



USUHS



DIRECTIVE SYSTEM TRANSMITTAL

NUMBER USUHS I-5501 (OGC) ch.1	DATE MAR 30 2001
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ATTACHMENTS

None

INSTRUCTIONS FOR RECIPIENTS

The following changes to USUHS Instruction 5501, "Allegations of Scientific Misconduct," dated September 28, 1995, have been authorized.

Pen Changes:

1. Please change the Office of Primary responsibility for this instruction from **OGC** to **REA**.
2. Enclosure 1 "References." Add the following:
(e) 65 Federal Register 76260, "Federal Policy on Research Misconduct"
3. Enclosure 2 "Definitions." Add after paragraph 2(a) as follows:
(1) Fabrication. Fabrication is making up data or results and recording or reporting them. (65 Federal Register 76260^e).
(2) Falsification. 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. The research record is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles. (65 Federal Register 76260^e).
(3) Plagiarism. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. (65 Federal Register 76260^e).

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INSTRUCTIONS FOR RECIPIENTS (Continued)

4. Enclosure 3 "Procedures." Add the following:

Paragraph 1.a., in the first sentence, change the word "**extraordinary**" to "**unusual.**"

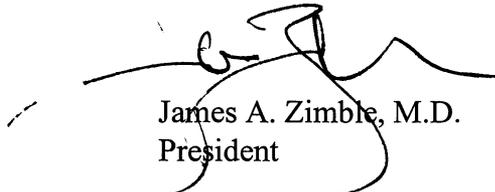
Paragraph 3.f., change "**clear and convincing evidence**" to "**a preponderance of the evidence.**" Delete the remainder of the subparagraph starting at "**Note**". Substitute the following in its place:

To make a finding that the respondent committed "scientific misconduct" there must be a preponderance of the evidence that

- (1) a significant departure from accepted practices of the relevant research community occurred; and
- (2) the misconduct was committed intentionally, or knowingly, or recklessly.

Effective Date

This change is effective immediately.



James A. Zimble, M.D.
President



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES



SUBJECT: Allegations of Scientific Misconduct

Instruction 5501

(OGC)

SEP 28 1995

ABSTRACT

This Instruction sets out the procedures for handling allegations of scientific misconduct.

A. Issuance and Purpose. This Instruction discusses the procedures for dealing with scientific misconduct as that term is defined by the Public Health Service (PHS) and the National Science Foundation (NSF). However, this Instruction does **not** apply to allegations of misconduct involving the care of patients. Allegations of such misconduct should be referred immediately to the appropriate chief of hospital services, and the hospital command. The Dean, School of Medicine (SOM) should also be notified. Furthermore, this instruction does not deal with academic misconduct by students.

B. References. *See Enclosure 1.*

C. Applicability. This Instruction is applicable to all Uniformed Services University of the Health Sciences (USUHS) personnel to include those having an academic appointment with the University but billeted elsewhere.

D. Definitions. *See Enclosure 2.*

E. Policy.

1. The USUHS is committed to maintaining the integrity of the scientific and academic community.

2. The Department Chair, often through a laboratory director, will be responsible for the quality and integrity of all research proposed, conducted, or reported from departmental laboratories.

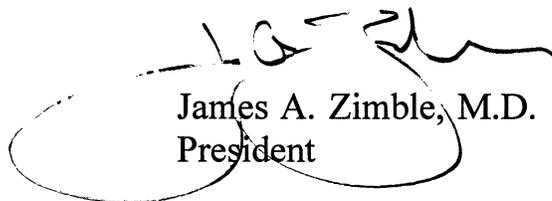
3. Confidentiality. The allegation(s) of misconduct should be given confidential treatment to the maximum extent possible.

4. Anonymity. To the extent possible, the identity of informants who wish to remain anonymous will be kept confidential.

5. "Good faith" whistleblowers are protected by the Whistleblower Protection Act of 1989^a and DoD Directive 7050.6^b.

F. Procedures. *See Enclosure 3.*

G. Effective Date. This instruction is effective immediately.



James A. Zimble, M.D.
President

Enclosures:

1. References
2. Definitions
3. Procedures
4. Timeline

REFERENCES

- | | |
|---|---|
| (a) The Whistleblower Protection Act of 1989, 5 USC 1201 note (Public Law 101-12) | Institutions for Dealing with and Reporting Possible Misconduct in Science" |
| (b) DoD Directive 7050.6, "Military Whistleblower Protection," dated September 3, 1992 | (d) 45 Code of Federal Regulations, Part 689, "Misconduct in Science and Engineering" |
| (c) 42 Code of Federal Regulations, Part 50, "Responsibility of PHS Awardee and Applicant | |

DEFINITIONS

1. Allegation. Notification to a USUHS official either orally or in writing that wrongdoing is suspected to have occurred.

2. Misconduct. At present, the PHS defines misconduct as: fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgements of data. (See 42 CFR Part 50^c)

For institutions receiving NSF funding, misconduct is defined as:

(a) fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from activities funded by NSF; or

(b) retaliation of any kind against a person who reported or provided information about suspected or

alleged misconduct and who has not acted in bad faith. (See 45 CFR Part 689^d)

3. Respondent. The subject of the allegation(s) of scientific misconduct.

4. Complainant. The person making the allegation(s) of scientific misconduct.

5. Final determination. For purposes of this instruction, a determination of scientific misconduct becomes a "final determination" when:

(a) the Dean, SOM concurs with the formal investigation committee's conclusion that scientific misconduct has occurred and the respondent does not appeal within the allowed period; or

(b) the respondent appeals the determination of scientific misconduct and the appeal is denied by the President, USUHS.

PROCEDURES

The procedures for the processing of an allegation of scientific misconduct are set forth in the paragraphs below. The sequence and timing of these procedures are illustrated in *Enclosure 4*.

1. **Allegation.** Any allegation(s) of misconduct (including an anonymous allegation) should be reported to the appropriate department chair unless that chair is directly involved in the misconduct, in which case it will be reported to the Associate Dean, Graduate Education (GEO). The complainant should reduce the allegation(s) to writing as soon as possible and the allegation(s) should be as specific as possible. This avoids any unintentional screening of facts by the hearer, allows reviewers to read the allegation(s) in the complainant's own words, and tends to make the allegation(s) more precise. As set forth below, the appropriate department chair will make an inquiry into the allegation(s).

a. Absent extraordinary circumstances, allegations of scientific misconduct that pertain to completed projects over two years old will not be considered.

b. The department chair will notify the Associate Dean, GEO of all allegations of scientific misconduct. The Associate Dean, GEO will notify the sponsor or agency which funded the research at any time he or she determines that it is necessary based on any one of the following factors:

(1) an immediate health hazard is involved;

(2) the seriousness of the alleged misconduct warrants;

(3) the need to protect the resources, reputation, or other interests of the sponsor or agency;

(4) the University's responsibility to the scientific community and the community at large;

(5) there is an immediate need to protect the interest of the person(s) making the allegation(s) or the interests of the individual(s) who is the subject of the allegation(s), as well as his or her coinvestigators or associates;

(6) it is probable that the alleged incident will gain public notoriety; or

(7) there is a reasonable indication of a possible criminal violation.

c. A **presumption of innocence** prevails until a "final determination" of scientific misconduct has been made. A presumption of innocence entitles the respondent to the procedural protections set out in this instruction. It also means that no disciplinary sanctions should be imposed until a "final determination" has been made. However, a presumption of innocence does not mean:

(1) that USUHS is constrained from taking appropriate action that it considers necessary to assure the health and safety of members of the community;

(2) that USUHS is precluded from exercising the investigative process such as seizure and protection of physical evidence (laboratory samples, logs, etc.), or compelling the presence and testimony of witnesses; nor

(3) that those investigating are prohibited from drawing adverse inferences or taking action based on a respondent's failure to cooperate with the proceeding.

d. If the alleged misconduct involves a crime, the Defense Criminal Investigative Service or other appropriate investigative authority will be contacted.

e. If the respondent resigns at any time prior to the completion of the entire process set out in this instruction, the inquiry/investigation should continue to its full conclusion.

2. **Inquiry.** The appropriate department chair (or individual appointed by the Associate Dean, GEO if the department chair is directly involved or has a conflict of interest) shall conduct an inquiry into the allegation(s).

a. The inquiry should be completed within 60 days unless circumstances clearly warrant a longer period.

b. The chair will have access to all relevant documents. Documents should be secured early to ensure that there is no perception that the respondent was able to "fix" the data or dispose of relevant evidence.

c. The chair will inform the respondent of the allegation(s) and give him or her an opportunity to present evidence either in written or oral form. The form and timing of evidence presented by the respondent will be at the discretion of the Chair.

d. In addition to documentary evidence, it may be necessary to conduct interviews to

obtain additional relevant evidence. The procedures used will be those decided upon by the Chair as best suits the needs of the inquiry. The respondent may decline to be interviewed or make a statement. All other government employees have a duty to cooperate with the inquiry. The Chair will consult with General Counsel (OGC) when any question arises pertaining to procedural requirements for the inquiry.

e. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. Copies of all relevant evidence will be attached to the report.

f. The respondent shall be given a copy of the report and have 10 calendar days from the date of receipt to comment on the allegation(s) and the findings by the department chair. Upon request by the respondent, the Chair may grant an additional 10-day period for comment. The respondent's comments will be attached to the report.

g. The report, along with the respondent's comments, will be forwarded to the Associate Dean, GEO. If the Associate Dean, GEO and the Dean, SOM concur that the

allegation(s) is (are) frivolous or clearly mistaken, they need not go forward with the appointment of an investigation. The rationale for their decision should be reduced to writing and maintained for at least three years. By the same token, if they agree that an investigation should be conducted, a committee will be appointed to do so. Should the Associate Dean, GEO and the Dean, SOM disagree, the President, USUHS will decide whether to proceed with an investigation.

3. Investigation.

a. If a formal investigation is warranted, the Associate Dean, GEO shall:

(1) notify the sponsor or agency which funded the research, as well the USUHS Director, Research Administration (REA), that an investigation is being conducted; and

(2) appoint a committee to conduct an investigation. The committee will consist of three or five senior faculty members and researchers with reputations for personal integrity and good judgment. (An odd number will prevent tie votes and decision-making paralysis.) Care should be exercised to ensure that there is no real or apparent conflict of interest on the part of any committee

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member. All members of the committee must be fair and impartial.

b. The committee will examine the evidence and the report provided by the department chair to determine the need for further evidence. The committee will conduct interviews, as necessary, to complete the investigation. A complete summary of the interviews should be prepared and provided to the person interviewed for revision or comment. The summary of interviews will become part of the investigation file. As with the Chair's inquiry, the respondent may decline to be interviewed or make a statement. All other government employees have a duty to cooperate with the investigation. The committee will consult with the OGC when any question arises pertaining to the procedural requirements.

c. The respondent may request the appearance of any reasonably available witness who the respondent believes is able to provide relevant information; such a request shall be in writing and presented to the Chair of the committee. Absent a compelling reason, any reasonably available witness requested by the respondent will be interviewed by the committee. The decision of the

committee to interview any requested witnesses shall be final. The respondent is not, however, entitled to be present at interviews of any of the witnesses.

d. Appropriate warnings shall be furnished to witnesses, informing them that the respondent is entitled to, and will be furnished, a copy of the witnesses' statements.

e. The respondent may consult with an attorney at any stage of the investigation or inquiry. However, this investigation is not an adversarial proceeding and the respondent does not have the right to have the attorney present when interviewed by the committee or during the interviews of other witnesses. (At the discretion of the Chair, the committee may allow the presence of the respondent's attorney during the interview of the respondent, with the understanding that the attorney's role is limited to privately conveying advice to the respondent. The attorney will not act as the respondent's advocate and will be asked to leave if he or she does so.)

f. Standard of Proof. The committee's findings must be based upon clear and convincing evidence. **Note:** a lesser standard of proof (i.e. preponderance of evidence test) is deemed inappropriate because of the potential damage to the respondent's

career. Both the PHS and NSF use the preponderance of evidence standard. Thus, it is conceivable that if the University makes a finding of "no misconduct" using the higher "clear and convincing evidence" standard, PHS or NSF may reach a different result using the lower standard of proof.

g. Each member of the committee will either sign the report or provide written comments as to why he or she dissents from the majority opinion. (See paragraph F.5.b.(2)(a) or (b) for the content of the report.) If the majority makes a determination of scientific misconduct, then it should also recommend what the committee considers the appropriate sanction. For example, the committee may recommend:

- a letter of reprimand;
- suspension from a particular project;
- special monitoring of future work and/or grant applications;
- removal from a particular project;
- probation;
- suspension;
- rank reduction;
- loss of academic appointment; or
- termination of employment.

Any action on the committee's recommendation for sanctions may be taken only after all steps set forth in this Instruction have been completed and after compliance with other applicable statutes and regulations.

h. The report should normally be completed within 60 days of appointment of the committee.

i. A copy of the signed report shall be given to the respondent who will have 10 calendar days from the date of its receipt to submit any comments and/or rebuttal to the report. Upon receipt of a request by the respondent, the Chair may grant an additional 10-day period for comment and/or rebuttal. The respondent's submission will be attached to the report. After a review of the respondent's report, the committee may choose to reopen the investigation, reconsider or modify its earlier decision, or affirm the committee's earlier conclusions and recommendations.

j. If the committee finds that scientific misconduct has occurred, the Associate Dean, GEO must forward the committee's report (with the respondent's submission, if any) to the Dean, SOM.

k. The Dean, SOM will make the final determination on the

case. The Dean, SOM is free to accept, reject, or modify the committee's conclusions and recommendations. The Dean's decision will be communicated in writing to the respondent.

4. Appeal.

a. If a determination of scientific misconduct has been made, the respondent shall have the right to appeal to the President, USUHS.

b. The appeal must be made in writing within 10 working days of the date of notification of the Dean's decision.

c. The basis for an appeal should be either:

(1) that the procedure set forth in this Instruction was not followed; or

(2) that the final determination is not substantially supported by the evidence.

d. The President, USUHS will not consider additional evidence offered by the respondent unless it is new. New evidence is that which was not known or should not have been known by the respondent at the time of the investigation.

e. The President, USUHS has the authority to take whatever action he or she deems appropriate; to affirm, modify, or reverse the Dean's determination.

5. Disposition.

a. If an allegation of scientific misconduct is not substantiated, those formally notified of the allegation should be notified of the outcome of the investigation.

b. If a determination of scientific misconduct is made and no appeal is taken or the appeal is not upheld, the following actions will be taken by appropriate officials within the University:

(1) Act upon the committee's recommendation pertaining to sanctions.

(2) Notify the extramural funding agency of the findings of the investigation.

(a) If the allegation involves research for PHS, the report must contain:

1 a clear articulation of the allegation(s);

2 the policies and procedures under which the investigation was conducted;

3 from whom information relevant to the investigation was obtained;

4 the findings, and the basis for the findings, including the actual text or an accurate summary of the views of any individual found to have engaged in misconduct; and

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5 any sanctions taken by the institution.

(b) If the allegation involves research for NSF, the report should include:

1 a description of the allegation(s) investigated;

2 a list of the individuals responsible for conducting the investigation;

3 the methods and procedures used to gather information and to evaluate the allegation(s);

4 a summary of the records compiled;

5 a statement of the findings with the reasoning supporting those conclusions; and

6 a description and explanation of any sanctions

recommended and/or imposed by the institution.

(3) Notify editors of journals in which previous abstracts and papers relevant to the investigation have appeared. All pending abstracts and papers that result from the misconduct may be withdrawn.

(4) As appropriate, notify collaborating scientists and their departmental supervisors from other research institutions.

(5) Notify, as necessary, hospitals with which the individual is associated.

(6) Notify, in the case of military officers, their appropriate chain of command.

