

16.6 – Research Misconduct

Policy

1. A disclosure of possible research misconduct must be reported immediately and will conform to the Public Health Service {Department of Health and Human Services} Final Rule 42 Code of Federal Regulations (CFR) Part 93. If the issue involves a member of the Case Western Reserve University (Case) faculty or grants awarded to Case, the relevant Case policy “University Policy for Responding to Allegations of Research Misconduct” will also apply.
2. This policy applies to any person paid by, under the control of, or affiliated with research conducted at, sponsored by, or administered by UHCMC. This includes scientists, trainees, technicians, students, fellows, guest researchers, and all staff members engaged in research. This policy and the associated procedures apply to all individuals at UHCMC engaged in any research whether funded or unfunded.
3. The CCRT will handle all allegations of scientific misconduct and will cooperate with the Office of Research Integrity. The CCRT reserves the right to change or modify any or all of the policies and procedures in whole or in part at any time without prior notice. All such changes would be consistent with applicable regulations.
4. The Vice-President of Research and Technology will designate a Research Integrity Officer (RIO) for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.
5. Responsibility to Report Misconduct - All persons affiliated with UHCMC, including faculty, staff, students, fellows, residents, nurses, visiting researchers, collaborators and research personnel will report observed, suspected, or apparent research misconduct. The perceived misconduct can be reported to:
 - 5.1. The Director of the Department in which the scientific misconduct occurred.
 - 5.2. The UHCMC Chief Medical Officer.
 - 5.3. The Vice-President of Research and Technology.
 - 5.4. UH Compliance & Ethics (Hotline (800)-227-6934 or compliance@uhhospitals.org).
6. The Department Director or the UHCMC Chief Medical Officer will inform the Vice-President of Research and Technology Management, who will assess the allegations to determine whether there is sufficient evidence of research misconduct to warrant an inquiry.
7. If the misconduct involves the Vice-President for Research and Technology or the area directly reporting to this institutional official (i.e., CCRT), the allegations will also

be reported to the UHCMC Chief Medical Officer by the RIO who will make the preliminary assessment as to whether an inquiry is warranted.

8. The Vice-President of Research and Technology will notify the Department of Health and Human Services Office of Research Integrity at any stage of the inquiry or investigation if:
 - 8.1. There is an immediate health hazard involved.
 - 8.2. There is an immediate need to protect Federal funds or equipment.
 - 8.3. Research activities should be suspended.
 - 8.4. There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any.
 - 8.5. The alleged incident may be reported publicly.
 - 8.6. The allegation involves an issue with an impact on public health (e.g., fraudulent results published for a clinical trial).
 - 8.7. There is a reasonable indication of possible criminal violation. In this instance, the CCRT must inform the Office of Research Integrity within 24 hours of obtaining that information.
9. If Requirements for findings of research misconduct - A finding of research misconduct requires that:
 - 9.1. There be a significant departure from accepted practices of the relevant research community; and
 - 9.2. The misconduct be committed intentionally, knowingly, or recklessly; and
 - 9.3. The allegation be proven by a preponderance of the evidence.
10. If allegations of research misconduct are substantiated by an investigation, the Vice-President of Research and Technology, UHCMC Chief Medical Officer, the UH Corporate Compliance Officer, the UHCMC Human Resources Department, and the Case Research Compliance Officer (if Federal funding or Case faculty), will take appropriate administrative actions, up to and including termination of employment or loss of UHCMC appointment or privileges. During any stage of possible research misconduct proceedings, the Vice-President of Research and Technology will take appropriate administrative action to protect Federal or other sponsor funds, including requiring immediate cessation of related research activities while maintaining confidentiality of the issues.
11. If the institution finds no misconduct, (and, where applicable, ORI concurs) after consulting with the respondent, the Vice-President of Research and Technology will undertake reasonable efforts to restore the respondent's reputation.
12. The Vice-President of Research and Technology will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the complainant (unless the allegations were not made in good faith, whereby the Deciding Official will determine whether any administrative action should be taken against the complainant).

13. In every instance of verified misconduct, the Vice-President of Research and Technology will report the facts and conclusions of its investigation confidentially to persons and entities connected with the research that are affected by the research misconduct as appropriate to the protocol including:

- 13.1. Funding agencies.
- 13.2. Publishers.
- 13.3. Research collaborators.
- 13.4. Research participants.

14. Assessment of Allegation:

- 14.1. Reports of alleged misconduct are to be made to the VP for Research and Technology. A preliminary and informal evaluation of the complaint will be made by the RIO, who may consult in confidence with other institutional officials as appropriate before passing on the matter.
- 14.2. If the RIO finds that there are no reasonable grounds for the allegation, the complaint will be dismissed without giving any further notice to the respondent. A written report stating the reasons for the dismissal shall be maintained, but will not be made a part of the record of the respondent. The complainant, who shall be notified of the dismissal, may request reconsideration of the decision for dismissal, directly to the VP for Research and Technology.

15. Inquiry:

- 15.1. The purpose of an inquiry is to determine whether an allegation or apparent instance of misconduct warrants a full investigation or requires that special actions be taken pending resolution of the allegation or apparent misconduct. The inquiry will determine whether the allegation of misconduct appears to be well founded, the seriousness of the alleged misconduct, scope of the alleged incident, and relevance of any other information that is available. An inquiry should be completed within sixty (60) calendar days after an allegation is made. To the extent possible, inquiries and resultant investigations will be conducted in a confidential manner so as to protect the affected parties.
- 15.2. The respondent shall be notified in writing of the complaint and shall be given a copy of the procedures for reviewing alleged misconduct. The departmental chair will also be notified. The inquiry will be conducted by an ad hoc committee of at least three (3) full-time clinical faculty members chosen by the VP for Research and Technology. Reasonable effort will be made to ensure that no committee member has any perceived conflicts of interest with the respondent. The respondent has the ability to request a replacement committee member(s) if they produce evidence of a potential conflict of interest.
- 15.3. The inquiry committee will review the merit of the allegations and recommend a course of action to the VP for Research and Technology, as appropriate, including whether a full investigation should be conducted. The inquiry committee may have access to documents relating to the alleged misconduct and may interview the complainant and the respondent. It shall not, however, attempt to reach a decision on the merits of the complaint.

- 15.4. After receiving the written report of the inquiry committee, the VP for Research and Technology will review the findings of the committee and will determine whether to dismiss the case or to proceed with an investigation. The respondent and the departmental chair will be notified in writing of the decision. If the complainant disagrees with a decision of the VP for Research and Technology to dismiss the case, the complainant may appeal to the UH Corporate Compliance Officer who then will review the case and make a final determination as to appropriate action.
- 15.5. If a decision not to investigate is rendered, all the information assembled in the course of the inquiry will be maintained for seven (7) years in confidence to permit a later assessment of the reasons for determining that an investigation was not warranted.

16. Investigation:

- 16.1. The purpose of an investigation is to examine thoroughly an allegation of research misconduct and to determine whether such misconduct has taken place. If the VP for Research and Technology determines to proceed with an investigation, he or she will appoint a committee and committee chair to investigate the complaint. When appropriate, the VP for Research and Technology may appoint experts from outside UHCMC to serve on the committee. Granting agencies supporting the research work under investigation and the Office of Research Integrity (ORI) will be notified within 30 days of commencing the investigation by the VP for Research and Technology and RIO. Specific agency requirements, such as the time within which certain steps are to be taken, will be observed and communicated by the VP for Research and Technology to the investigating committee and to the respondent. The investigation will include, but not be limited to, review of grant or contract files, reports, publications, manuscripts, research records, regulatory and other documents; inspection of laboratory or clinical research facilities, and/or materials; interviewing of parties with an involvement in, or knowledge about, the case; and submission of a formal report of committee findings, including response of the respondent.
- 16.2. The respondent will be given a copy of the complaint, the report of the inquiry committee, and the charge to the Investigation committee by the VP for Research and Technology. The subject also will be kept informed by the Investigation committee chairperson of the progress of the investigation and will be given the opportunity to respond to the complaint orally and in writing and to provide information for consideration by the committee. The Investigation committee will focus on matters limited to the charge given to it by the VP for Research and Technology, but may review previous research efforts of the affected personnel or records of previous complaints of research misconduct, if germane to the investigation.
- 16.3. Neither UHCMC, the respondent, nor witnesses may have legal counsel present at the meetings of the committee, except at the express invitation of the committee. Should legal counsel be invited, the invitation will be extended to both parties. When invited, legal counsel may observe but shall not participate

- in the proceedings. With the prior approval of the Investigation committee, the respondent may be accompanied by a non-attorney colleague.
- 16.4. The Investigation committee will prepare a draft report and provide a copy of such report to the respondent and complainant who may review and comment, offer corrections, accept its conclusions, or deny the allegations. The final report of the committee will be transmitted to the VP for Research and Technology, along with any minority reports and responses by the respondent and the complainant. The committee's report will respond to the charge given by the VP for Research and Technology and will assess the validity of the allegations. The report of the committee and its attachments will be forwarded to the VP for Research and Technology for review and disposition. If the RIO and the Investigation committee find that the respondent has not engaged in research misconduct, the VP for Research and Technology will dismiss the complaint. If the VP for Research and Technology confirms that the respondent has engaged in research misconduct, the VP for Research and Technology may initiate UHCMC procedures leading to possible sanctions. The VP for Research and Technology will inform the respondent of his/her decision.
- 16.5. The VP for Research and Technology will also notify those institutional officials who need to know of the decision. The VP for Research and Technology must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.
- 16.5.1. The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if the VP for Research and Technology determines that the investigation will not be completed within this 120-day period, he or she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The VP for Research and Technology will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.
- 16.5.2. The VP for Research and Technology is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.
17. The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution's responsibilities under 42 CFR Part 93.
18. If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses

to participate in the process after resignation, the VP for Research and Technology and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

19. Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the VP for Research and Technology must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.

20. Notice to ORI of Institutional Findings and Actions:

20.1. Unless an extension has been granted, the VP for Research and Technology must, within the 120-day period for completing the investigation, submit the following to ORI: (1) a copy of the final investigation report with all attachments; (2) a statement of whether the institution accepts the findings of the investigation report; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.

21. Additional Considerations:

21.1. During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the VP for Research and Technology must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.

21.2. If relevant, the VP for Research and Technology will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the VP for Research and Technology determines that there was an absence of good faith he or she will determine whether any administrative action should be taken against the person who failed to act in good faith.

22. Maintaining Records:

22.1. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.

Related Policies

University Policy for Responding to Allegations of Research Misconduct
UH Code of Conduct

Definitions

Allegation: 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 Health and Human Services (HHS) official.

Center for Clinical Research and Technology (CCRT): The CCRT is a division of University Hospitals of Cleveland Case Medical Center (UHCMC). The CCRT administratively oversees all active research at UHCMC.

Complainant: A person who in good faith makes an allegation of research misconduct.

Conflict of Interest: The real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

Deciding Official: The Institution Official who makes final determinations on allegations of research misconduct and any responsive institutional actions.

Good Faith Allegation: An allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with knowing or reckless disregard for the information that would negate the allegation.

Inquiry: Preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR 93.307-93.309.

Investigation: The formal development of a factual record and the examination of that record leading to a decision to either not make a finding of research misconduct; or to make a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions under 42 CFR 93.313

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

Public Health Service (PHS): 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, Substance Abuse and Mental Health Services Administration and the offices of the Regional Health Administrators.

Research Integrity Officer (RIO): The institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations require an investigation.

Research Misconduct: Fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results. It does not include honest error or honest differences in interpretations or judgments of data.

Research Record: 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.

Respondent: The person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Retaliation: An adverse action taken against a complainant, witness or committee member by an institution or one of its members in response to a good faith allegation of research misconduct; or good faith cooperation with a research misconduct proceeding.

APPROVALS

Frederic Rothstein MD

CHIEF EXECUTIVE OFFICER

3/27/08

Date

W.P.

SENIOR VICE PRESIDENT

3/27/09

Date