



Ohio Administrative Code

Rule 3361:10-17-05 Conduct and ethics: policy for investigation of research misconduct.

Effective: February 15, 2008

(A) Definitions

As used herein, the following terms have the indicated meaning:

"Fabrication": making up data or results and recording or reporting them.

"Falsification": 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.

"Inquiry": Gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

"Investigation": the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and if so, to determine the responsible person and the seriousness of the misconduct.

"ORI": office of research integrity, the office within the United States department of health and human services (HHS) that is responsible for the scientific misconduct and research integrity activities of the public health service (PHS).

"Plagiarism": the appropriation of another person's ideas, processed, results, or words without giving appropriate credit.

"Research integrity officer or RIO": the individual appointed by the provost responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

"Research records": any data, document, computer file, external hard drive/flash drive, or any other



written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, grant or contract progress and other reports, laboratory notebooks, notes, correspondence, videos, photographs, x-ray film, slides, biological materials, manuscripts and publications, equipment use logs, laboratory procurement records, animal facility records, human and animal subject protocols, consent forms and patient record files.

(B) The university endorses the following introductory statement in the "Framework for Institutional Policies and Procedures to Deal with Fraud in Research," issued November 4, 1988, by the "Association of American Universities, National Association of State Universities and Land-Grant Colleges, and Council of Graduate Schools."

"Fraud in research undermines the scientific enterprise in ways that go far beyond the waste of public funds. Although an uncommon event relative to the large scientific literature, violations of accepted standards inevitably appear in this as in all human pursuits. Institutions engaged in research have a major responsibility, not only to provide an environment that promotes integrity, but also to establish and enforce policies that deal effectively and expeditiously with allegations or evidence of fraud.

In dealing with this problem it is important not to create an atmosphere that might discourage openness and creativity. Good and innovative science cannot flourish in an atmosphere of oppressive regulation. Moreover, it is particularly important to distinguish fraud from the honest error and ambiguities of interpretation that are inherent in the scientific process and are normally corrected by further research."

Generation of new knowledge through scholarly and creative works is a fundamental goal of the University of Cincinnati. This work is broadly defined as research. Individuals directly engaged in research, those charged with supervision of research, and collaborators of university investigators outside their own units shall bear obligations to pursue their studies in an ethical manner. Supervisors of research shall bear responsibility for the ethical conduct of research in their own unit as well as the laboratories of their collaborators.



This rule is designed to be consistent with the Public Health Service (PHS) policies on research misconduct, 42 CFR part 93, adopted 16 June 2005. However, the policy and process is generally applicable to all research irrespective of funding source.

(C) Research misconduct is defined as fabrication, falsification or plagiarism in proposing, performing, or reviewing research proposals or in reporting research results. Research misconduct does not include honest error or differences of opinion that arise out of proposing, performing, reviewing or reporting research.

(D) Misconduct, which has been established by a preponderance of evidence, may constitute grounds for administrative action including termination of the individual's appointment at the university. It shall be recognized that accusations of falsifying or misrepresenting data or authorship shall be among the most serious charges that may be lodged against an investigator. Any person contemplating such accusations shall fully consider the gravity of the accusation and its consequences and shall make every reasonable effort to avoid lodging charges that shall prove to be devoid of a substantial element of truth. Frivolous or false accusations may also constitute grounds for administrative action. Likewise, it shall be the policy of the University of Cincinnati that no individual who, in good faith, shall have reported apparent scientific misconduct of research shall be subject to retaliation by the university or any member of the university community. Impermissible retaliation shall be subject to university discipline. The reputations of all involved parties will be protected to the extent possible and measures to restore reputations will be undertaken as appropriate. Documentation of any adverse action taken with respect to any individual employee shall remain permanently in that employee's personnel file.

(E) When misconduct shall have been alleged, a sequence of events shall take place within the institution to provide maximal opportunity for reaching valid conclusions about the alleged misconduct. In addition to reaching valid conclusions, it shall be imperative that due process shall be followed and protection be afforded to the rights and reputation of both accuser and accused, collaborators of the accused, those investigating the allegations, any sponsoring agency, any publisher, and the university. Thus, university legal counsel shall provide advice and counsel throughout the proceedings.

(F) During inquiry into and investigation of allegations, confidentiality shall be observed in the



interests of all parties except that the appropriate college dean (hereafter referred to as dean) shall inform, and keep apprised of the investigation, the vice president for research and the senior vice president and provost for baccalaureate and graduate education. The dean may delegate any authority described herein.

(G) Appropriate administrative action may be taken as necessary to ensure the integrity of the research, to protect the rights and interests of research subjects and the public, to protect sponsoring agency funds, and to assure that the purposes of the financial assistance are met.

Allegations which meet the following criteria for special circumstances should be reported to the vice president for research, the research integrity officer, the appropriate funding agencies and office of research integrity. These include, but are not limited to: (1) risk to public health or safety including immediate need to protect human or animal subjects; (2) Threats to agency resources, reputation or other interests that need protecting; (3) any reasonable indication of possible violations of civil or criminal law; (4) suspension of research activities; (5) need for federal action to protect the interests of a subject of the investigation or of others potentially affected; or (6) the scientific community or the public should be informed.

(H) All proceedings shall be in accordance with applicable rules and contractual obligations of the university of Cincinnati. Any individual meeting with an inquiry or investigating committee may be accompanied by a representative. Each committee may establish its own rules of conduct within these guidelines. All members of the university of Cincinnati community are expected to cooperate with the proceedings, inquiries, and investigations.

(1) Allegations:

Charges of misconduct shall be brought to the research integrity officer (RIO) who will assess the allegations to determine whether they are credible and specific and warrant further investigation. If the decision is in the affirmative, the RIO will communicate them immediately to the director or head of the department or unit in which such conduct allegedly occurred. The director or head shall immediately inform the dean of the college. If the person being accused is a department or unit director or head, the charge shall be brought directly to the dean.



Assessment of allegations. The RIO shall make an initial assessment of whether the reported allegations are credible and specific so that

- (a) Potential evidence of research misconduct may be identified.
- (b) The allegations fall within the jurisdictional criteria of 42 CFR 93.102(b).
- (c) The allegation falls within the definition of research misconduct in this policy and 42 CFR 92.103.

If these criteria are met then an inquiry must be conducted. The assessment should be concluded within one week. The RIO shall convey charges of misconduct to the dean of the college.

(2) Initial inquiry: if the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether or not there may be substance to the allegations that warrants an investigation. All proceedings shall be in accordance with applicable rules and contractual obligations of the university of Cincinnati.

(a) Notice to the accused: at the time of or before beginning an inquiry, a good faith effort must be made to advise the accused of the allegations in writing.

(b) Prior to or concomitant with, notification of the respondent concerning the allegation, the RIO will obtain custody of, inventory and sequester all research records and evidence necessary to conduct the research misconduct proceedings.

(c) The RIO will consult with the ORI for advice and assistance where appropriate.

(d) The RIO, in consultation with the dean shall appoint an inquiry committee of no more than three individuals to conduct an initial inquiry into the allegations. Appointments shall avoid any real or apparent conflict of interest. The inquiry committee shall contain individuals with the necessary and appropriate expertise to interview the principals and key witnesses, and conduct a thorough and equitable inquiry. University legal counsel shall advise the inquiry committee. The dean shall identify one member as the chair of the body. The object of the initial inquiry shall be to determine whether or



not there may be substance to the allegations that warrants an investigation and to recommend appropriate action to the dean.

(e) In the inquiry stage, factual information is gathered by the inquiry body and reviewed to determine if an investigation is warranted. The inquiry is designed to separate allegations deserving further investigation from unsubstantiated or frivolous allegations. Private and separate sessions shall be conducted to hear the accuser, the accused, and others as determined necessary by the inquiry committee. All relevant evidence that is produced shall be reviewed and secured. Once sufficient information is obtained to decide whether an investigation is warranted, the inquiry process shall conclude and an inquiry report will be submitted to the dean.

The inquiry committee shall make a written report and recommendation to the dean within fifteen working days after the dean has been informed of the charge. Under exceptional circumstances the dean may extend this period. The written report shall state what evidence was reviewed, a summary of relevant interviews, the reason for any delays, and the recommendation of the inquiry committee. The determination of the dean shall be final and should be completed within thirty days of receiving the draft report.

(f) Two basic recommendations may follow from this initial inquiry: (1) the allegations are without merit; or (2) the allegations have sufficient substance to warrant further investigation. In either case, subsequent action may be recommended. If the student was supported with PHS funds, the RIO will provide ORI with the dean's written decision and a copy of the inquiry report. The RIO must provide the following information to the ORI upon request:

- (i) The institutional policies and procedures under which the inquiry was conducted.
- (ii) The research records and evidence reviewed, transcripts or recordings of any interviews and copies of all relevant documents.
- (iii) The charges to be considered in the investigation.

(g) The dean shall review the recommendation of the inquiry committee and decide whether to request complete investigation as described in paragraph (G)(3) of this rule or take any other



appropriate action pursuant to university rules or contractual agreements. This decision shall be delivered in writing with the inquiry committee report and recommendation to the accused, accuser, the inquiry committee, the vice president for research and the senior vice president and provost for baccalaureate and graduate education who in turn shall notify the president of the university without unnecessary delay. Any comments submitted by the accused may be added to the record. If the dean decides that an investigation is not warranted, the RIO shall secure and maintain for seven years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

(3) Investigation: (if warranted) An investigation must begin within thirty days of the completion of the inquiry and must be completed within one hundred twenty days of its initiation. The purpose of the investigation is to develop a factual record exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. If there is evidence to suggest that there are additional instances of possible research misconduct, the scope of the investigation may be broadened beyond the initial allegations. This is particularly important if the alleged misconduct involves clinical trials, potential harm to human subjects, the general public or if it affects research that forms the basis for public policy, clinical practice or public health practice.

(a) The dean shall determine whether sponsored research is involved and shall so inform the vice president for research who shall determine if the sponsoring agency shall be notified that an investigation is under way. If the allegations involve PHS support, on or before the date on which the investigation begins the RIO must:

(i) Notify the ORI director of the decision to begin the investigation and provide ORI a copy of the inquiry report.

(ii) Notify the respondent in writing of the allegations to be investigated and notice if any new allegations of misconduct are to be included in the investigation.

(b) The RIO, in consultation with dean shall appoint an investigating committee and the committee chair within ten days to conduct a complete investigation of the allegations to determine if



misconduct has occurred and, if so, to assess its extent and consequences. Appointments shall avoid any real or apparent conflict of interest. The investigating committee shall not be excessive in size but shall contain individuals with sufficient expertise and dedication to conduct a thorough and equitable investigation. University legal counsel shall advise the investigating committee.

(c) The investigation shall be thorough and timely and shall provide both notice of all allegations to the accused and an opportunity for the accused to fully respond to all allegations and findings. It shall require the dedicated attention of the investigating committee. An investigation must begin within thirty days of the completion of the inquiry and must be completed within one hundred and twenty days of its initiation. Extensions may be approved only by the vice president for research and the senior vice president and provost for baccalaureate and graduate education who shall first secure any necessary approvals from sponsoring agencies.

(d) Investigative process: necessary support (e.g., clerical, information gathering, witnesses, organizational, security, record keeping and confidentiality) shall be arranged by the office of the dean. The investigation committee and the RIO must:

(i) 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 each allegation.

(ii) Take reasonable steps to ensure the investigation is impartial and unbiased to the maximum extent practical

(iii) Conduct private and separate sessions to hear the accuser, the accused and others as determined necessary by the investigating committee.

(iv) Produce and review all relevant evidence (including, but not limited to research data, publications, correspondence and telephone memoranda) that has been produced shall be reviewed and secured.

(v) Interviews with any individuals shall be recorded by tape recorder or court reporter unless the investigating committee shall otherwise be advised by legal counsel.



(e) The investigative report: the investigating committee shall provide a written report of its findings, conclusions and recommendations, together with all pertinent documentation and evidence, to the dean. The RIO will assist the investigation committee in finalizing the draft report to be submitted to ORI within one hundred twenty days. Each member of the investigating committee shall sign the report or submit a signed dissenting report. The dean will determine in writing, (i) whether the institution accepts the investigation report, its findings and the recommendations and (ii) the appropriate institutional actions in response to the finding. If this determination varies from the findings of the committee, the dean will, as part of the written determination, explain in detail the basis for rendering a decision different from the committee.

(4) External review:

The dean may appoint an external committee of faculty members and/or administrators from another institution or institutions to review and provide written comment on the findings, conclusions and recommendations of the investigating committee. They shall be appointed in a manner that ensures the official nature of their involvement and provides them with legal protections available to university employees to the extent possible.

(5) Administrative action:

(a) The dean shall review the report of the investigating committee and the comments of the external committee, if any, and recommend further action to the vice president for research and the senior vice president and provost for baccalaureate and graduate education. This recommendation shall be delivered in writing together with the committee report and any comments from the external committee to the accused, the accuser, and the investigating committee. Any comments submitted by the accused shall also become part of the record. The vice president for research and the senior vice president and provost for baccalaureate and graduate education shall inform the president of the university without unnecessary delay.

(b) With the advice of the university legal counsel, the vice president for research and the senior vice president and provost for baccalaureate and graduate education shall decide how to proceed under applicable university rules and contractual agreements and shall deliver that decision in writing to the accused, the accuser, both committees, the dean, and the president without unnecessary delay. A copy



shall be permanently placed in the personnel file of the accused. Collaborators of the accused shall be advised of any substantiated misconduct or questions related to their research. The president shall advise the board of trustees as necessary.

(c) At any time that misconduct as defined herein or significant errors are substantiated in any sponsored or reported research, the vice president for research and the senior vice president and provost for baccalaureate and graduate education shall notify the sponsoring agency or publisher without delay in writing.

(d) If PHS funds are involved, the dean will make the final determination whether to accept the investigation report, its finding and recommendations for action. If this determination varies from that of the investigation committee, the dean will explain in detail the basis for rendering a decision in the report transmitted to ORI. The RIO must maintain and provide to ORI upon request records of research misconduct proceedings as that term is defined by 42 CFR 93.317. 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 seven years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The RIO 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.

(e) Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the RIO will, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation should first be approved by the dean.