

**POLICY AND GRIEVANCE PROCEDURE GOVERNING RESEARCH  
MISCONDUCT**  
**University of Kansas Medical Center**  
**Recommended for adoption by the Research Advisory Committee on 6/25/03**  
**Approved by Legal Counsel January 2004**  
**Adopted June 2004**

The following document replaces section IX.E (Guidelines for Dealing with Allegations of Scientific and Other Scholarly Misconduct) in the Faculty Unclassified Staff Handbook

## **POLICY GOVERNING RESEARCH MISCONDUCT**

### **Background**

The University of Kansas Medical Center (KUMC) is committed to promoting an academic community that adheres to the highest ethical standards of honesty and integrity. KUMC seeks to do this without inhibiting the productivity and creativity of its research community, while establishing a firm expectation that all individuals engaged in research will not knowingly or intentionally commit misconduct.

### **Legal Basis**

- Federal Policy on Research Misconduct, Executive Office of the President. Federal Register, December 6, 2000 (Volume 65, Number 235): Office of Science and Technology Policy
- PHS regulation (42 CFR Part 50, Subpart A): Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science<sup>1</sup>, 8/8/89 (revisions proposed 4/16/04) [<http://ori.dhhs.gov/multimedia/acrobat/42CFRParts50and93.pdf>]. 42 CFR 50.103(a): "Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary that the applicant: (1) Has established an administrative process that meets the requirements of this Subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this Subpart." 42 CFR 50.103(b): "The institution's assurance shall be submitted to the [ORI], on a form prescribed by the Secretary . . . and updated annually thereafter . . . An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe."
- NSF Regulations (45 C.F.R. Part 689) governing research misconduct, revised 10/1/02) [[http://www.access.gpo.gov/nara/cfr/waisidx\\_00/45cfr689\\_00.html](http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr689_00.html)]
- ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research (November 20, 1995) [[http://ori.dhhs.gov/html/publications/guidelines\\_guidelin.ASP](http://ori.dhhs.gov/html/publications/guidelines_guidelin.ASP)]
- Whistleblower Protection Act of 1989

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<sup>1</sup> ~~Places several requirements on institutions receiving or applying for funds under the PHS Act. The institutional requirements are monitored by ORI's Assurance Program. Institutions must submit to ORI an Annual Report on Possible Research Misconduct (PHS form #6349). In administering the Assurance Program, ORI determines whether an institution has a current assurance on file so that PHS funds may be awarded, and reviews the information submitted on the Annual Report form to see whether the institution is complying with the regulation.~~

## **Policy Statements**

The University of Kansas Medical Center affirms its commitment to ensuring responsible conduct of research by the following policy statements:

- All individuals participating in research activities are prohibited from engaging in misconduct.
- It is the responsibility of all individuals to report instances of research misconduct, as well as instances of retaliation against those who, in good faith, raise charges of research misconduct.
- The University shall establish and maintain policies and procedures required by federal regulations and ensure that they are disseminated to, and understood by, its scientific and administrative staff.
- The University shall take immediate and appropriate action as soon as research misconduct is suspected or alleged, and will inform and cooperate with federal officials with regard to each investigation of possible misconduct.
- The Executive Vice Chancellor shall appoint a Research Integrity Officer who will be responsible for implementing these policies, educating the campus community about research misconduct, and administering the complaint procedure.

## **Scope**

These policy statements apply to the following:

- all research conducted at KUMC, the KU School of Medicine-Wichita and their associated facilities or through their affiliated entities, including non-funded projects and projects supported by the Public Health Service, the National Science Foundation, other governmental entities, and private funding sources;
- the collection of all research data, storage of records and proper assignment of credit in publication;
- any person paid by, subject to the rules and policies of, or affiliated with the University of Kansas Medical Center or the School of Medicine-Wichita including scientists, trainees, technicians and other staff members, students, fellows, visiting scientists or other collaborators involved in the conduct of research.

## **Applicability**

These policy statements and procedure apply only to misconduct involving research. Non-research related misconduct that involves fraud, plagiarism or fabrication shall be addressed through appropriate KUMC policies and procedures contained in the Faculty/Unclassified Handbook, GME Handbook, or Student Handbook.

## **Agency Involvement**

In most cases, federal funding agencies will rely on KUMC's initial responses to allegations of research misconduct. When allegations of research misconduct are

made directly to a funding source, it will generally refer the complainant to KUMC. However, at any time, the agency may proceed with its own inquiry or investigation. Agencies may elect not to defer to KUMC if they determine KUMC is not prepared to handle the allegation in a manner consistent with federal policy, or if agency involvement is needed to protect the public interest for health and safety reasons.

## **Definitions**

**Allegation:** any written or oral statement or other indication of possible research misconduct made to an appropriate University official.

**Complainant:** a person who 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 or entity, where the potential bias may occur due to prior or existing personal or professional relationships.

**Deciding Official:** the KUMC official who issues final determinations on allegations of research misconduct and any related actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the inquiry or investigation of research misconduct allegations. Dr. Barbara Atkinson, Executive Vice Chancellor, is the Deciding Official for KUMC, and is endowed with authority to name a designee.

**Fabrication:** making up research 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.

**Good Faith Allegation:** an allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if made with reckless disregard for, or willful ignorance of, facts that would disprove the allegation.

**Inquiry:** gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

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

**ORI:** the Office of Research Integrity in the U.S. Department of Health and Human Services (DHHS). ORI is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Services (PHS).

**Plagiarism:** the appropriation of another person's research ideas, processes, results,

or words without giving appropriate credit.

**Research:** all basic, applied and demonstration research in any field of science, engineering or mathematics. This includes, but is not limited to, research in education, medicine, basic sciences, and research involving human or animal subjects.

**Research Integrity Officer:** the institutional official responsible for making an inquiry into allegations of research misconduct and determining when such allegations warrant an investigation.

**Research Record:** the record of data or results that embody the facts resulting from scientific inquiry. The research record includes but is not limited to: research proposals, laboratory records (both physical and electronic), grant or contract applications, progress reports, abstracts, theses, oral presentations, correspondence, internal reports and journal articles. Research records may be in the form of documents, videos, photographs and slides, x-rays, biologic materials, equipment use logs, laboratory procurement records, animal facility records, human and animal subject protocols, consent forms, medical charts, case report forms, computer files, computer diskettes, and non-written accounts or objects that reasonably may be expected to provide evidence or information regarding the proposed, conducted, and/or reported research.

**Respondent:** the person(s) against whom an allegation of research misconduct is directed or whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

**Retaliation:** any action taken by the University that adversely affects the employment or other institutional status of a complainant, who, acting in good faith, has made an allegation of research misconduct. Adverse actions taken against any individual who has cooperated in good faith with an investigation of alleged research misconduct also constitute retaliation.

**Research Misconduct:** Research misconduct is broadly defined as any conduct which violates requirements of KUMC's research protection program or funding source regulations. Research misconduct as defined by the federal government includes fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results. Research misconduct does not include honest error, scholarly or political disagreements, and differences of opinion in interpretations or judgments of data. Other practices that seriously deviate from ethical standards for proposing, conducting, or reporting research may constitute misconduct governed by this policy and procedure.

A finding of research misconduct requires that:

- there be a significant departure from accepted practices of the relevant research community;

- the misconduct be committed intentionally, or knowingly, or recklessly; and,
- the allegation be proven by a preponderance of evidence.

### **Procedure for Responding to Allegations of Research Misconduct**

General Principles. While federal agencies have ultimate oversight authority for federally funded research, KUMC bears primary responsibility for preventing and detecting research misconduct, and for the inquiry, investigation and adjudication of alleged research misconduct.

Purpose and Jurisdiction of the Procedure. This procedure shall be used to receive and process allegations of research misconduct as defined by University policy.

Resolution Strategies. A response to an allegation of research misconduct consists of three phases:

- **Inquiry** – an assessment of whether the allegation has substance and if an investigation is warranted
- **Investigation** – the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies
- **Adjudication** – stage during which recommendations are reviewed and appropriate corrective actions determined.

Responsibility for Implementation. The Executive Vice Chancellor is responsible for assuring compliance with federal, state and university policies and procedures governing the responsible and ethical conduct of research. The Executive Vice Chancellor delegates responsibility for responding to allegations of research misconduct to the Research Integrity Officer, who shall be responsible for the following:

- securing the necessary and appropriate level of expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation;
- taking precautions to ensure impartiality of those involved in the inquiry or investigation;
- defining the scope of the investigation in accordance with the terms of this regulation, any applicable KUMC rules, and any applicable state or federal laws;
- preparing and maintaining all documentation gathered or generated during the inquiry and investigation;
- in the case of research conducted with outside funds, taking timely and appropriate interim administrative actions to protect the funds and ensure that the purpose of the funding is carried out;
- notifying sponsors about the status of investigations in accordance with the applicable rules and regulations of the funding entity; and,
- when required, notifying appropriate outside entities of the outcome of an inquiry or investigation.

Timelines. KUMC shall respond immediately to an allegation or other evidence of possible research misconduct.

- An inquiry shall be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period. Timelines for the inquiry stage of this procedure may be extended by the EVC at his/her discretion, or upon written request from the complainant or respondent to the Research Integrity Officer.
- An investigation shall commence within 30 calendar days after finalization of the inquiry report, and shall be completed within 90 calendar days of its initiation. This includes conducting the investigation, preparing the report of findings, making the report available for comment by the respondent, imposing recommended corrective actions, and submitting the report to funding agencies as required by regulation or statute.

Extensions of investigative timelines must be authorized by the funding agency; when no funding agency is involved, timelines may be extended by the EVC at his/her discretion, or upon written request from the complainant or respondent to the Research Integrity Officer. The Research Integrity Officer or designee shall inform all parties when timeline extensions are made in either the inquiry or investigation procedure.

Filing. Anyone having reason to believe that a faculty, staff member or student has violated KUMC's policy governing research misconduct should immediately report the matter to the Research Integrity Officer or the KUMC Compliance Hotline. This report is assumed to be a "good faith allegation."

An allegation may also be initiated by the Research Integrity Officer in response to the following:

- compliance committee proceedings
- notifications from school deans, department chairs, or center directors
- direct observations of the research record in which potential research misconduct is identified
- any information which is sufficiently credible to justify such an inquiry

Whistleblower and Complainant Protection. Institutional representatives who receive or learn of an allegation of research misconduct will treat the whistleblower or complainant with fairness and respect, and when the allegation has been made in good faith, will take reasonable steps to protect the position and reputation of the individual who reports, and other individuals who cooperate with the institution against retaliation. KUMC employees will immediately report any alleged or apparent retaliation to the Research Integrity Officer.

Respondent Protection. KUMC employees who receive or learn of an allegation of research misconduct will treat the respondent with fairness and respect, and will take reasonable steps to ensure that the safeguards in these procedures are followed. The

Research Integrity Officer will report any allegation not made in good faith to the Deciding Official for appropriate action.

Preliminary Assessment of Allegations. Upon receiving an allegation of research misconduct, the Research Integrity Officer will immediately assess the allegation to determine if PHS support or PHS applications for funding are involved, if the allegation falls under the PHS definition of research misconduct, if there is sufficient evidence to warrant an inquiry, and if referral is appropriate.

- *PHS Support.* Allegations involving research supported by PHS-funded grants, contracts, or cooperative agreements, or applications for PHS funding connote PHS support. If the allegation does not involve PHS support, it will be handled under KUMC's own definition of research misconduct and procedures without regard to the PHS regulation at 42 C.F.R. Part 50, Subpart A.
- *PHS Definition.* The allegation will be carefully reviewed to determine whether it potentially constitutes fabrication, falsification, plagiarism, or other serious deviation from commonly accepted practices for proposing, conducting, or reporting research. In case of doubt, the Research Integrity Officer will consult with KUMC Legal Counsel and/or ORI on whether the allegation falls within the PHS definition of scientific misconduct.
- *Sufficient Evidence to Proceed.* There is not always sufficient evidence or information to permit further inquiry into the allegation. For example, an allegation that a researcher's work should be subjected to general examination for possible misconduct is not sufficiently substantial or specific to initiate an inquiry. In case of such a vague allegation, the Research Integrity Officer shall obtain more information before initiating an inquiry. This information may be sought from any reasonable source, including the whistleblower or complainant, if known.
- *Referral of Other Issues.* Regardless of whether it is determined that a research misconduct inquiry is warranted, if the allegation involves PHS support and concerns possible failure to protect human or animal subjects, financial irregularities, or criminal activity, the allegation shall be referred to the appropriate PHS or DHHS office.

Sequestration of Records. The Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately secured. The Research Integrity Officer may consult with KUMC Legal Counsel and/or ORI for advice and assistance in this regard.

### **Inquiry Process**

- The respondent will be informed that an inquiry has been initiated within five working days after the inquiry has begun.
- The Research Integrity Officer or a duly appointed designee shall conduct the inquiry. The services of other individuals and entities may be utilized in order to make a complete inquiry as to whether evidence exists which would warrant an

investigation. Such individuals may be required to sign a confidentiality agreement if they are not already bound by such an agreement.

- The Research Integrity Officer or designee shall prepare a written report stating what evidence was reviewed, summarizing relevant interviews, and including any conclusions reached as a result of the inquiry. The respondent shall be given a copy of the inquiry report. If the respondent chooses to comment on the report, s/he must submit a written response to the Research Integrity Officer within five working days after receiving the report in order for it to be made a part of the record.
- If it is determined that an investigation is not warranted, all parties will be notified in writing. This decision may not be appealed internally.
- If it is determined that an investigation is needed, the Research Integrity Officer shall notify the Executive Vice Chancellor, appropriate funding and oversight agencies, KUMC Legal Counsel, and the appropriate Dean and Department Chair or Center Director before proceeding to the investigation procedure.

## **Investigation**

- The EVC or designee shall notify the complainant and respondent in writing that an investigation is being commenced. The notice shall indicate upon what grounds the determination was made, and will include a copy of any applicable policies or procedures.
- The investigation shall be conducted by the Research Integrity Officer or duly appointed designee. The Research Integrity Office may convene a committee to assist in the investigative process depending on the nature of the issue, and the expertise base required to capably evaluate the allegations.
- Should an investigative committee be convened, it shall have no less than three members, at least one of whom is a faculty member in the same discipline as the respondent (in the case of faculty members), a staff member whose discipline and job responsibilities are substantially similar to those of the respondent (in the case of staff members), a post-doctoral fellow (in the case of post-doctoral fellow), or a student or resident (in the case of students or residents). Committee members shall be selected for their expertise, their ability to ensure fairness throughout all phases of the investigation, and absence of unresolved conflicts of interest. Committee members shall sign a confidentiality agreement, and all individuals involved in conducting the investigation shall ensure fairness and protect the rights of all parties to the greatest extent possible.
- The investigation normally will include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews will be conducted with all individuals making the allegation, all respondents, and

other individuals who are determined to have relevant information regarding key aspects of the allegations.

*Witness Interviews.* Witness interviews may be recorded during the course of the investigation, and transcripts of recorded testimony shall be made when deemed appropriate by the Research Integrity Officer.

*Representation.* The respondent may be accompanied by counsel of his or her own choosing. Counsel may advise the respondent, but may not question witnesses or otherwise take part in the proceedings.

*Testimony.* As far as reasonably possible, witnesses shall be allowed to give narrative testimony, but shall also be required to answer specific questions from the Research Integrity Officer, designee, or committee member.

*Written Report.* Upon completion of the investigation, the Research Integrity Officer or designee shall prepare a written report stating what evidence was reviewed, summarizing relevant interviews, and including any conclusions reached as a result of the investigation. A finding of federally reportable research misconduct requires that: (a) there be a significant departure from accepted practices of the relevant research community; (b) the misconduct be committed intentionally, knowingly, or recklessly; and (c) the allegation be established by a preponderance of the evidence.

The investigative report shall also recommend an administrative response which may include sanctions, corrective actions or other institutional measures. The respondent shall be given a copy of the investigative report. If the respondent chooses to comment on the report within five working days after receiving the report, his or her comments shall be made a part of the record. The report shall be provided to the Executive Vice Chancellor, appropriate funding agencies, KUMC Legal Counsel, and the appropriate Dean and Department Chair or Center Director.

Within 15 calendar days after receiving the investigative report, the Deciding Official (DO) shall render a written decision regarding the recommended administrative response(s). The DO shall either accept all recommendations (with or without modification), or reject the recommendations and instruct the Research Integrity Officer to meet with appropriate institutional officials to consider alternative administrative responses.

*Corrective Actions.* Corrective actions for findings of research misconduct shall be based on the seriousness of the misconduct, including, but not limited to, the degree to which the misconduct: a) was intentional, knowing, or reckless; b) was an isolated event or part of a pattern; and c) had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare. The range of corrective actions includes, but is not limited to, termination, expulsion, suspension, leave without pay, letters of reprimand, and suspension or termination of an active award.

*Criminal or Civil Violations.* In the case of criminal or civil fraud violations, the DO shall ensure that the matter is referred promptly to the Department of Justice, the Inspector General for the funding agency, or other appropriate body.

*Appeal and Adjudication of Corrective Actions and Non-Punitive Measures:* If the administrative response results only in the imposition of corrective actions or non-punitive measures, the decision of the DO shall be final.

### **Adjudication Procedure**

If the administrative response results in termination or other adverse change in an employee's terms and conditions of employment, the respondent may appeal the decision through the appropriate procedure contained in the Faculty Unclassified Handbook. If the administrative response results in expulsion or suspension of a student or punitive action for a resident, the respondent may appeal the decision in accordance with applicable procedures maintained by the Dean of Students or the Office of Graduate Medical Education.

### **Institutional Notification of the Funding Agency**

KUMC is required to notify the funding agency (or agencies in some cases) of an allegation of research misconduct when: a) it involves Federally funded research or a proposal for Federal funding and meets the Federal definition of research misconduct; and, b) if the institution's inquiry determines there is sufficient evidence to proceed to an investigation.

Upon completion of the investigation, the Research Integrity Officer will forward to the appropriate funding agency a copy of the evidentiary record, the investigative report, recommendations made to the institution's adjudicating official, and the subject's written response to the recommendations (if any).

Upon completion of the adjudication phase, the Research Integrity Officer will forward the DO's official's decision and notify the agency of any corrective actions taken or planned.

At any time during an inquiry or investigation, the Research Integrity Officer will immediately notify the Federal agency if any of the following conditions exist:

- public health or safety is at risk
- agency resources or interests are threatened
- research activities should be suspended
- there is reasonable indication of possible violations of civil or criminal law
- Federal action is required to protect the interests of those involved in the investigation

- KUMC believes the inquiry or investigation may be made public prematurely, and needs to take appropriate steps to safeguard evidence and protect the rights of those involved
- if the research community or public should be informed.

When more than one agency is involved, a lead agency may be designated to coordinate responses to allegations of research misconduct; however, each agency is empowered to implement administrative actions in accordance with applicable laws, regulations, policies, or contractual procedures.

Retention and Custody of Records. The Research Integrity Officer is delegated responsibility for preparing and maintaining all documentation gathered or generated during the inquiry and investigation. Documentation of an inquiry that was not followed by an investigation shall be sufficiently detailed to permit a later assessment of the reasons for determining that an investigation was not warranted. All records shall be maintained in a secure manner for at least seven years after completion of KUMC proceedings, or the completion of any PHS proceeding, whichever is later [42 CFR Part 93.317, proposed 4/16/04].

Procedural Changes and Amendments. Changes in this procedure may be made at any time by the Research Integrity Officer in consultation with the EVC, the Research Advisory Council, and Legal Counsel in response to shifts in federal research misconduct regulations or guidelines. These changes will be reflected on KUMC's official research compliance web-site within 7 working days after they occur.

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