

Administrative Policy No. 12.06

Subject: Research Misconduct

Information Contact: Coordinator
Human Research Review Section
MS 45205, (360) 902-8075

Authorizing Source: Office of the Secretary
[42 CFR Part 93, Subparts A, B, and C](#)
[Chapter 388-04 WAC](#)

Effective Date: September 1, 2001

Revised: February 28, 2018

Approved By: Original signed by Sharon Swanson
Senior Director, Policy & External Relations

Purpose

This policy establishes a process for reporting, assessing, and conducting inquiries and investigations into allegations of research misconduct within the jurisdiction of the Department of Social and Health Services (DSHS).

Scope

This policy applies to all DSHS employees and contractors engaged in any research activities within the jurisdiction of DSHS regardless of source of funding or support.

Definitions

- A. **Deciding Official** means the DSHS official who makes final determinations on allegations of research misconduct. The Deputy Secretary or designee is the Deciding Official and determines whether to conduct an investigation, whether research misconduct occurred, whether to impose sanctions, and whether to take other appropriate administrative actions.
- B. **ORI** means the Office of Research Integrity, the office to which the Secretary of the Department of Health and Human Services has delegated responsibility for addressing research integrity and misconduct issues related to U.S. Public Health Service-supported activities.

- C. **Research Integrity Officer** means the DSHS official who assesses allegations of research misconduct and determines when such allegations warrant inquiries, and who oversees any inquiries and investigations. The Executive Secretary of the Washington State Institutional Review Board is the Research Integrity Officer and has primary responsibility for implementing the procedures described in this policy.
- D. **Respondent** means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding. An inquiry or investigation can involve more than one respondent.
- E. **Research Misconduct** means fabrication, falsification, or plagiarism, in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion.
1. **Fabrication** means making up of data or results and recording or reporting them.
 2. **Falsification** means 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** means using another person's ideas, processes, results, or words without giving appropriate credit.
- F. **Complainant** means a person who in good faith makes an allegation of research misconduct. An inquiry or investigation can involve more than one complainant.
- G. **Good Faith** as applied to a complainant witness means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's position could have based on the information known to the complainant 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 policy. A committee member does not act in good faith if his or 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.

Policy

The mission of DSHS is to improve the quality of life for individuals and families in need and to help people achieve safe, self-sufficient, healthy and secure lives. In support of this mission, DSHS sponsors, conducts and participates in a variety of research activities involving department clients, employees and members of the general public. All research conducted within the Department's jurisdiction must meet accepted professional standards of research integrity, honesty and ethics. Departures from these standards may jeopardize the mission of the Department and the well-being of the citizens of the State. Therefore, the Department will conduct inquiries of all reported instances of observed, suspected or apparent misconduct in research.

All employees and contractors of the Department must promptly report any observed, suspected, or apparent misconduct in research to the Research Integrity Officer. The Department must conduct inquiries and investigations in a manner that ensures fair treatment and protects the confidentiality of all involved parties. The Department must take reasonable steps to protect the position and reputation of the complainant and to restore the reputation of the respondent when allegations are not confirmed.

Procedures

A. Preliminary Assessment

1. Complainants must submit written reports of allegations of observed, suspected, or apparent misconduct in research to the Research Integrity Officer. The Research Integrity Officer must promptly assess whether the allegation falls under the definition of research misconduct and whether there is sufficient evidence to warrant an inquiry.
2. If there is sufficient evidence to support an inquiry into an allegation of research misconduct, DSHS must follow the steps outlined in these procedures, and refer to the Office of Research Integrity (ORI) *Model Policy for Responding to Allegations of Scientific Misconduct and Sample Policy and Procedures for Responding to Allegations of Research Misconduct* if additional guidance is needed.

B. Conducting the Inquiry

1. If the Research Integrity Officer determines that the allegation falls under the definition of research misconduct and that sufficient information to allow follow-up has been provided, he or she must promptly initiate the inquiry process. The Research Integrity Officer must take steps to ensure that all original research records and materials relevant to the allegation are secured.
2. The Research Integrity Officer must promptly notify the respondent, the complainant, the respondent's supervisor and appropriate DSHS officials when an inquiry is opened. The respondent must be informed of the allegations in writing. The respondent and the complainant are responsible for cooperating with an inquiry or investigation and maintaining appropriate confidentiality of any information and documents reviewed as part of inquiry or investigation.
3. If the research is supported by Public Health Services (PHS) funds, the Research Integrity Officer must notify ORI immediately if he or she has reason to believe any of the following conditions exist: 1) the health or safety of the public is at risk, including an immediate need to protect human subjects; 2) research activities should be suspended; 3) there is an immediate need to protect Federal funds or equipment; 4) there is an immediate need to protect the interests of the persons(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his or her co-investigators and associates, if any; 5) it is probable that the alleged

incident is going to be reported publicly; 6) there is a reasonable indication of possible criminal violation, in which case the Research Integrity Officer must inform ORI within 24 hours of obtaining that information. When appropriate, the Deciding Official must take appropriate interim actions to protect Federal funds and assure that the intent of Federal financial assistance is carried out.

4. When a formal inquiry is required under this policy, the Research Integrity Officer, in consultation with other DSHS officials as appropriate, must appoint an Inquiry Committee. The Inquiry Committee must include at least three persons who are unbiased and do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses. These individuals must have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. Members of the Inquiry Committee must agree in writing to preserve the confidentiality of the proceedings and any information or documents reviewed as part of the inquiry.
5. The Research Integrity Officer must notify the respondent of the proposed committee membership within ten days of initiation of the inquiry. If the respondent submits a written objection to any of the persons appointed to the Inquiry Committee, the Research Integrity Officer may replace the challenged member with a qualified substitute at his or her discretion.
6. The Inquiry Committee conducts interviews with the complainant(s), the respondent(s) and other key witnesses at its discretion, examine relevant research records and materials, and decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. Interviews should be transcribed or recorded.
7. The Inquiry Committee must prepare a written inquiry report that provides a summary of the inquiry process; summaries of interviews; a description of the evidence reviewed; and the Committee's recommendation about whether an investigation should be conducted.
8. The Research Integrity Officer must provide the respondent with a copy of the inquiry report for comment and rebuttal. The Research Integrity Officer also must provide the complainant with those portions of the report that address the complainant's role and opinions. Any comments that the respondent or complainant submit on the report become a part of the final inquiry report and record.
9. The Research Integrity Officer will transmit the final inquiry report, along with any comments submitted by the respondent and complainant, to the Deciding Official within 60 calendar days of initiation of the inquiry. If the Research Integrity Officer approves an extension of this time limit, the reason will be noted in the records of the case and the report. The Research Integrity Officer will notify the respondent of any extension.

10. Within ten days of receiving the inquiry report, the Deciding Official must make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation.
11. Within 30 days of a determination that findings from an inquiry warrant an investigation into possible research misconduct, the Research Integrity Officer will inform ORI in writing and submit a copy of the full inquiry report. The report will include all information required in 42 CFR 93.309(a).

C. Conducting the Investigation

1. If the Deciding Official determines that the findings from the inquiry provide a sufficient basis for conducting an investigation, the Research Integrity Officer must initiate an investigation and appoint an Investigation Committee within 30 days of completion of the inquiry. The Research Integrity Officer must request any additional pertinent research records that were not previously secured during the inquiry.
2. The Research Integrity Officer must notify the respondent, the complainant, the respondent's supervisor and appropriate DSHS officials in writing when an investigation is opened on or before the date the investigation begins. The Research Integrity Officer must give these individuals written notice of any new allegations of research misconduct not addressed during the inquiry or in the initial notice of investigation. The Research Integrity Officer must notify ORI in writing of investigations involving research supported by PHS.
3. The Research Integrity Officer, in consultation with other DSHS officials as appropriate, must appoint an Investigation Committee of at least three persons who are unbiased who do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses. These individuals must have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the investigation. Individuals who served on the Inquiry Committee may also be appointed to the Investigation Committee. At least one member of the Investigation Committee should be unaffiliated with DSHS. Members of the Investigation Committee must agree in writing to preserve the confidentiality of the proceedings and any information or documents reviewed as part of the investigation.
4. The Research Integrity Officer must notify the respondent of the proposed committee membership within ten days. If the respondent submits a written objection to any of the persons appointed to the Investigation Committee, the Research Integrity Officer may replace the challenged member with a qualified substitute at his or her discretion.
5. The Investigation Committee must examine all documentation relevant to the allegations and interview the complainant(s), the respondent(s), and other individuals

who might have information regarding the allegations. The Investigation Committee must evaluate the evidence and determine whether, based on a preponderance of the evidence, research misconduct occurred and if so, to what extent, who was responsible, and its seriousness.

6. The Investigation Committee must prepare a report that describes the policies and procedures under which the investigation was conducted, describes how and from whom information relevant to the investigation was obtained, includes the actual texts or summaries of interviews, states the findings, and explains the basis for the findings, as required in 42 CFR93.313.
7. The Research Integrity Officer must provide the respondent with a copy of the investigation report for comment and rebuttal. The Research Integrity Officer also must provide the complainant, if he or she is identifiable, with those portions of the report that address the complainant's role and opinions. Any comments that the respondent or complainant submit on the report becomes a part of the final investigation report and record.
8. The Research Integrity Officer must submit the final investigation report to the Deciding Official within 120 days of initiation of the investigation. Any request for extension of this time limit 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. The Research Integrity Officer must notify the respondent of any extension. He or she must also request in writing an extension from ORI for investigations involving research supported by PHS.
9. The Deciding Official must make the final determination whether to accept the Investigation Committee's report and its findings within ten days of receiving the report. If the Deciding Official does not concur with the Committee's findings, he or she may return the report to the Committee requesting further fact finding or analysis.
10. When the Deciding Official reaches a final decision on the case, the Research Integrity Officer must notify both the respondent and the complainant in writing. For cases involving research supported by PHS funds, the Research Integrity Officer must submit the investigation report, including the Deciding Official's final determination and a description of any sanctions imposed by DSHS, to ORI. If the Deciding Official's determination varies from that of the Investigation Committee, the Deciding Official must explain in detail the basis for rendering his or her decision in the institution's letter transmitting the report to ORI.

D. Other Considerations

1. If the Deciding Official determines that the alleged misconduct is substantiated by the investigation, the supervisor of the respondent must take disciplinary action per [Administrative Policy 18.40](#) (for non-represented employees), the Current Collective

Bargaining Agreements (for represented employees), or by the terms of the contract (for contractors). If research misconduct alleges employee criminal misconduct, supervisors must follow [Executive Order 96.01](#) and the DSHS/Washington State Patrol Interagency Agreement and Protocol dated September 17, 1996.

2. The Research Integrity Officer determines whether professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case.
3. The Research Integrity Officer must ensure compliance with all notification requirements of funding or sponsoring agencies.
4. If DSHS plans to terminate an inquiry or investigation of a case involving research supported by PHS for any reason without completing all relevant Federal requirements, the Research Integrity Officer must submit a report of the planned termination, including a description of the reasons for such termination, to ORI.
5. If an inquiry or investigation fails to substantiate an allegation of research misconduct, the Research Integrity Officer, in consultation with the Deciding Official and the respondent, must undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, and deleting all reference to the research misconduct allegation from the respondent's personnel file.
6. During an inquiry or investigation the Research Integrity Officer must take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses and committee members and protect them from retaliation by respondents and other institutional members. Upon completion of a case, the Research Integrity Officer must make reasonable efforts to protect the positions and reputations of complainants regardless of whether an allegation of research misconduct is substantiated.
7. The Research Integrity Officer must keep all records and relevant documents of any inquiry or investigation for seven years after completion of the case. The Research Integrity Officer must send ORI or other authorized DHHS personnel copies of records and documents upon request.