

System Policy

Code: S: (Code)

Entity: Fairview Health Services

Manual: Research Administration

Category:	(JC Category)
Subject:	Research Misconduct
Purpose:	The purpose of this policy is to ensure that all research conducted within Fairview observes applicable standards of scientific integrity and ethical behavior. This expectation also applies to publishing the results of research.
Policy:	<p>All research conducted within Fairview is to be conducted in compliance with all applicable scientific, ethical, legal, and regulatory standards. Any practice or conduct by a Fairview Researcher that deviates from those standards for proposing, conducting, reporting, and publishing research that are commonly accepted within the professional community constitutes research misconduct in violation of the Fairview Research Misconduct policy.</p> <p>This policy applies to all research conducted within Fairview, including research using Fairview resources or patients, and the data contained in Fairview’s records, whether stored electronically or on physical media.</p>
Definitions:	<p><i>Administrative action:</i> “Administrative action” shall mean (a) an HHS (Health and Human Services) action in response to a research misconduct proceeding taken to protect the health and safety of the public, to promote the integrity of Public Health Service (PHS) supported biomedical or behavioral research, research training, or activities related to that research or research training and to conserve public funds and (b) a Department of Health and Human Services (HHS) action in response either to a breach of a material provision of a settlement agreement in a research misconduct proceeding or to a breach of any HHS debarment or suspension.</p> <p><i>Allegation:</i> “Allegation” shall mean the disclosure of possible research misconduct through any means of communication. The disclosure may be written or oral statement or other communication to an institutional official or HHS official.</p>

Debarment or suspension: “Debarment or suspension” shall mean the Government-wide exclusion, whether temporary or for a set term, of a person from eligibility for Federal grants, contacts, and other cooperative agreements under the HHS regulations at 45 CFR part 76 (nonprocurement) and 48 CFR subparts 9.4 and 309.4 (procurement).

Debarring official: “Debarring official” shall mean an official authorized to impose debarment or suspension. The HHS debarring official is either (a) the Secretary, or (b) an official designated by the Secretary.

Evidence: “Evidence” shall mean 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.

Evidentiary Standards:

(a) Standard of proof: A Fairview or HHS finding of research misconduct must be proved by a preponderance of the evidence.

(b) Burden of proof: Fairview or HHS has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent’s failure to provide research records adequately documenting the questioned research is evidence of research misconduct where Fairview or HHS establishes by a preponderance of evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent’s conduct constitutes a significant departure from accepted practices of the relevant research community. The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether Fairview or HHS has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

Fairview Researcher: “Fairview Researcher” shall mean any Fairview

employee and any non-employed medical staff member or other person conducting or participating in research in whole or in part at a Fairview facility or using Fairview nonpublic information, patients or resources for purposes of research.

Good Faith: “Good faith” shall mean as applied to a complainant or witness, having a belief in the truth of one’s allegation or testimony that a reasonable person in the complainant’s or witnesses position could have based on the information known to the complainant or witness known 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 the 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.

Inquiry: “Inquiry” shall mean preliminary information gathering and preliminary fact-finding that meets the criteria and follows the procedures contained within this policy.

Inquiry/Investigative Panel or Panel: "Inquiry/investigative panel" or "panel" shall mean the impartial group of individuals appointed by the senior administrator and given the charge to determine whether the allegations are frivolous or to identify sufficient information to warrant an investigation (see also section VII). If an investigation is warranted, the same panel shall be given the additional charge by the senior administrator to further seek and analyze all relevant information regarding the allegation, and then determine whether sufficient evidence exists to report that research misconduct occurred. The report of the panel is the basis of any disciplinary action assigned by the senior administrator.

Institution: “Institution” shall mean any individual or person that applies for or receives financial support for any activity or program that involves the conduct of biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to colleges, universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, small research institutions, and

independent researchers.

Institutional Member: “Institutional member” or “members” shall mean a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured, and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents and contractors, subcontractors, and sub-awardees, and their employees.

Investigation: “Investigation” shall mean 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 that may include other appropriate actions, including administrative actions.

Notice: “Notice” shall mean 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.

Office of Research Integrity: "ORI" shall mean the Office of Research Integrity, an independent entity within the United States Department of Health and Human Services to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct reporting to the Secretary of Health and Human Services.

Preponderance of the evidence: “Preponderance of the evidence” shall mean proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research: “Research” shall mean the 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, confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

Research Misconduct: “Research Misconduct” shall mean the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. (a) Fabrication is making up data or results and recording or reporting them (b)

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 (c) Plagiarism is the appropriation of another person’s ideas, processes, results or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.

Research Misconduct Proceeding: “Research Misconduct Proceeding” shall mean any action related to alleged research misconduct taken under this part, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals.

Research Record: “Research record” shall mean 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 to an institutional official by a respondent in the course of the research misconduct proceeding.

Respondent: “Respondent” shall mean the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

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.

Science Advisory Board (SAB): “SAB” shall mean a committee representing the scientific interests at Fairview. The SAB shall appoint the members of the inquiry/investigative panel and advise the Senior Administrator on an appropriate review and determination of an allegation, inquiry and/or investigation. The SAB shall consist of the Chief Compliance Officer, Chief Medical Officer, Director of Research, Senior Vice President of Research & Graduate Medical Education, Fairview legal, and other members appointed from time to time by the Chief Medical Officer.

Senior Administrator: “Senior Administrator” shall mean the appropriate institutional official or entity Chief Executive Officer or Senior Vice President designated by the Fairview system Chief Executive Officer. The Senior Administrator has the responsibility of directing the proceedings from the allegation to the inquiry

	<p>process through the final disposition of the case. It is the responsibility of the Senior Administrator to ensure that the inquiry is conducted in a fair and just manner.</p> <p><i>Sponsor:</i> “Sponsor” shall mean any entity, including, but not limited to, a company, foundation, agencies of the U.S. federal and state governments, industry associations, and others that support the work upon which the allegation is based.</p>
<p>Procedure:</p>	<p>This policy applies to any Fairview employee conducting or participating in the conduct of research or using Fairview non-public information, patients or resources for purposes of research. This policy also applies to any non-employed medical staff member or other person conducting or participating in the conduct of research in whole or in part at a Fairview facility or using Fairview nonpublic information, patients or resources for purposes of research. Fairview recognizes that the Academic Health Center (AHC) of the University of Minnesota is obligated to comply with certain reporting requirements relating to allegations of research misconduct.</p> <p>Therefore, when an allegation involves an AHC faculty member, Fairview will notify the appropriate AHC representative in accordance with the Board of Regents Academic Misconduct Policy. The policy and procedures set forth herein shall apply to all research and scholarly activities of all Fairview Researchers who are involved in such activities. In those instances in which it is not clear whether this policy should apply to an individual, the SAB will adjudicate the question.</p> <p>OVERVIEW OF RESEARCH MISCONDUCT</p> <p>Requirements for Findings of Research Misconduct</p> <p>A finding of research misconduct made under this part requires that:</p> <ul style="list-style-type: none"> (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. <p>Sequence of Events in Research Misconduct Proceedings</p> <ul style="list-style-type: none"> <input type="checkbox"/> Allegation/Proceedings/Findings/Reporting <input type="checkbox"/> Inquiry/Proceedings/Findings/Reporting <input type="checkbox"/> Investigation/Proceedings/Findings/Reporting <input type="checkbox"/> Subsequent to Investigation Findings <p>Application of Requirements</p> <p>Fairview has determined that the June 2005 Rule will be adopted for</p>

all research (including non-federally funded) conducted within its facilities and will use the revised policies and procedures developed in response to that Rule. The following provisions apply at any stage of the research misconduct proceedings, including allegation, inquiry, investigation, formal finding, and disposition.

Conflict of Interest

Possible conflicts that must be avoided in the appointment of the senior administrator and members of the panel or the assignment of a SAB panel member to the case include the following:

1. Co-authoring a book, paper, or grant proposal with any of the individuals directly involved with the misconduct case (complainant or respondent);
2. Professional or personal relationship with any of these individuals (e.g., current or former students or mentor, direct supervisory or subordinate relationship, direct collaborator within the past seven years;
3. Professional differences of opinion with any of the involved individuals that might reasonably be expected to affect the objectivity in considering the case;
4. Financial ties to the involved individuals; or other reasons that might affect the ability of the individuals to make fair and impartial judgments

Time Limitations

1. Six-year limitation. This part applies only to research misconduct occurring within six years of the date HHS or Fairview receives an allegation of research misconduct.

2. Exceptions to the six-year limitation. Paragraph (a) of this section does not apply in the following circumstances:

(a) **Subsequent use exception.** The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.

(b) **Health or safety of the public exception.** If the Office of Research Integrity (ORI) or Fairview, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

(c) **“Grandfather” exception.** If HHS or Fairview received the allegation of research misconduct before the effective date of this part.

Confidentiality

All parties involved shall be afforded confidential treatment to the

maximum extent possible.

(a) Disclosure of the identity of the respondents and complainants in research misconduct proceedings is limited, to the maximum 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 that:

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

(b) 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.

Communication with Federal Agencies

All communication with federal agencies regarding the requirements in this policy shall be conducted by the entity Senior Administrator designated by the Fairview system Chief Executive Officer.

Notification to ORI

PHS regulations (42 CFR part 50, subpart A) require that the director of the ORI be notified when, on the basis of the initial inquiry, Fairview determines that an investigation is warranted or prior to the decision to initiate an investigation under the following conditions:

- a. there is an immediate health hazard involved;
- b. there is an immediate need to protect federal funds or equipment;
- c. there is an immediate need to protect the interests of the persons making the allegations or of the individuals who are the subject of the allegations, as well as the co-investigators and associates, if any;
- d. it is probable that the alleged incident is going to be reported publicly;
- e. there is reasonable indication of possible criminal violation. In that instance, Fairview must inform ORI within 24 hours of obtaining that information. ORI will immediately notify the Office of the Inspector General. If the inquiry is to be terminated, the ORI shall be notified including a description of the reasons for termination.

Interim Administrative Action

As provided by federal regulations (42 CFR part 50, subpart A and 45 CFR part 689) at any stage in the process of allegation, inquiry, investigation, formal finding, and disposition, Fairview reserves the right and may take interim administrative action to protect:

- (a) the health and safety of research subjects and patients; and
- (b) the interests of students and colleagues;
- (c) federal funds

	Such actions may range from slight restrictions to reassignment of the activities of the respondent. In extreme circumstances, the respondent may be suspended temporarily. Any actions shall be in accordance with the procedures specified in this Fairview Health Services policy, any agreements, or other applicable policies. Interim administrative actions shall be taken in full awareness of how they might affect the respondent and the ongoing research projects of Fairview Health Services.
External Ref:	<i>Federal Policies on Research Misconduct</i> , 42 CFR 50 and 93; University of Minnesota Board of Regents and Administrative Policies on Academic Misconduct
Internal Ref:	
Source:	System Director, Research Administration
Approved by:	Research Institutional Official
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