological examination report in a physician's progress note and entered the falsified document in the patient's research chart; and
- (3) Fabricated progress notes for four patients and a case report form for one of these patients.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on January 7, 2008:

- (1) Mr. Monte **is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government** pursuant to HHS' implementation of the OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 CFR Part 376; and
- (2) Mr. Monte **is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.**

[[Federal Register: January 23, 2008 (Volume 73, Number 15)]]

Questions



Clifford R. Robinson, Ph.D., University of Delaware: Based on the reports of investigations conducted by 3-Dimensional Pharmaceuticals, Inc. (3DP) and the University of Delaware (UD) and additional analysis conducted by ORI during its oversight review, the U.S. Public Health Service (PHS) found that Clifford R. Robinson, Ph.D., a former Assistant Professor, Department of Chemistry and Biochemistry, UD, engaged in misconduct in science involving research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grants.

Federal Register: November 24, 2006 (Volume 71, Number 226)