Workshop B Potti Case Study for Small Group Discussion [1]

"In raising these concerns, I have nothing to gain and much to lose." - Bradford Perez

In October 2006, Anil Potti, a superstar clinical researcher at Duke University, published a paper in *Nature Medicine*. The authors described genetic markers that could be used to predict a person's response to a specific type of chemotherapy. Other researchers were excited and wanted to use their methods.

Biostatisticians at the University of Texas MD Anderson Cancer Center, couldn't reproduce the results and wrote a letter to *Nature Medicine* questioning Potti's method. Potti and his mentor, supervisor & collaborator, Joseph Nevins, partly acknowledged the criticism, but argued that their findings still stood.

Bradford Perez, a 3rd year medical student on Howard Hughes Medical Institute (HHMI) fellowship in Potti's lab, submitted a paper to *Journal of Clinical Oncology*. Reviewers noted the concerns raised by U-Texas biostatisticians and questioned the methods used. Perez realized that the methods used by Potti's research group were not correctly validated. He was very worried because they were being used to assign patients to clinical trials. Perez attempted to discuss methodological flaws with Potti, but he took the questioning as a personal insult.

Perez talked with Robert Sanders Williams, dean of the School of Medicine, about his concerns. Williams noted that controversial papers would not help Perez's career.

In March 2008, Perez was still unable to resolve his problems. Perez was thinking about leaving the Potti lab and removing his authorship from all Potti lab papers. If he did this, he might lose his HHMI fellowship because of lack of research progress. It also would delay his graduation by one year.

In late March, Perez met with Duke medical education associate deans. They recommended Perez write a letter explaining his concerns and meet with Potti's mentor and supervisor, Nevins. Perez wrote a memo titled "*Research Concerns*".

Nevins and Potti responded to the memo with a promise to Perez that they would fix the study errors. But they didn't. In the weeks after the meeting, Perez made the decision to resign from the Potti lab and have his name removed from all publications.

Nevins, worried that the *Research Concerns* memo could start an internal investigation at Duke, asked Perez to not send it to HHMI. Perez agreed to not send the memo to HHMI. Duke, in turn, supported his HHMI application for an extra year of study, presenting the matter to HHMI as an honest difference of opinion between a medical student and two senior scientists. The vice dean said that there were no allegations of scientific misconduct and hoped that HHMI would continue to support Perez.

In September 2009, *Annals of Applied Statistics* published a paper by Baggerly and Coombes, claiming that there was potential for patient harm in the Duke Potti/Nevins trials. Duke suspended the trials and investigated the claims with internal and external reviewers. *Nevins decided which criticisms and documents were given to reviewers.* In December 2009, the external reviewers said that Potti's methods were scientifically valid. In January 2010, Duke restarted the trials.

In July 2010, *The Cancer Letter* reported that Potti had falsely claimed to be a prestigious Rhodes Scholar on a grant application. Duke placed Potti on administrative leave during the investigation. Within days, thirty-one biostatisticians and bioinformatics experts sent a letter, "Concerns about prediction models used in Duke clinical trials", to National Cancer Institute. In the same month, *Lancet Oncology* issued an expression of concern about validation of gene signatures used by Duke group to predict models. Duke then suspended the trials a second time.

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[1] Adapted from "Duke Officials Silenced Med Student Who Reported Trouble in Anil Potti's Lab" The Cancer Letter http://www.cancerletter.com/articles/20150109_1.

In August 2010, Duke identified issues of substantial concern. In October 2010, Duke administrators discussed the Perez matter in the context of their misconduct investigation. In November 2010, Potti resigned.

In December 2010, Harvey Fineberg, president of the National Academy of Science's Institute of Medicine (IOM), asked the IOM to investigate Potti's research, and seek lessons from it. In January 2011, Potti et al. *Nature Medicine* paper was retracted.

In August 2011, Duke administrators met with the IOM committee, stating that Duke has a "culture of openness" and that there are no whistleblowers. They did not give the Perez memo or emails to IOM.

In September 2011, a lawsuit was filed on behalf of eight patients in Potti clinical trials. The lawsuit named Duke, Potti, and Nevins. When the lawsuit was filed, only two of eight plaintiffs named in the lawsuit were alive. Duke argued that patients were not harmed as they were in late stages of disease, and Potti's predictor model was used to assign patients to existing therapies. The attorneys, however, argued that Duke had a plethora of opportunities to recognize Potti's method as fraudulent. The lawsuit was settled out of court with no admission of guilt by anyone involved.

From 2011 to 2015, Potti settled 19 additional cases of malpractice.

In November 2015, after a five-year investigation conducted by Duke School of Medicine and the federal Office of Research Integrity (ORI), ORI ruled that Potti was guilty of research misconduct. ORI found that Potti both fabricated and falsified data. As of today eleven of his papers have been retracted, seven of his papers have been corrected, and one of his papers has been partially retracted.

The full story of Bradford Perez was not widely known until a January 2015 article in The Cancer Letter.

Workshop B Sam and Julia Case Study for Small Group Discussion [1]

Julia Cruz and Sam Bergen are both graduate students working with Dr. Mark Chan, an eminent environmental chemist. Although both Julia and Sam are in their fourth year of study, neither has published a manuscript. Both are beginning to worry that if they do not publish soon they will not be able to obtain good postdoctoral positions.

Julia's project starts to look promising: she synthesized a crucial intermediary compound needed for her thesis molecule. Julia now has to produce more compound and perform a series of analyses on the compound to verify some of its properties.

Dr. Chan is excited about Julia's progress, and tells her to repeat her experiment and to begin to write up the results, because even the synthesis and some properties of the intermediate molecule are unique enough to be published in *Nature*.

Dr. Chan recruits Sam to assist Julia in some analyses of the key compound. Dr. Chan feels that performing the analyses will teach him some skills that he could apply to his own project. Dr. Chan promises him a second authorship on the paper if his analytic studies pan out. Although Julia does not think highly of Sam, believing him to be sloppy, she wants to move ahead and gives him the compound in two batches for the analytic studies.

Sam uses the first batch and verifies three of the four chemical groups that the compound is supposed to have. Sam performs another experiment using the second batch to identify the fourth chemical group. However the spectral pattern he gets is not what is expected, and he phones Julia and asks her if a contaminant might have gotten mixed up in the compound. Julia asks him to save the remaining material from the second batch, telling him that she will perform the second round of analyses.

When Sam comes back to the lab, he does not give Julia the leftover of the compound and tells her that his mistake in the original interpretation was due to tiredness. There is no way for Julia to validate Sam's findings, since there is not enough compound left to do another run. Sam tries to reassure Julia by showing her the instrument readout on the second batch, pointing to the results for the fourth chemical group. Dr. Chan is ecstatic, and tells Julia to quickly write up a manuscript. Julia doesn't want to accuse Sam of manipulating research results, but later in the day she looks through his research notebook and sees a written procedure and data for the first experiments. For the second tests, she sees only the instrument readout, which looks too clean. It also has no accompanying text.

Julia wonders whether she can trust Sam's findings, but she proceeds to write about the synthesis of the compound and its analysis by Sam. The article is published in *Nature*, but soon others who repeat the synthesis report finding different spectra. Julia repeats the analysis on the fourth chemical group in the compound and produces a different spectral pattern from what Sam found and what was published. She believes that he must have done something to the data.

Q1: Put yourself in Julia's shoes. What would you have done after receiving the second test results from Sam?

Q2: Put yourself in Julia's shoes. What would you have done after repeating the work and getting different results?

Q3: Was it appropriate for Dr. Chan to promise Sam second authorship based on performing some analyses?

Q4: If science is self-correcting, as shown in this case study, why have federal laws and regulations against misconduct?

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[1] Adapted from "Case Study 1: Truth or Consequences" Center for Teaching and Learning at the Columbia University http://ccnmtl.columbia.edu/projects/rcr/rcr_misconduct/case.

Workshop B Norton Case Study for Small Group Discussion [1]

Albert Jurczyszyn is a graduate student at Tennessee Western University. For the last 18 months, Albert has been involved in a research project in the lab of Prof. Danielle Norton, who expects Albert to complete his thesis by the end of the following semester. The project was conducted largely under the direct supervision of a postdoc, Dr. Minh Thant.

When Albert sits down to do the final analysis of the data before writing his thesis, he is pleased to see that the vast majority of the data he collected strongly supports his hypothesis and are consistent with the literature that he read while planning the project. However, Albert also finds that some of the data he collected are not fully consistent with the bulk of his results. He is convinced that his research is sound overall and worries that by including the ambiguous data, it will detract from the essential thrust of his work.

Albert approaches Dr. Thant with his concerns and asks for advice. Dr. Thant suggests that a few more experiments might help clear up the ambiguities. Albert points out that his fellowship ends in a few months and he really doesn't have time to get back in the lab now and still be able to complete his thesis on schedule to graduate. Dr. Thant then proposes that there may be a different way to analyze the data so that the inconsistent results aren't necessary for the thesis write-up. Dr. Thant adds that Albert might need to modify his hypothesis to make this second suggestion work.

[As you discuss the questions below, note any details not described above that would influence your conclusions one way or the other.]

Q1: Time pressures can be real; re-running experiments can be costly. Is Albert justified in seeking a solution that will allow him to graduate as planned?

Q2: Can Albert cut a few corners for his master's thesis as long as he resolves any inconsistencies before writing a journal article about the project?

Q3: Are there circumstances under which Albert can ignore the inconsistent data, or present it in a different manner so that it downplays inconsistencies? If so, describe them.

Q4: Should Albert or Dr. Thant alert Prof. Norton about the data ambiguity?

Q5: What do you think about Dr. Thant's suggestion to reformulate a hypothesis that would allow Albert to avoid explaining the ambiguous data?

Q6: Who might be impacted by Albert reformulating the hypothesis?

Q7: If Albert omits the ambiguous data in his thesis, can his actions be considered misconduct? Explain why you reached your conclusion.

Q8: Under what conditions might Dr. Thant and/or Prof. Norton face professional liability if Albert omits data from the thesis?

Q9: Assume Albert discusses the data inconsistencies with Prof. Norton. Is Prof. Norton obligated to extend his fellowship so that the additional experiments may be completed?

Q10: Which is the more important goal: show how the majority of the data collected support the overall conclusion or understand and explain the ambiguous data?

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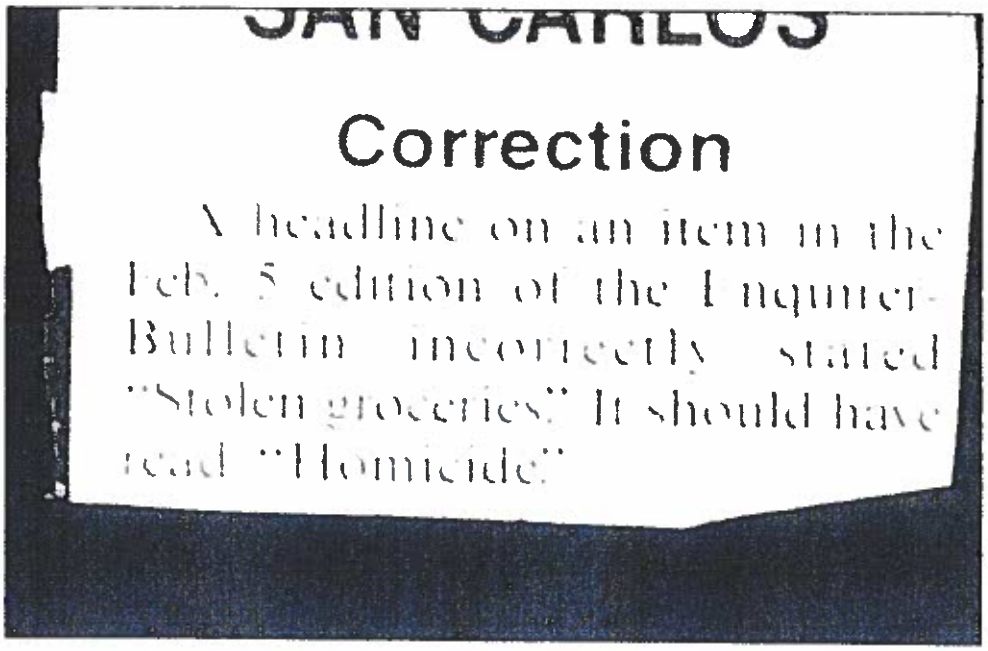
[1] Adapted from "Engineer's Duty To Report Data Relating to Research - Case No. 85-5" Online Ethics Center for Engineering, http://www.onlineethics.org/Resources/Cases/ec85-5/nspe85-5.aspx, downloaded 6/21/11; and "Data Torturing," Atlanta Clinical and Translational Science Institute, *Ethical Dilemmas in Scientific Research and Professional Integrity*, http://www.actsi.org/areas/erks/ethics/data_representation.html, downloaded 6/8/2011.



Honest Mistakes

Mistakes happen. Even the most careful engineer and scientists make mistakes, though one of the goals of being careful is always double checking and working with your colleagues to help uncover errors prior to publication.

You are working under a tight deadline to produce results from an experiment that you need for a chapter of your thesis and publication in a special issue of a journal devoted to "extreme" parameter space. You have presented preliminary data to your advisor and research group and even presented the results at a national meeting. In running the new experiment, you discover a bug in the data processing code that doesn't impact most of the work, but for the extreme (and most interesting) range of parameter space, the bug completely invalidates the results. The Thesis Deadline and the special issue deadline is this week.

Please discuss with your group the following:

What do you do? Eliminate the "very interesting" results? Include the results but put a note in the Thesis and paper about the "uncertainty" in the "special" results? Tell your advisor about the bug and that you don't have time to redo the analysis of that section of parameter space and therefore will not be able to submit the paper to the special issue? The aspect of the research is important, but not the central aspect of your Thesis. Should you delay your dissertation to redo the analysis?

Research Guides

Responsible Conduct of Research and Scholarship (RCRS)

Search

Ethics resources for individuals at the UM College of Engineering, including how to keep a lab notebook; publishing resources for authors; how to locate and cite sources, and resources for avoiding plagiarism and complying with copyright laws.

Lab Notebook

- **Laboratory Notebooks**
  This guide by the Stanford library system has a list of useful links for keeping a lab notebook.
- **Instructions for Using Your Laboratory Notebook [PDF]**
  Instructions and examples for using a lab notebook from MIT.
- **The Laboratory Notebook**
  Detailed description of how to prepare a lab notebook from the chemistry lab at Truman State University.

University of Michigan Library
818 Hatcher Graduate Library South
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Ann Arbor, MI 48109-1190
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contact-mlibrary@umich.edu

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SPG U-M Standard Practice Guide

UNIVERSITY OF MICHIGAN

Standard Practice Guide Policies

Policy Statement on the Integrity of Scholarship 303.03

Applies to: Faculty, students, other trainees, staff, and all other members of the University of Michigan's academic community

A. Introduction

Integrity in scholarship and research is a fundamental value upon which the University is founded. Without integrity, we cannot justify the privilege of academic freedom intrinsic to scholarship and research, nor can we provide to society the advancements of knowledge that derive from free and open inquiry.

It is, therefore, a fundamental responsibility of the faculty, staff, students, and administration of the University of Michigan to maintain the trust of the public in all research and scholarly activity. It is the shared responsibility of all members of our academic community to ensure that misconduct in scholarship and research is dealt with in a timely and effective manner, and that the reputation of the University for high standards of scholarly and research integrity is preserved.

At the University of Michigan, misconduct in the pursuit of scholarship and research (henceforth termed *research misconduct*) is generally defined as *fabrication*, *falsification*, or *plagiarism* in proposing, performing or reviewing research or in reporting research results. Research misconduct does not include honest error, author disputes, or differences of interpretation inherent in the scientific and creative process that are normally corrected through further research and scholarship. For definitions of italicized terms, see Section B of the associated procedures: Definition of Research Misconduct (http://research-compliance.umich.edu/research-integrity).

The purpose of this policy is to reaffirm the University's commitment to integrity of research and scholarship, and outline the principles that govern the procedures that will be followed in the University's review of allegations of research misconduct. These principles are outlined in Section B of this policy, while the review procedures may be found on the University's Research Integrity (http://research-compliance.umich.edu/research-integrity) web page.

B. General Principles

The principles set forth in this policy apply to allegations of research misconduct in connection with any research conducted at the University of Michigan, regardless of the presence or absence of external funding or sponsorship of the specific research project.

Federal requirements: The National Science Foundation, the Public Health Service, and other federal agencies have published formal regulations regarding the investigation of allegations of research misconduct in the context of activities supported by those agencies (See Exhibit A) (http://spg.umich.edu/sites/default/files/policies/303x3_ExhibitA.pdf). The University will comply with those statutory and regulatory requirements if applicable.

1. Requirements for findings of research misconduct: A finding of research misconduct requires a determination that there has been a significant departure from accepted practices of the relevant academic community; that

the research misconduct was committed intentionally, knowingly, or recklessly; and that the allegation has been proved by a preponderance of evidence.

2. Handling of questionable research practices: Concerns in the context of research and scholarship that do not rise to the level of research misconduct, such as carelessness or questionable research practices, as well as authorship disputes, will generally be handled through the appropriate administrative channels.
3. Whistleblower protection: It is a violation of University policy to retaliate against a complainant for reporting in good faith an allegation of research misconduct.
4. Unsupported allegations: Complainants, respondents, and other participants in the research misconduct review process are expected to act in good faith throughout. Failure to act in good faith may lead to disciplinary action.
5. Prompt reporting: Prompt reporting of research misconduct is critical for ensuring timely and appropriate fact gathering.

C. Sanctions

The University may take disciplinary action, up to and including termination of employment, upon a finding of research misconduct.

D. Procedures

Procedures for SPG 303.03 (http://research-compliance.umich.edu/sites/default/files/resource-download/spg_303.03_procedures.pdf)

File Attachments

Printable PDF of SPG 303.03, Policy Statement on the Integrity of Scholarship (http://www.spg.umich.edu/sites/default/files/policies/SPG%20303.03%20Policy%20EO%20approved%20042418.pdf)
SPG 303.3 ExhibitA - Federal Research Misconduct Policies (http://www.spg.umich.edu/sites/default/files/policies/303x3_ExhibitA.pdf)

SPG Number:
303.03

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July 1, 1994

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April 25, 2018

Next Review Date:
April 25, 2023

Applies To:
Faculty, students, other trainees, staff, and all other members of the University of Michigan's academic community

Owner:
Office of the Vice President for Research

Primary Contact:
Office of the Vice President for Research

Related Links:
Procedures (http://research-compliance.umich.edu/sites/default/files/resource-download/spg_303.03_procedures.pdf)

Hard copies of this document are considered uncontrolled. If you have a printed version, please refer to the University SPG website (spg.umich.edu) for the official, most recent version.

Procedures for Investigating Allegations of Misconduct in the Pursuit of Scholarship and Research under SPG 303.03

A. Applicability of the Procedures

This document sets forth the implementing procedures to the Policy Statement on the Integrity of Scholarship and Research (SPG 303.03). These procedures apply to allegations of research misconduct and other serious deviations from accepted research practices when the respondent is one of the following individuals:

1. All instructional faculty (tenure track and clinical track), research faculty, librarians, and other University staff members, including without limitation: graduate student research assistants, graduate student teaching assistants, graduate student staff assistants, postdoctoral fellows and postdoctoral research associates, house officers, visiting faculty and students or staff, sponsored affiliates, temporary staff or student employees, faculty or staff on sabbatical leave, adjunct faculty and emeritus faculty when performing University work, faculty or staff on leave without pay, paid and unpaid interns, and all other members of the University of Michigan's academic community;

2. Undergraduate students engaged in research or other scholarly activity. In cases in which the alleged misconduct relates to a student's coursework or other academic activities, the applicable school or college procedure for handling allegations of academic misconduct by students will apply. In cases in which the status of a student respondent is unclear, the responsible administrator will elect whether to employ these procedures or other procedures available for the investigation and adjudication of alleged academic misconduct by students; and

3. Former University students or employees, if the alleged misconduct occurred during the period of attendance or employment at the University.

B. Definition of Research Misconduct. Research Misconduct is defined as *fabrication*, *falsification*, and *plagiarism*.

1. *Fabrication*: making up data or results and recording them in the research record.

2. *Falsification*: 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.

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

C. Other Violations of Research Integrity. In addition, the University of Michigan may apply these procedures to other serious deviations from accepted research practices, including but not limited to the following:

1. *Abuse of confidentiality*: taking or releasing the ideas or data of others by one with whom they were shared with the legitimate expectation of confidentiality (e.g., stealing ideas from others' grant proposals, award applications, or manuscripts for publication when one is a reviewer for granting agencies or journals, or is an internal reviewer);

2. *Dishonesty in publication*: knowingly publishing material that will mislead readers (e.g., misrepresenting data, misrepresenting research progress; or adding the names of other authors without permission);

3. *Property violations*: stealing, tampering with, or destroying property of others, such as research papers, supplies, equipment, or products of research or scholarship;

4. *Failure to report observed research misconduct*: covering up or otherwise failing to report observed, suspected, or apparent research misconduct by others;

5. *Retaliation*: taking punitive action against an individual for having reported alleged research misconduct;

6. Directing or encouraging others to engage in any of the above listed offenses.

D. Responsibilities of the Research Integrity Officer (RIO)

The RIO is appointed by the Vice President for Research and has the primary responsibility for overseeing the procedures described in this document. The RIO assesses allegations to ascertain whether they could, if true, constitute research misconduct under SPG 303.03, determines when the allegations warrant further inquiry, oversees inquiries, and oversees the activities of any investigation committees to ensure compliance with SPG 303.03 and the appropriate federal policies, if applicable. The RIO is also responsible for making timely reports to the relevant external agencies, as required, and for appropriately maintaining documentation of all research misconduct proceedings.

E. Considerations

1. **Confidentiality**
   Because of the potential jeopardy to the reputation and rights of a respondent, great care will be taken to handle reporting, preliminary assessments, inquiries, and investigations in a way that preserves confidentiality, and to provide information only to those with a need to know, which includes those within the University who need the information to perform their University roles. The procedures used are intended to safeguard the rights of the respondent and the complainant, if a complainant is identified, and to recognize the interest of the University's academic community in research integrity. The University will protect, to the best of its ability, the privacy of those who, in good faith, report allegations of research misconduct, as well as of those who are the subjects of such allegations. The University will also provide, to the best of its ability, an expeditious and thorough review of the allegation, and will provide the respondent the opportunity to comment, as appropriate, during the review process.

2. **External Notifications**
   Despite the University's general commitment to preserving confidentiality noted above, there may be cases in which the University may need – at any stage of the process, including before the University's review has concluded – to notify and/or consult with external entities about the allegation or aspects thereof. In any cases involving potential external notification, the Vice President for Research, in consultation with the Office of the General Counsel, will decide if and when a notification should occur, what any such notification will include, and to whom it should be directed.

3. **Interim Measures**
   In some cases, it may be necessary to take interim measures pending final resolution of the research misconduct allegation. These interim measures could include actions to protect human subjects or to preserve federal or other sponsor funds (including suspension of the research at issue), or other appropriate steps. In such cases, the appropriate University official, in consultation with the Office of the General Counsel, will determine whether interim measures are needed and what measures are appropriate under the circumstances.

4. **Conflict of Interest**
   The integrity of the process will be maintained by disclosure and evaluation of any prejudicial conflict of interest. Individuals judged by the appropriate University official to have a conflict of interest that would jeopardize the credibility of the inquiry or investigation will not be assigned decision-making roles in the process.

5. **Access to Research Records**
   In accordance with University policies and Standard Practice Guides, during its review of an allegation of research misconduct, the University may access and take custody of all records, whether physical or electronic, that are generated in the course of the research and that may be relevant to its review of the allegation, regardless of where the records are stored.

6. **Admissions of Responsibility**
   In cases in which the respondent admits responsibility, the RIO in consultation with the appropriate University officials and, if needed, federal oversight agencies may consider whether to modify or eliminate any of the procedural stages of the procedures set forth below.

F. Review of Reported Allegations and Sequestration of Evidence

The review of allegations may have three sequential stages: (1) preliminary assessment to assess whether the allegation meets the University of Michigan's definition of research misconduct, as set forth in SPG 303.03; (2) an inquiry to determine whether the allegation warrants further formal investigation; and (3) when warranted, a formal investigation to thoroughly examine and evaluate all relevant facts to assess the validity of the allegation. Generally, the RIO will oversee the review process to ensure that these procedures are followed in a manner that is fair and unbiased. In cases in which the respondent is a faculty member, the Office of the Vice President for Research will consult with the Office of the Provost to determine whether and how that office would like to be involved in the review of the research misconduct allegation.

Initial sequestration of evidence may occur at any time after allegations are received. The RIO will take all reasonable and practicable steps to obtain custody of relevant research records and evidence, as soon as feasible, and store them in a secure manner in accordance with the University policies outlined in Section III.A of the Standard Practice Guide 601.11. All data and records that could be relevant to the University's review of the allegation will be sequestered by the RIO. Sufficiently detailed documentation will be kept to permit later assessment of the adequacy of the inquiry by the RIO. (This is particularly important in those instances in which the Vice President for Research determines that a formal investigation is not warranted). The documentation will be kept in a secure manner.

Different academic disciplines may have different forms of research records, both physical and electronic. Examples of research records include, but are not limited to, the following: research proposals; laboratory records, both physical and electronic, including lab notebooks; progress reports; theses; abstracts; oral presentations; internal reports; manuscripts and publications; notes; correspondence including emails, videos; biological materials; equipment use logs; laboratory procurement records; certifications; and records related to the planning, conduct, management, and reporting of human or animal subject research.

1. **Preliminary Assessment**
   Upon receipt of a research misconduct allegation, the RIO will assess the allegation to determine whether, if taken as true, it falls within the University of Michigan's definition of research misconduct, such that the policy stated in Standard Practice Guide 303.03 applies. If so, (s)he may continue to the next step in the process, which is an inquiry. Situations that are determined by the RIO not to involve research misconduct may be referred to other administrative channels, as appropriate

2. **Inquiry**
   a. Purpose
      An inquiry is information-gathering and initial fact-finding to determine whether the allegation or apparent instance of misconduct has substance and warrants a formal investigation. It is intended to separate serious allegations deserving further formal investigation through this process from trivial, frivolous, unjustified, or clearly mistaken allegations.

   b. Notification to Respondent
      Upon initiation of an inquiry, the respondent will be informed of the allegation(s) and given an opportunity to respond to them.

   c. Inquiry Process
      The RIO may conduct the inquiry or may assign an individual or individuals without conflict of interest to conduct the inquiry. In rare cases, if relevant expertise is lacking within the University, the RIO may seek the assistance of an external expert. The RIO will consult with the Office of the General Counsel prior to consulting with an external expert. Typically, the inquiry will include gathering and review of relevant information and may include interviews with the complainant(s), respondent(s), and other witnesses, as deemed appropriate.

   d. Inquiry Report
      The individual(s) appointed to conduct the inquiry will prepare a written report. The report will include a statement of the allegation; a description of the evidence reviewed; summaries of the relevant interviews, if any; and the conclusions of the inquiry regarding whether there is sufficient evidence to warrant a formal investigation.

   e. Inquiry Report Review and Actions
      If the inquiry recommends that a formal investigation be pursued, the respondent will be provided the opportunity to comment on the inquiry report and any such comment will become part of the record. If the report of the inquiry recommends that a formal investigation is not warranted, then no comments will be sought.

The report of the inquiry, along with any written comments on the report received from the respondent, will be forwarded to the Vice President for Research.

If the Vice President for Research concurs that an investigation is warranted, (s)he will decide whether additional notification (e.g., to the appropriate Dean or Director), if any, is necessary, and the RIO will convene the research misconduct investigation.

If the inquiry will not proceed to a formal investigation, the RIO will inform any persons involved in the inquiry to whom the identity of the respondent was disclosed by the University that the inquiry did not produce sufficient evidence to warrant formal investigation.

3. **Investigation**

a. Purpose

An investigation is the formal examination and evaluation of all relevant facts by a committee of knowledgeable faculty or, as needed, other individuals to determine if the preponderance of evidence supports the conclusion that research misconduct has taken place.

b. Selection of the Investigation Committee

Upon determining that a formal investigation is warranted, the RIO will appoint an investigation committee, the composition and size of which will be determined by the RIO. The appointed committee must have the necessary and appropriate expertise to carry out a thorough formal investigation and authoritative evaluation of the relevant evidence. The committee members must not have any personal, professional, or financial conflicts of interest with either the respondent, the complainant, or witnesses. The investigation committee should include at least one faculty member who is an expert in the field of research that gave rise to the allegation and may, if necessary, also include one or more such experts from outside the University. The RIO will consult with the Office of the General Counsel prior to consulting with an external expert.

c. Notification to Respondent

The RIO will inform the respondent of the initiation of the formal investigation, the composition of the investigation committee, and the charge to that committee. If the respondent has concerns that any committee member has a conflict of interest, the respondent can identify the basis for those concerns to the RIO, who will review and determine whether a conflict exists such that one or more alternative committee members should be appointed.

d. Charge to the Investigation Committee

The Vice President for Research will provide the charge to the investigation committee, which will include: (1) the purpose of the formal investigation, (2) copies of the allegations and the inquiry report, (3) responsibilities of the investigation committee, as set forth below, (4) the requirements needed to support a finding of research misconduct, and (5) the expected timeframe for formal investigation (consistent with applicable regulatory requirements, if any). The committee will also be provided with a copy of SPG 303.03 and its associated procedures.

e. Responsibilities of the Investigation Committee

The Committee will gather evidence and promptly (ideally, within 120 days of its initial meeting, in the absence of extraordinary circumstances) reach a determination of whether research misconduct has occurred. The committee's determination of research misconduct may also include recommended sanctions (e.g., reprimand, demotion, or discharge) or other actions appropriate for resolution of the matter.

During the formal investigation, every reasonable effort will be made to protect the confidentiality of the respondent(s), the complainant(s), and any witnesses, as set forth in Section E.1. However, at this stage the respondent will normally be entitled to know the identity of all witnesses, if any, called before the investigation committee. Cases that depend solely upon the observations or statements of the complainant may be unable to proceed without the involvement of that individual, or the ability to review may be severely limited; other cases that can rely on documentary evidence may permit the complainant to remain uninvolved without compromising the investigation.

f. Rights of the Respondent at Fact-Finding Meetings
When the respondent is interviewed by the committee, the respondent may be accompanied by an advisor, who may be an attorney. The advisor's role (whether an attorney or not) will be limited to advising the respondent. The advisor may not address the committee or any witnesses. If counsel is present with the respondent, the Office of the General Counsel will likewise be asked to be present at the meeting, for the limited purpose of advising the RIO and the investigation committee.

The investigation committee will keep the respondent and the Vice President for Research apprised of any additional allegations or other significant developments during the formal investigation, particularly if those developments might support expansion of the committee's investigative charge.

g. Summary of Interviews
The investigation may include interviews, which will be recorded or transcribed. Transcripts will be provided to the interviewed party for comment and will be included, along with any comments received, as part of the formal investigation file.

h. The Investigation Report
The investigation committee will prepare a written report that summarizes its conclusion regarding whether misconduct occurred and that may recommend sanctions or remediation, as appropriate. The report must describe: the identity of the respondent; the nature of the allegation(s); the specific allegations; funding source(s); methods used to examine the evidence; a list of evidence reviewed; a statement of findings for each allegation specifying whether research misconduct occurred and whether it was committed intentionally, knowingly, or recklessly; the identity of the responsible individual for each finding of research misconduct; any publications that need correction or retraction; any federally funded projects that may have been impacted by the misconduct; any sanctions or remediation that the committee recommends; and comments on the draft investigation report by the respondent.

i. Review of the Investigation Report and Actions
The respondent will be afforded the opportunity to provide written comments on the report. The comments of the respondent on the draft report, if any, must be submitted within 30 days of the date on which the respondent received the draft and such comments will become part of the record.

The investigation committee will submit its report, along with the complete investigatory file, to the Vice President for Research. The Vice President for Research will take the following steps, in consultation with the Office of the Provost and the Office of the General Counsel, as necessary: (1) decide on what actions to take in light of the report, (2) notify the respondent and the dean or director of the decision, (3) decide whether or not the complainant will be notified, and (4) decide if and when external agencies or others, if any, are to be notified, what any such notification will include, and to whom it should be directed.

G. Resolution and Outcome

When allegations are not confirmed by the inquiry or the investigation, the University will consider, as appropriate and feasible, ways to restore the reputations of persons alleged to have engaged in misconduct, and to protect the positions and reputations of those persons who, in good faith, made allegations.

If the University determines that research misconduct has occurred, the next step(s) depend upon the type of appointment the respondent holds, the seriousness of the misconduct, and the sanctions recommended. The substantive determination of misconduct itself will not, however, be subject to challenge. Below are some examples:

1. **Faculty Cases Covered by Regents' Bylaw 5.09**
If the Vice President for Research accepts the recommendations made by the investigation committee for sanction or dismissal, demotion, or terminal appointment against a faculty member to whom Regents' Bylaw 5.09 applies, the Provost and Executive Vice President for Academic Affairs may initiate the procedures required by the Bylaw.

2. **Faculty Cases in Which Bylaw 5.09 Does Not Apply**
In cases to which R 5.09 does not apply, but which are covered by a school or college faculty grievance procedure, the dean will decide on the appropriate outcome, which the faculty member may then challenge through the applicable faculty grievance procedures.

3. **Cases Not Involving Faculty**
In cases not involving faculty, the appropriate University manager and personnel department will initiate procedures required by the University's Standard Practice Guide 201.12, "Discipline", or the appropriate collective bargaining agreement.

Staff members subject to the terms and conditions of collective bargaining agreements should consult the specific provisions in their current agreements dealing with misconduct. Any provision in such agreements that provide greater protections than the provisions stated herein supersede the affected provision of these procedures. Information concerning staff members covered by collective bargaining agreements may be obtained from the appropriate human resources office.

Cases involving students will be referred to the appropriate school or college for disciplinary actions.

4. **Record Retention**
All inquiry and investigatory files and final reports will be maintained and secured by the RIO for a period of seven years from the date of receipt of the allegation, or for the period required by applicable regulations.

5. **Questions**
Questions regarding these procedures may be directed to the Office of the Vice President for Research or the Office of the General Counsel.

Exhibit A: Federal Research Misconduct Policies

The Public Health Service Office of Research Integrity **(ORI)** maintains a list of web sites for the PHS policy on research misconduct and the policies of other federal agencies. [http://ori.dhhs.gov/policies/federal_policies.shtml].

The Health and Human Services (HHS) Regulations, effective May 17, 2005, appear in 42 CFR Part 50 Parts 50 and 93 and implement section 493 of the Public Health Service Act. Copies of the regulation, entitled iPublic Health Service Policies on Research Misconducti are available from the Office of the Vice President for Research, 3-1289, or at (http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf, 5/17/05).

PHS must be notified when the institution determines that an investigation is warranted or prior to the decision to initiate an investigation if it has reason to believe that any of the following exist:

a. Health of safety of the public is at risk, including an immediate need to protect human or animal subjects.
b. HHS resources or interests are threatened.
c. Research activities should be suspended.
d. There is reasonable indication of possible violations of civil or criminal law.
e. Federal action is required to protect the interests of those involved in the research misconduct proceeding.
f. The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
g. The research community or public should be informed.

The **National Science Foundation** (NSF) Regulations, effective March 18, 2002, appear in 45 CFR Part 689. Copies of the regulations, entitled iResearch Misconducti are available from the Office of the Vice President for Research, 3-1289, or at (http://www.nsf.gov/oig/misconscieng.jsp)

NSF expects institutions to promptly notify the NSF Office of Inspector General should the institution become aware during an inquiry or investigation that:

a. Public Health or safety is at risk;
b. NSFis resources, reputation, or other interests need protecting;
c. There is reasonable indication of possible violations or civil or criminal law;
d. Research activities should be suspended;
e. Federal action may be needed to protect the interests of a subject of the investigation or of others potentially affected; or
f. The scientific community or the public should be informed.

Research Misconduct policies of other Federal Research Sponsors:

Department of Defense
DoD INSTRUCTION 3210.7 (May 14, 2004) which implements DoD DIRECTIVE 3216.2/
http://www.dtic.mil/whs/directives/corres/html/321007.htm

Department of Energy
70 FR 123, 6/28/05

Department of Labor
68 FR 117, 53861-53866
http://www.dol.gov/_sec/regs/fedreg/notices/2003023248.htm

Department of Transportation
http://ori.dhhs.gov/documents/rmguidancefinal_228002.pdf

Department of Veterans Affairs
http://ori.dhhs.gov/policies/documents/ViewPublication-VAMisconduct.pdf

Environmental Protection Agency
http://ori.dhhs.gov/documents/epapolicy.pdf

National Aeronautics and Space Administration
14 CFR Part 275, 7/14/2004
http://edocket.access.gpo.gov/2004/04-15432.htm

National Endowment for the Humanities
http://neh.gov/grants/guidelines/researchmisconduct.html

Smithsonian Institution (not available on-line)

Last reviewed: July 2008, technical revisions only