

The MetroHealth System

Policy: I-47

Subject: Misconduct in Research

- I. POLICY: The MetroHealth System recognizes its obligation for maintaining the integrity and quality of all scientific programs for which it has direct responsibility. This includes the availability of a process for receiving, investigating, and reporting suspected incidents of misconduct in science related to research, research training, applications for research or research training, or related activities. The System provides an impartial, internal and investigative component for responding expediently, comprehensively and fairly to all such allegations and reports. This process assures compliance with Subpart A to 42 CFR part 50 of the Public Health Services Act, and protects the rights and reputations of all individuals involved, respecting both their confidential entitlements and the public's best interests.
- II. PURPOSE: The purpose of this policy is to establish a formal process that will safeguard the scientific integrity of all biological and human research programs conducted under the responsibility of The MetroHealth System. This process will assure that the System has in-place a method for preventing, detecting, investigating, reporting and resolving allegations of scientific misconduct.
- III. SCOPE: The procedures set forth in this policy apply to all staff of The MetroHealth System and other persons associated with the System who use its resources in responding to and fulfilling an external funding source's requirements for a contract/grant.
- IV. DEFINITION: Research misconduct is defined as fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up results and recording or reporting them. 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. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit,

including those obtained through confidential review of others' research proposals and manuscripts. Research misconduct does not include honest error or honest differences of opinion.

V. PROCEDURE

- A. Responsibility: The MetroHealth System's Vice President for Research will be responsible for handling all inquiries, allegations, investigations, reports and follow-up in all instances involving misconduct in science. All such allegations should be forwarded directly to the Vice President for Research who will be responsible for initiating appropriate action as required to satisfactorily investigate the situation. The Vice President for Research has the duty to protect the rights and reputation of all individuals, including those persons alleged to have engaged in the misconduct and those who have made the allegation. All involved individuals will have equal opportunity to review the case confidentially with the Vice President for Research or his designee. If early findings indicate that the research may be in question, the Vice President for Research must inform the primary party in charge of the research and keep them current on all subsequent developments.
- B. Inquiries, Investigations - Specific Requirements
1. All allegations must be inquired upon within 5 days from receipt and all inquiries must be completed within 60 calendar days of its initiation unless unusual circumstances require a longer period. A written report shall be prepared that identifies what evidence was reviewed, summarizes relevant interview, and includes the conclusions of the inquiry. A copy of the report will be given to the individual(s) against whom the allegation was made. Their response to the conclusions may be part of the record if they so choose. If an inquiry is not completed within 60 days, the report must document the reasons why it was delayed.

2. The investigative and reporting functions must protect to the maximum extent possible, the privacy of those who reported the alleged misconduct.
3. The process must provide confidential treatment to all affected individuals. Investigations must be prompt, thorough and allow opportunity for comment on allegations and findings.
4. If the initial inquiry warrants an investigation, the Vice President for Research will prepare and forward a notification to the Office of the Inspector General (OIG), a component of the National Institutes for Health when federal research grants are involved.
5. If any reasonable indication of possible criminal violations is found, the OIG must be notified within 24 hours.
6. The Vice President for Research shall maintain sufficient documentation of all inquiries for three years after the termination of the inquiry.
7. If findings from an inquiry warrant an investigation, the Vice President for Research shall appoint a committee to undertake the investigation within 30 days from the completion of the inquiry. The investigation should include interviews with all involved individuals, and examination of all relevant documentation. Summaries of all interviews should be kept and provided to the interviewed party for comment and revision and should be part of the investigator file.
8. The Vice President for Research will be responsible for securing appropriate expertise to perform thorough inquiries and investigations.

9. The Vice President for Research will take precautions against conflicts of interest on the part of the involved individuals and the investigative party.
10. The Vice President for Research is responsible for preparing and maintaining documentation to substantiate the investigation's findings. This documentation will be provided to the Director of the Office of Research Integrity (ORI), HHS and the OIG, who will determine to either proceed with its own investigation or act on the findings.
11. The Vice President for Research will take interim administrative action to protect Federal funds and insure that the purpose of the Federal financial assistance is carried out. The Vice President for Research may require the assistance of the Executive Vice President or the Chief Executive Officer.
12. The Vice President for Research will keep the ORI and the OIG apprised of all developments during an investigation that may affect current or potential Department of Health and Human Services funding for the individuals under investigation or that the Public Health Service (PHS) needs to know to ensure appropriate use of federal funds.
13. The Vice President for Research will assure that appropriate and diligent steps are taken to restore the reputations of persons alleged to have engaged in misconduct when such allegations could not be confirmed. The committee must also assure that equally diligent efforts are made to protect the positions and reputations of those who make allegations in good faith.
14. When an allegation has been substantiated, the Vice President for Research will recommend appropriate sanctions to the Chief Executive Officer. The Chief Executive Office or his designee shall be responsible for final determination and application of sanctions.

15. The Vice President for Research will be responsible for notifying the ORI of the final outcome of all investigations.

C. Reporting Requirements

1. A decision to initiate an investigation must be reported to the Director, ORI and the OIG, on or before the investigation begins. The notification must include the name(s) of the person(s) against whom the allegation was made, the nature of the allegation, and the PHS application or grant involved.
2. An investigation should be completed within 120 days, which includes preparing the report of findings, making the report available to all subjects of the investigation, and submitting the report to the ORI.
3. If the Vice President for Research has determined to terminate an investigation for any reason, they must prepare and forward a report to the ORI explaining the reason for termination.
4. The final report must describe the policies and procedures under which the investigation was conducted, how information was obtained, from whom information was obtained, findings and basis, summary of the views of each person alleged to have contributed to the misconduct, and the sanctions taken by the MetroHealth System.
5. If the investigation will not be completed within 120 days, the Vice President for Research must submit an interim report to the ORI explaining the reasons for the delay and the current status of the investigation. They must also identify the date when the investigation and final report will be completed.
6. If the ORI requires further clarification and investigation beyond the final report, the Vice President for Research will comply.

7. At any stage of the inquiry or investigation, the ORI must be informed if any of the following conditions exist.
 - 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 person making the allegation or the person alleged to have caused the misconduct.
 - d) It is probable that the alleged incident will be reported publicly.
 - e) There is reasonable indication of possible criminal violation. If this is indicated, the ORI must be informed within 24 hours.

VI. DATES

- A. Initiated: January 17, 1990
- B. Reviewed/Revised:
 1. October 1996
 2. February 2000

VII. APPROVED

Terry R. White
President and
Chief Executive Officer

Melinda L. Estes, M.D.
Executive Vice President/
Chief of Staff