

Western Michigan University

Research Misconduct Policy and Procedures

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REGULATIONS

Office of Research Integrity, U.S. Department of Health and Human Services
<http://www.ori.hhs.gov/>

42 CFR Parts 50 and 93

Public Health Service Policies on Research Misconduct; Final Rule
http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf

Research Misconduct Policy and Procedures

POLICY

I. Introduction

Research rests on a foundation of mutual trust. Any allegation of research misconduct, irrespective of discipline, is a serious matter to be dealt with deliberately for the integrity of Western Michigan University (WMU), those associated with it, and the discipline itself. This policy is designed to comply with federal regulations. Health and Human Services policies can be found at: <http://www.ori.hhs.gov/> and to reassure the public and ourselves that our traditional standards are upheld. This document contains the University's Research Misconduct Policy and specifies procedures and appropriate safeguards for handling investigations of misconduct. The procedures conform to the Public Health Service (PHS, Department of Health and Human Services) 42 CFR Parts 50 and 93 Public Health Service Policies on Research Misconduct; Final Rule. The exact language for this final rule can be found at: http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf

II. Policy

It is the policy of WMU that research misconduct as defined by this document is prohibited. Researchers shall comply with all applicable laws, regulations and guidelines, University policies, and contractual and grant requirements. The research misconduct policy applies to all persons affiliated with WMU including, but not limited to, faculty, students, trainees, and all members of the research staff. Cases of research misconduct involving students are subject to the normal disciplinary rules governing students, but will be reviewed, as appropriate, under this policy. The policy applies to: (a) the conduct of research and/or related activities, whether or not the research is externally funded; (b) the presentation and/or publication of results; (c) the process of applying for funds; (d) the expenditure of project funds; and (e) the fiscal reporting on the use of project funds. Persons found to have committed research misconduct are subject to discipline, up to and including discharge or expulsion. In addition the findings will, where appropriate, be reported to external entities or authorities and the external entity or authority may take additional action. Disciplinary action proceedings shall be in accordance with applicable University policies, codes, procedures, and/or collective bargaining agreements.

III. Definition of Research Misconduct

Research misconduct is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those commonly accepted within the academic community for proposing, performing, reviewing or in reporting research results. Research misconduct is to be distinguished from honest error and differences of interpretation (§ 93.103, 42 CFR Part 93). A finding of research misconduct made under this part requires that:

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

Research Misconduct includes, **but is not limited to** the following definitions:

- A. **Fabrication:** Making up data or results and recording or reporting them.
- B. **Falsification:** Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately the research record.
- C. **Plagiarism:** The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- D. **Abuse of confidentiality**, including use of ideas and preliminary data gained from:
 - 1. Access to privileged information through the opportunity for editorial review of manuscripts submitted to journals, and
 - 2. The peer review of proposals being considered for funding or by internal committees, such as the Human Subjects Institutional Review Board (HSIRB), Faculty Research and Creative Activities Support Fund (FRACASF), or Institutional Animal Care and Use Committee (IACUC).
- E. **Misuse of data or failure to comply** with policies on human subjects, radiation use or animal care and use committee policies.
- F. **Financial misconduct:** The use of grant or other research funds in a fashion not authorized by the grant and/or for a purpose not authorized by or in furtherance of the grant and/or research; the failure to properly manage the grant and/or research funds including the failure to exercise proper oversight; and/or the failure to properly account for the expenditure of grant and/or research funds.

This policy is limited to research misconduct occurring within six years of the date on which the institution receives the allegation of misconduct. Exceptions to the six year limit include renewed allegations of misconduct and those having substantial effect on the health or safety of the public.

IV. Confidentiality

To the extent possible, the University shall maintain the identity of Respondents and Complainants securely and confidentially and shall not disclose any identifying information except to:

- A. Those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding.
- B. If appropriate, the Office of Research Integrity (ORI) as it conducts its review of the research misconduct proceedings and any subsequent proceedings.

To the extent allowed by law, records or evidence obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding or as required by law.

PROCEDURE

V. Phases

The proceedings consist of four phases:

- A. **Preliminary Assessment** of Allegations – a review to determine whether the accusations constitute good faith allegations of research misconduct. See 93.200
- B. **Inquiry** – an initial review of the evidence to determine if the criteria for conducting an investigation have been met. See 93.212
- C. **Investigation** – an Investigative Committee is appointed to determine whether it is more likely than not that research misconduct has occurred and, if so, to make recommendations with respect to the imposition of disciplinary sanctions. See 93.215
- D. **Disciplinary or Reputation Restoration** – where appropriate.

VI. Preliminary Assessment

The Vice President for Research (VPR), who is the research integrity officer (RIO), assesses the reported incident to determine if it constitutes a good faith allegation of research misconduct. After receiving an allegation of research misconduct, defined as a disclosure of possible research misconduct through any means of communication, the VPR in consultation with the appropriate dean or other appropriate University official shall assess the allegation to determine if it meets the definition of misconduct:

- A. It involves the Public Health Service supported research or applications for PHS research support;
- B. It involves research records specified in 42 CFR Section 93, 102(b); and,
- C. The allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

If it is concluded by the VPR that a good faith allegation of research misconduct has been made, the misconduct procedure enters its inquiry phase.

The Preliminary Assessment shall be completed within 30 business days of the receipt of the report or the event giving rise to the Preliminary Assessment unless circumstances prevent the VPR from completing the assessment within that time frame, in which event the VPR shall document the reasons for the delay and complete the assessment as soon as is practical.

If the VPR determines an Inquiry is not warranted, the VPR shall so inform the Complainant and Respondent in writing. Employees who report, in good faith, documented, reliable information about unethical conduct are assured they may do so without fear of retaliation.

VII. Inquiry

If the VPR determines an inquiry is warranted, the VPR initiates the inquiry process which must be completed within 60 calendar days of the inquiry's initiation. The purpose of an inquiry is to conduct an initial review of the available evidence to determine whether an allegation warrants an investigation and what additional records may be needed for the inquiry and subsequent investigations.

A. Notification of Respondent, and Maintenance and Custody of Research Records and Evidence. The VPR will notify the Respondent in writing that an inquiry has been initiated. The VPR shall take the following specific steps to obtain, secure and maintain the research records and evidence pertinent to the research misconduct proceeding:

1. Either before or when the University notifies respondent of the allegation, inquiry, or investigation, the VPR shall promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory those materials, and sequester them in a secure manner. In those cases where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
2. Confidentiality of the research records will be maintained as described in IV.
3. When appropriate, the Respondent will be given copies of, or reasonable, supervised access to the research records.
4. The University shall undertake every reasonable and practical effort to take custody of additional research records and evidence that are discovered during the course of the research misconduct proceeding including new allegations as these arise, from the initial stages of inquiry and throughout the investigation, subject to the exception for scientific instruments in (1) above.

5. The University shall maintain all records of the research misconduct proceeding, as defined in 42 CFR Section §93.317(a), for seven years after completion of the proceeding, or any ORI or HHS proceeding under Subparts D and E of 42 CFR Part 93, whichever is later, unless the VPR has transferred custody of the records and evidence to HHS, or ORI has advised the University that the VPR no longer needs to retain the records.

B. Appointment of the Inquiry Committee

The VPR will appoint an Inquiry Committee and designate the chair within 10 business days of the initiation of the inquiry. The Inquiry Committee should consist of three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be subject matter experts, administrators, lawyers, or other qualified persons.

C. Notification to Respondent of Committee Members

The VPR will notify the Respondent of the proposed committee membership. The Respondent has seven business days to challenge, in writing, the committee's membership based on bias or conflict of interest. The VPR will determine whether the evidence of perceived bias or conflict warrants replacement of the challenged member.

D. Inquiry Report

The inquiry report shall contain the following information:

1. The name and position of the Respondent;
2. A description of the allegations of research misconduct;
3. If appropriate, the grant support involved, including, for example, grant numbers, grant applications, contracts, and publications listing grant support;
4. Description of data reviewed and interviews;
5. If applicable, the basis for recommending that the alleged actions warrant an investigation;
6. The Inquiry Committee will provide the Respondent(s) seven business days to comment on the draft Inquiry Report. The Inquiry Committee may either attach the comments to the report and/or make the corrections in the report as necessary. The VPR may grant additional time to respond if circumstances warrant.
7. The Inquiry Committee will make a written determination of whether an investigation is warranted based on the Inquiry Report and the Federal guidelines Sec. 93.307. The VPR shall notify the Respondent of the result of the inquiry and attach to the notification copies of the Inquiry Report and these institutional policies and procedures for the handling of research misconduct allegations.
8. If the Committee determines that an investigation is warranted, the investigation shall begin within 30 calendar days of that determination.

VIII. Investigation

Within a reasonable time after determination that an investigation is warranted, but not later than 30 calendar days after that determination, the VPR shall constitute an Investigative Committee. The VPR shall select those conducting the investigation on the basis of research expertise that is pertinent to the matter and who do not have personal, professional, or financial conflicts of interest with the Respondent, Complainant or others involved in the matter. Any such conflict which a reasonable person would consider to demonstrate potential bias shall disqualify the individual from selection. The Investigative Committee differs depending upon the Respondent.

A. In the case of a bargaining unit faculty member, the Investigative Committee is appointed by the VPR. It will be constituted from tenured WMU faculty, and contain at least three members.

B. In the case of academic researchers (visiting scholars, postdoctorate fellows, professional researchers, non-faculty academics, etc.), the VPR appoints an Investigative Committee that will include a member of the researcher's relevant peer group plus one or two tenured faculty.

In the case of a student, the VPR appoints an Investigative Committee of from one to three tenured faculty and designee from the Office of the Associate Dean of Students.

The committee shall select the chair of the committee. It is the responsibility of the chair to issue all required communications and to schedule all necessary meetings, interviews, and other events.

C. In all cases the VPR will notify the Respondent in writing that an investigation is being undertaken, will inform him/her of the allegations that are under investigation, as well as of the composition of the Investigative Committee, and the procedures that will be followed by the VPR in the course of the investigation.

1. The Respondent has seven business days to challenge, in writing, the committee's membership based on bias or conflict of interest. The VPR will determine whether the evidence of bias or conflict warrants replacement of the challenged member(s).

2. The investigation phase must be completed within 120 calendar days from the appointment of the Investigative Committee, unless circumstances warrant a longer period. This time frame includes conducting the investigation, preparing the report of findings, providing the draft report for comment, the appeal process, and sending the final report to ORI, if appropriate. This time period does not apply to the disciplinary phase hearings. If the investigation stage is extended beyond 120 calendar days, the reasons for doing so must be documented.

3. The VPR shall instruct the Investigative Committee to:

- a. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations.
- b. Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct and continue the investigation to completion.
- c. Use all reasonable steps to ensure an impartial and unbiased research misconduct proceeding to the maximum extent practicable.
- d. Interview each Respondent, Complainant, and any other available person

who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the Respondent. When interviewing, the committee should record or transcribe each interview, provide the recording or transcript to the interviewee for correction of transcription errors, and include the recording or transcript in the record of investigation. The Respondent shall be notified in writing no less than five business days in advance of the scheduling of his/her interview in the investigation and may arrange for the attendance of legal counsel, if the Respondent wishes. In the event the Respondent intends to have legal counsel present at the interview, Respondent shall inform the VPR of her/his intent no later than two business days before the interview.

4. Investigation Report

When the investigation is completed, the Chair of the Investigative Committee shall prepare, and submit to the VPR, a written report of the results, reviewing the facts, and stating the committee's findings. The VPR shall make the report available to the Respondent for comment. In a separate communication to the VPR, the Investigative Committee shall offer its recommendations with respect to disciplinary sanctions, if any. The final investigation report shall:

- a. Describe the nature of the allegations of research misconduct.
- b. Describe and document the grant support including, for example, any grant numbers, grant applications, contracts and publications listing grant support, if appropriate.
- c. Describe the specific allegations of research misconduct considered in the investigation.
- d. Include the institutional policies and procedures under which the investigation was conducted, if not already provided to ORI.
- e. Identify and summarize the research records and evidence.
- f. Identify any evidence taken into custody, but not reviewed. The report should also describe any relevant records and evidence not taken into custody and explain why.
- g. Provide a finding as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation, and if misconduct was found, identify it as falsification, fabrication, plagiarism or other and determine whether it was intentional, knowing, or in reckless disregard,.
 1. Summarize the facts and the analysis supporting the conclusion and consider the merits of any reasonable explanation by the Respondent and any evidence that rebuts the Respondent's explanation.
 2. Identify any publications that need correction or retraction; identify the person(s) responsible for the misconduct and list any current support or known applications or proposals for support that the Respondent has pending.
- h. The subject(s) shall have 21 calendar days to submit to the VPR comments on the investigative report. The committee shall include and consider any comments made by the Respondent and Complainant on the draft investigation report.
- i. When the Investigative Committee report and the Respondent's response have been received, the VPR will meet with the appropriate administrative

officials to discuss the report's findings so that either the disciplinary phase of the process or the restoration of reputation aspect of the process can begin.

j. If appropriate and/or required, communicate the committee's findings to relevant agencies external to the university.

IX. Reporting to Federal Agencies

When federal funding is involved, the pertinent agency will be informed by the VPR that an investigation will be initiated within 30 calendar days of the submission of the inquiry report to VPR. When it is required by federal agencies, such as ORI or DHHS, an extension of the investigation beyond 120 calendar days must be requested in writing from the relevant agency. The extension request must include an explanation for the delay, an interim report on the progress to date, an outline of what remains to be done, and an estimated date of completion. If an investigation is terminated before its completion, a report of the planned termination, including the reasons for such an action, must be made to those federal funding agencies that require it (the Office of Research Integrity of DHHS, for example).

A. The VPR will notify relevant federal funding agencies if, during the course of the investigation, facts are disclosed that may affect current or potential federal funding for individuals(s) under investigation or that the federal agency needs to know to ensure appropriate use of funds and otherwise protect the public interest. The VPR shall maintain and provide to ORI upon request all relevant research records and records of our research misconduct proceeding, including results of all interview and the transcripts or recordings. The University will follow the regulations or the relevant federal funding agency requirements in preparing its report. The final report to ORI must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained, the findings, and the basis for the findings, as well as a description of any sanctions taken by the University. Documentation to substantiate an investigation's findings will also be made available to the Director of ORI. The University will cooperate with and assist ORI and HHS, as needed to carry out any administrative actions HHS may impose as a result of a final finding of research misconduct by HHS.

B. At any time during a research misconduct proceeding, the University shall take appropriate interim action to protect public health, federal funds and equipment, and the integrity of the grant supported research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approval for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that be affected by an allegation of research misconduct.

C. At any time during a research misconduct proceeding, OVPR shall notify ORI immediately if the VPR has reason to believe that any of the following conditions exist:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
2. HHS resources or interest are threatened.
3. Research activities should be suspended.
4. There is a reasonable indication of violations of civil or criminal law.
5. Federal action is required to protect the interest of those involved in the research misconduct proceeding.

X. Reputation Restoration

WMU shall undertake all reasonable, practical and appropriate efforts to protect and restore the reputation of any person alleged to have engaged in research misconduct, but against whom no finding of research misconduct was made, if that person or his/her legal counsel or other authorized representative requests that the VPR do so. WMU shall undertake all reasonable and practical efforts to protect the position and reputation of any Complainant, witness, or committee member and to counter potential or actual retaliation against those Complainants, witnesses and committee members.

XI. Disciplinary Procedure

WMU shall take appropriate administrative actions against individuals only when an allegation of misconduct has been formally substantiated. The University has a number of sanctions and disciplinary actions available.

A. Research Sanctions

Research sanctions may include but are not limited to:

1. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found
2. Removal of the responsible person from the particular project
3. Restricting or prohibiting future grant submissions and/or reviewing grant proposals for agencies
4. Special monitoring of future research publication

B. Disciplinary Actions

1. Employee related disciplinary actions may include:
 - a. Discipline by documentation, including letters of reprimand
 - b. Suspension
 - c. Salary reduction
 - d. Initiation of steps leading to possible rank reduction or termination of employment or
 - e. Restitution of funds as appropriate.
2. Actions for student researchers may include:
 - a. Loss of credit for research
 - b. Loss of assistantship
 - c. Suspension
 - d. Expulsion from the University.

C. Disciplinary Procedures

1. Bargaining unit employees:

In the case of a bargaining unit faculty member, the processing of charges will proceed in accordance with the provisions of Article 22, Progressive Review and Discipline for Cause, of the Agreement between WMU and the WMU Chapter of the AAUP, or its successor. Disciplinary sanctions against members of other bargaining units will proceed in accordance with the appropriate collective bargaining agreement.

2. Non-student, non-bargaining unit employees (staff):

The researcher shall be notified in writing of the intent to initiate disciplinary action,

and is invited to respond to the proposed discipline in a personal conference with the appropriate University official.

a. The researcher and the appropriate University official shall each be entitled to bring a representative of their choice to such a conference. If the University official and the researcher arrive at a mutually agreeable settlement, the matter is disposed of in accordance therewith.

b. If discipline is to be imposed upon the researcher pursuant to the settlement, or if there is no settlement, but the researcher has informed the University official that he/she does not intend to contest the proposed discipline, the university may thereupon impose such discipline.

c. If discipline is imposed without the agreement of the researcher, the researcher may use any of the dispute resolution services described in the WMU Department of Human Resources Employee Handbook.

3. Students:

If, in the case of a student, the Investigative Committee makes a finding of research misconduct, its report, the student's response, and the recommendation of the VPR as to appropriate conduct sanctions, if any, are forwarded to the Office of Student Conduct, which will determine sanctions from those listed in the Western Michigan University Student Code.

DEFINITIONS TO RESEARCH MISCONDUCT POLICY

Abuse of confidentiality, including use of ideas and preliminary data gained from:

1. Access to privileged information through the opportunity for editorial review of manuscripts submitted to journals, and
2. The peer review of proposals being considered for funding or by internal committees, such as the Human Subjects Institutional Review Board (HSIRB), Faculty Research and Creative Activities Support Fund (FRACASF), or Institutional Animal Care and Use Committee (IACUC).

Allegation.

Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or HHS official. (§ 93.201)

Fabrication.

Making up data or results and recording or reporting them. (§. 93.103)

Falsification.

Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately the research record. (§ 93.103)

Financial misconduct.

The use of grant or other research funds in a fashion not authorized by the grant and/or for a purpose not authorized by or in furtherance of the grant and/or research; the failure to properly manage the grant and/or research funds including the failure to exercise proper oversight; and/or the failure to properly account for the expenditure of grant and/or research funds.

Complainant.

Complainant means a person who in good faith makes an allegation of research misconduct. (§ 93.203)

Confidentiality.

1. Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Provided, however, that:

(a) The institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings under § 93.403.

(b) Under § 93.517(g), HHS administrative hearings must be open to the public.

(2.) Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding. (§. 93.108)

Evidence.

Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. (§ 93.208)

Funding component.

Funding component means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training, e.g., agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS. (§. 93.209)

Good faith.

Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding. (§. 93.210)

Inquiry.

Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of § 93.307-93.309. (§ 93.212)

Investigation.

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions. (§ 93.215)

Misuse of data or failure to comply.

With policies on human subjects, radiation use or animal care and use committee policies.

Notice.

Notice means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the addressee. Several sections of Subpart E of this part have special notice requirements. (§ 93.216)

Office of Research Integrity or ORI.

Office of Research Integrity or ORI means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities. (§ 93.217)

Plagiarism.

The appropriation of another person's ideas, processes, results, or words without giving appropriate credit. (§ 93.103)

Preponderance of the evidence.

Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not. (§ 93.219)

Public Health Service or PHS.

Public Health Service or PHS means the unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators. (§ 93.220)

PHS support.

PHS support means PHS funding, or applications or proposals therefore, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: Funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts. (§ 93.221)

Research.

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied. (§ 93.222)

Research misconduct.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. (§ 93.103)

Research record.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory

records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding. (§ 93.224)

Respondent.

Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding. While the policy refers to a single respondent, it is recognized that in some cases there may be multiple respondents.

(§ 93.225)

Retaliation.

Retaliation for the purpose of this part means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to—

- (a) A good faith allegation of research misconduct; or
- (b) Good faith cooperation with a research misconduct proceeding. (§ 93.226)