

EASTERN VIRGINIA MEDICAL SCHOOL

GUIDE FOR SCIENTIFIC MISCONDUCT

**Revised: March, 2013
Office of Research, EVMS**

The Scientific Misconduct Guide has been revised in accordance with Public Health Service Guideline established in 42 CFR Parts 50 and 93, Federal Register, May 17, 2005. An assurance, which affirms that policies and procedures are in place for dealing with allegations of Public Health Service (PHS) sponsored biomedical and behavioral research, is updated annually and submitted to the Office of Research Integrity (ORI). ORI oversees and directs the PHS research integrity effort, with the exception of the regulatory research authorities of the Food and Drug Administration (FDA).

Eastern Virginia Medical School *Scientific Misconduct Guide*

The following policies and procedures have been established as a way to deal fairly, expeditiously, and effectively with all allegations or evidence of scientific misconduct and as a mechanism to maintain and promote integrity in the research environment at EVMS. The intent is not to create an atmosphere of oppressive regulation, but to assure careful, confidential, and thorough handling of allegations of misconduct.

It is expected that all authors named on a collaborative study accept full responsibility for their work, including their conduct of research at EVMS and the work they publish. It is the role of the Principal Investigator to ensure that laboratory personnel are familiar with this Scientific Misconduct Guide.

Process for Handling Allegations of Misconduct

1. It is the responsibility of an Investigator's technician, peers, or others involved in the research community, to bring to the attention of an Investigator's immediate supervisor documented or well-founded suspicions of possible scientific misconduct. The term "scientific misconduct" as used in this Guide is defined as falsification, fabrication, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Misconduct does not include honest error or differences of opinion.
2. The Investigator's immediate supervisor should then notify the appropriate Department Chairman, Associate Dean for Research, and the Dean or designee of the Medical School of the allegation. An immediate inquiry of the allegation shall take place. "Inquiry" as used in this Guide is defined as information gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation. During the course of the inquiry, the Chairman, Associate Dean for Research, and Dean or designee will meet with the accused Investigator and, separately with the individual making the allegation of scientific misconduct, to determine if, in fact, there is any basis to the allegation which warrants an investigation. Strict confidentiality will be maintained during this process. The privacy of those who, in good faith, report apparent misconduct and those accused of possible misconduct will be protected. **The inquiry must be completed within 60 calendar days of its initiation** unless circumstances clearly warrant a longer period. A written report shall be prepared which includes evidence that was reviewed, summaries of relevant interviews, and the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of the inquiry. If they comment on that report, their comments may be made part of the record. 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.

- a. A written report of the inquiry findings will be securely maintained in the Office of Research for at least three (3) years after the termination of the inquiry, and shall, upon request, be provided to authorized HHS personnel.
3. If the conclusions of the inquiry are that there is no sufficient basis for conducting an investigation as hereinafter defined, the Chairman will so notify the Investigator. In addition, the Chairman, Associate Dean for Research, and Dean or designee will attempt to determine if there was a malicious or dishonest intent behind the initial allegation of misconduct and, if found, appropriate actions will be taken. If the institution determines that an investigation is not warranted, the reasons for the decision and the findings of the inquiry will be documented in sufficient detail to permit later assessment of the decision, if necessary. Diligent efforts will be undertaken, as appropriate, to restore the reputations of person(s) alleged to have engaged in misconduct when allegations are not confirmed.
4. If the findings of the inquiry indicate that there is sufficient basis for conducting an investigation, the Associate Dean for Research will officially notify in writing the accused Investigator, appropriate co-investigators, appropriate external agencies, and if PHS research is involved, the Office of Research Integrity (ORI), that certain allegations of misconduct have been made concerning the accused Investigator's research and that a formal investigation is warranted and is being initiated. This notification will take place on or before the date the investigation begins. The notification to ORI will include the name of the person(s) against whom the allegations have been made, the general nature of the allegations, and the PHS application or grant number(s) involved. The term "investigation" as used herein shall be defined as the formal examination and evaluation of all relevant facts to determine if misconduct has occurred. This investigation will begin within thirty (30) days after completion of the inquiry. During the inquiry and/or the investigation, interim administrative actions may be taken by the Associate Dean for Research, as appropriate, to protect federal or other research funds and to ensure that the purposes of the federal or other financial assistance are carried out and generally to protect the interests of the institution and the public.
5. The Associate Dean for Research will establish a five (5) member *ad hoc* Review Panel composed of four (4) professorial level faculty members from EVMS and one (1) professorial level faculty member from another institution to conduct the investigation. All members of the Review Panel will possess appropriate scientific expertise to assure a sound knowledge base from which to work. The Review Panel is authorized to secure, if necessary, any additional expertise to carry out a thorough and authoritative evaluation of the relevant evidence in the inquiry or the investigation. Precautions should be taken against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation and to ensure that the members of the Review Panel do not have any personal involvement in the work to be investigated. Confidentiality must be maintained throughout the process, and the privacy of those reporting the apparent misconduct and those accused of misconduct must be protected. ORI will be promptly advised of any development

during the course of the investigation which discloses facts that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of federal funds and otherwise protect the public interest.

6. The Review Panel, during the course of the investigation, will be charged with the responsibility of determining whether or not the allegations of scientific misconduct on the part of the accused Investigator are substantiated. It will perform its investigation by reviewing the data that the Review Panel may request and by investigating the matter with both the accused Investigator and the accuser. The investigation normally will include examination of all documentation, including but not limited to, relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved, whether in making the allegation or to whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegation. Complete written summaries of these interviews should be prepared and provided to the interviewed party for comment or revision, and be included as part of the investigation file. During the investigation, the accused Investigator will have the right to receive, review and file written comments regarding all documentation and summaries to be considered by the Review Panel, all of which shall be made a part of the record of the investigation. The findings and conclusions reached by the Review Panel, together with all documentation substantiating such findings, will be reported to the Associate Dean for Research in writing as soon as possible, consistent with a thorough review process, but not later than 120 days from its initiation, unless extended. The findings of the Review Panel shall also be reported to the accused Investigator with the opportunity afforded to comment on the allegations and findings. The findings must also be reported to ORI, if PHS research is involved, and the final report must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by the institution.
7. If the Review Panel finds that the allegation of misconduct against the accused Investigator is not confirmed, the Associate Dean for Research will officially notify in writing the Investigator, appropriate co-investigators, the department chairman, the funding agencies, and ORI, if necessary. Diligent efforts will be made to restore fully the reputation of the person(s) alleged to have engaged in misconduct. Additionally, the Associate Dean for Research will request the Review Panel to investigate the basis for the initial charges. Following the submission of a written report by the Review Panel, appropriate action will be taken against any, and all, accusers whose involvement in the initial charges can be demonstrated to have been malicious or intentionally dishonest. With regard to both the inquiry and the investigation, diligent efforts will be undertaken to protect the positions and reputations of those persons who, in good faith, make an allegation.

8. If the Review Panel finds that the accusation of scientific misconduct against the accused Investigator is substantiated by its investigation, the Associate Dean for Research will notify in writing the Investigator, the sponsors of the Investigator's work, and those agencies previously notified, of the Review Panel's findings. Pending abstracts and papers that resulted from the work under question should be withdrawn. Editors of journals in which previous abstracts and papers relating to work in question will also be notified. The actions of the accused Investigator should be considered a breach of contract with the institution as delineated in the yearly letter of appointment from the President of Eastern Virginia Medical School ("EVMS"), and the appropriate action will be taken, together with the imposition of any other sanctions as the Review Panel may feel appropriate under the circumstances.
9. The investigation should ordinarily be completed within 120 days of its initiation. The 120 days include conducting the investigation, preparing the report of findings, making the report available for comments by subjects of the investigation, and submitting the report to ORI, if PHS research is involved. A written request for an extension, if PHS research is involved, must be submitted to ORI when it appears that an investigation cannot be completed within 120 days. Accompanying this extension request to ORI, must be an explanation for the delay that includes an interim report on the progress-to-date and an estimate for the date of completion of the report and other necessary steps. Any consideration for an extension must balance the need for a thorough and rigorous examination of the facts versus the interest of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted by ORI, the Review Panel must file periodic progress reports as requested by ORI. If satisfactory progress is not made in the Review Panel's investigation, ORI may undertake an investigation of its own. Records of the investigation will be maintained in a secure manner in the Office of Research for a period of at least three (3) years after the termination of the investigation. The records may be provided to authorized Department of Health and Human Services personnel upon request.
10. If an inquiry or a later investigation involving PHS research is planned to be terminated for any reason without completing all relevant requirements as set forth above, a report of such planned termination, including a description of the reasons for such termination, shall be made to ORI which will then decide whether further investigation should be undertaken.
11. Within fifteen (15) days following receipt of the Review Panel's complete report by the accused Investigator, a written appeal may be filed by the accused Investigator to the Review Panel's final decision and report. The appeal is to be filed with the Associate Dean for Research and should be restricted and limited to the body of evidence already presented. The grounds for appeal should be limited to failure to follow appropriate procedures in the inquiry or in the investigation or on the basis of arbitrary and capricious decision making by the Review Panel. Newly discovered

evidence not available to the accused Investigator during the course of the inquiry and the investigation may warrant grounds for the initiation of a new investigation of the allegations of misconduct.

12. A Vice President or an Associate Dean of EVMS, who has not been involved in any way in the inquiry or investigation or the work under investigation, will hear and decide the appeal. After this appeal is concluded, a final review shall be made by the President of EVMS, if requested by the accused Investigator, within ten (10) days after receipt of the decision or appeal. The decision of this review is final and the President shall implement all decisions made upon his final review.

Office of Research Integrity (ORI)

While the primary responsibility for conducting inquiries and investigations of all allegations of scientific misconduct lies with the institution, the U.S. Department of Health and Human Services (HHS) reserves the right, where such allegations involve PHS research, to perform its own investigation any time prior to, during, or following the institution's inquiry and investigation, and to monitor and be involved in the institution's inquiry and investigation of such allegations through ORI.

In addition to sanctions EVMS may impose, the HHS also may pose sanctions of its own upon investigators or the institution, if such action is deemed appropriate.

The institution is also responsible for notifying ORI if it ascertains at any stage of the inquiry or investigation, that any of the following exist:

1. There is an immediate health hazard involved;
2. There is an immediate need to protect federal funds or equipment;
3. There is an immediate need to protect the interest of the person(s) making the allegation or of the individual(s) who is the subject of the allegation as well as his/her co-investigators and associates if any;
4. It is probable that the alleged incident is going to be reported publicly; and
5. There is reasonable indication of possible criminal violation. In that instance, the institution must inform ORI within 24 hours of obtaining that information. ORI will immediately notify the Office of the Inspector General.