

**Hennepin Healthcare Research Institute  
Administrative Policies and Procedures  
for Dealing with Misconduct in Science**

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**INTRODUCTION**

Fraud in research and other scholarly activities undermines the scientific enterprise in ways that go far beyond the waste of public funds. Although a rare event relative to the large scientific literature, occasional violations inevitably appear in this as in all human pursuits. As a leading research institution, the Hennepin Healthcare Research Institute (HHRI) and its parent organization, Hennepin County Medical Center (HCMC), have a major responsibility, not only to provide an environment that promotes integrity, but also to establish and enforce policies and procedures that deal effectively with allegations or evidence of fraud.

HCMC and its research foundation, HHRI, expect the utmost of professionalism from their employees at all times and in all circumstances. Employees may not engage in actions which constitute fraud in research or other scholarly activities. The scholarly and research community are totally committed to the principles of this policy.

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 heavy regulation. Moreover, it is particularly important to distinguish fraud from honest error and the ambiguities of interpretation that are inherent in the scientific process and are normally corrected by further research.

If an allegation is raised, HCMC and HHRI have the following procedures: (I) to initiate an inquiry to determine whether the allegation or related issues warrant further formal investigation; (II) when warranted by the initial inquiry, to initiate a formal investigation to collect and thoroughly examine evidence; (III) to provide a formal written report detailing the findings of the inquiry/investigation; and (IV) to recommend appropriate disposition of the matter. Throughout these four stages, HCMC and HHRI shall be guided by the following principles:

- HCMC and HHRI shall take care that the process pursued to resolve allegations of fraud does not damage science itself.
- HCMC and HHRI shall provide vigorous leadership in the pursuit and resolution of all charges.
- HCMC and HHRI shall strive to treat all parties with justice and fairness and shall be sensitive to their reputations and vulnerabilities.
- HCMC and HHRI procedures shall strive to preserve the highest attainable degree of confidentiality, compatible with an effective and efficient response and the need to protect public safety and health.
- The integrity of HCMC and HHRI processes shall be maintained by painstaking avoidance of real or apparent conflicts of interest.

- HCMC and HHRI procedures shall be as expeditious as possible, and the resolution of charges shall be completed in a timely manner.
- HCMC and HHRI shall document the pertinent facts and actions at each stage.
- HCMC and HHRI shall recognize and discharge its responsibilities after resolving allegations of scientific misconduct -- internally, to individuals involved; and externally, to the public, sponsors of research, the scientific literature, and the scientific community, to the extent that is appropriate and allowable.
- HCMC and HHRI shall also: (1) provide education about scientific misconduct; (2) interpret the HCMC and HHRI policy on scientific misconduct; (3) counsel faculty and staff; and (4) disseminate the policy.

## **APPLICATION**

The policy and procedures set forth herein shall apply to all HCMC and HHRI employees and members engaged in research and other scholarly activities under the aegis of HHRI. Copies of this policy and procedures will be provided to all HCMC and HHRI employees as part of their employment information. All investigators conducting research under the auspices of HHRI and their staff will receive written notification and be required to sign to the effect that they have read and understood the policy and procedures.

## **DEFINITION OF SCIENTIFIC MISCONDUCT**

Scientific misconduct is an act of deception. It is different from those factors intrinsic to the process of science, such as honest error, conflicting data, or differences in interpretation or judgments about data. The term scientific misconduct is used here to include a broad range of deceptive practices, including the following:

1. Falsification of Data -- ranging from fabrication to deceptively selecting and reporting, including the purposeful omission of conflicting data with the intent to falsify results.
2. Plagiarism -- representation of another's work as one's own.
3. Other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research including, for example, the misappropriation of others' ideas -- unauthorized use of privileged information (such as violation of confidentiality in peer review), however obtained.

## **Process for Handling Allegations of Scientific Misconduct**

### **GENERAL PRINCIPLES**

The responsibility to pursue an allegation of scientific misconduct belongs to HCMC and HHRI and shall be carried out fully to resolve questions regarding integrity of the research. Even in the absence of a specific complaint, HCMC and HHRI shall be alert to questionable academic conduct that might raise legitimate suspicion of fraudulent research. In an inquiry and any investigation which may follow, HCMC and HHRI shall focus on the substance of the issues and shall be vigilant not to permit any personal conflicts between colleagues to obscure the facts.

In order to address all allegations of research misconduct expeditiously, HCMC and HHRI shall designate a committee of senior administrators to whom allegations shall be reported; ordinarily, the President of HHRI and the Chief of the investigator's primary department will be the designees. The Chairman of the Board of HCMC, the Foundation's parent organization, will be the third senior person involved with evaluation and allegations. If any of these individuals has a conflict of interest with the case, the Medical Director of Hennepin County Medical Center will substitute for that individual. These three senior administrators will pursue all allegations to resolution.

The President will counsel confidentially any individual who comes forward with an allegation of scientific misconduct and will determine whether the allegation falls within the scope of the misconduct policies and procedures. Regardless of the nature of the concern, the President will seek to assist in the resolution of the allegation through whatever institutional processes are appropriate. If the President determines that the concern is properly addressed by the policies and procedures set forth herein, specific policies and procedures relating to the inquiry and investigation will be discussed with the individual who has questions about the integrity of a research project. Once these discussions are completed, the committee of senior administrators as outlined above will be convened. If the individual chooses not to make a formal allegation, but the President believes there is sufficient cause to warrant an inquiry, the matter shall be pursued by the President in consultation with the committee members outlined above. Even if the respondent leaves the Foundation before the case is resolved, HCMC and HHRI have a responsibility to continue the examination of the allegations and reach a conclusion. Further, HCMC and HHRI shall cooperate with another institution's process to resolve such questions.

The Foundation will secure the necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation. As appropriate, the Foundation will take interim administrative actions to protect both Federal and non-Federal funds and to insure that the purposes of the Federal financial assistance are carried out.

The Foundation will strive to carry its investigations through to completion and to pursue diligently all significant issues. If it plans to terminate an inquiry or investigation involving any Public Health Service (PHS) related research for any reason without completing all the requirements identified in Title 42, Subchapter D of the Code of Federal Regulations, Section 50.103 (d), it shall make a report of such planned termination, including a description of the reasons for such termination, to the OSI, which will then decide whether further investigation should be undertaken.

The Foundation will notify the OSI if it ascertains at any stage of an inquiry or investigation involving PHS-related research that any of the following conditions 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 interests of 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;
4. It is probably that the alleged incident is going to be reported publicly; and
5. There is a reasonable indication of possible criminal violation. In this instance, the Foundation will inform the OSI within 24 hours of obtaining such information. The OSI will immediately notify the Office of the Inspector General.

Additionally, the Foundation recognizes the right of the Department of Health and Human Services to perform its own investigation at any time prior to, during, or following the Foundation's investigation.

## **I. INQUIRY**

### **A. Purpose**

Whenever an allegation or a complaint involving the possibility of scientific misconduct or fraud is made, the President of HHRI in consultation with the Chief of the relevant Department and the Chairman of the HCMC Board of Governors shall initiate an inquiry - the first step of the review process. In the inquiry stage, factual information is gathered and expeditiously reviewed to determine if any investigation of the charge is warranted. An inquiry is not a formal hearing; it is designed to separate allegations deserving of further investigation from frivolous, unjustified, or clearly mistaken allegations.

### **B. Structure**

The inquiry will be handled by a formal committee. Ordinarily, this will be constituted by the President of HHRI, the HCMC Board of Governors, and the Medical Director of Hennepin County Medical Center. In addition, the investigator's primary department Chief will function as an ex officio and non-voting member. In the situation that any of these individuals has a conflict of interest with the case, that individual will designate the next administratively responsible individual from that organization to membership on this committee. It is the responsibility of the committee to ensure that the inquiry is conducted in a fair and just manner. Additional individuals may be chosen to assist in the inquiry process, but they shall have no conflicts of interest with the case in question, be unbiased, and have appropriate backgrounds for judging the issues being raised. The President of HHRI shall be responsible for coordinating the activities of this committee.

HCMC/HHRI's Legal Counsel shall be consulted to minimize the risk of liability for actions taken in the conduct of the inquiry and investigation.

### C. Process

Upon initiation of an inquiry, the committee is responsible for notifying the respondent within a reasonable time of the charges and the process that will follow. If a larger committee is to be used the committee members shall be appointed and convened promptly.

Whether a case can be reviewed effectively without the involvement of a complainant depends upon the nature of the allegation and the evidence available. Cases that depend specifically upon the observations or statements of a complainant cannot proceed without the open involvement of that individual; other cases that can rely on documentary evidence may permit a complainant to remain anonymous. While it may be desirable to keep the identity of a complainant confidential during an inquiry, the Minnesota Data Practices Act and amendments may make such confidentiality impossible. During an inquiry, confidentiality is desirable in order to protect the rights of all parties involved.

The President shall assume responsibility for disseminating the information to the appropriate individuals. Notification normally shall be made in writing, and copies shall be filed in the Office of the President. The safety and security of all documents shall be assured.

When an inquiry is initiated, the respondent shall be reminded of the obligation to cooperate in providing the material necessary to conduct the inquiry. Uncooperative behavior is unacceptable and may result in immediate implementation of a formal investigation and appropriate HCMC/HHRI sanctions.

Due to the sensitive and serious nature of an allegation of scientific misconduct or fraud, each case shall be resolved expeditiously. Reasonable deadlines shall be established for each case to facilitate the process. An inquiry normally shall be completed and a written report of the findings shall be filed within 60 days of initiation of the inquiry. If the committee cannot meet the established deadlines, a report, citing the reasons for the delay and progress to date, shall be submitted for the record, and the respondent and appropriately involved other individuals shall be informed.

### D. Findings of the Inquiry

The completion of an inquiry is marked by a determination of whether or not a formal investigation is warranted. There shall be written documentation to summarize the process, including the evidence reviewed and relevant interviews, and conclusion 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 the report, their comments may be part of the record. The complainant also shall be informed by the President whether or not the complainant's allegations will be subject to further investigation.

If the initial inquiry of the committee finds that the allegations are of substance and require a Formal Investigation (Section II), the agency sponsoring the research shall be notified at this point. In the case of research, research-training, or research-related grant or cooperative agreement funding obtained through any Public Health Service agency, the Director of the Office of Scientific Integrity (OSI) shall be informed in

writing that an investigation is warranted. This shall be done on or before the date the investigation begins. At a minimum, the notification of a formal investigation shall include the name of the person(s) against whom the allegations have been made, the general nature of the allegation and the Public Health Service application or grant number(s) involved. If a reasonable indication of possible criminal violations is obtained, the OSI shall be notified within 24 hours of this determination.

If an allegation is found to be unsupported but has been submitted in good faith, no further formal action, other than informing all parties involved, shall be taken. The proceedings of an inquiry, including the identify of the respondent, shall be held in strict confidence to protect the parties involved. However, sufficiently detailed documentation of this inquiry shall be maintained in a secure manner for a period of at least three years after termination of the inquiry and shall, upon request, be provided to authorized Department of Health and Human Services personnel. If confidentiality is breached, HCMC and HHRI shall take reasonable steps to minimize the damage to reputations that may result from inaccurate reports. Allegations that have not been brought in good faith may lead to appropriate disciplinary action. Complainants shall be made aware from the outset that their confidentiality will not be maintained if a complaint is maliciously motivated and false.

Where a complaint has been brought in good faith, even if mistakenly, HCMC and HHRI shall seek to protect the complainant against retaliation.

## **II. FORMAL INVESTIGATION**

### **A. Purpose**

A formal investigation shall be initiated only after an Inquiry Committee issues a finding that an investigation is warranted. The investigation's purpose is to explore further the allegations and determine whether fraud has been committed. In the course of an investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations. The respondent shall be informed when significant new directions of investigation are undertaken. The investigation shall focus on accusations of fraud as defined above and shall examine the factual materials of each case. The investigation shall look carefully at the substance of the charges and examine all relevant evidence.

### **B. Structure**

The investigation will be undertaken by an ad hoc committee which will be formed to evaluate the specific case. Members of the Investigative Committee may be chosen from within or outside HHRI/HCMC. Members will be selected by the Inquiry Committee. It is important that the committee have appropriate scientific and scholarly expertise to assure a sound knowledge base from which to work.

Conflicts of interest by committee members toward the individual(s) accused shall be avoided. Those investigating the allegations shall be selected in full awareness of the closeness of their professional or personal affiliation with the complainant or the respondent. Any member of the Investigative Committee who has a conflict of interest in a given case shall not be permitted to be involved in any aspect of the committee's handling of that case.

### C. Process

If an investigation is warranted, the President of HHRI shall initiate an investigation within 30 days of the completion of the inquiry.

An investigational process shall be established for each formal investigation, and the complainant and respondent shall be notified of the investigation. All parties involved are obligated to cooperate with the proceedings in providing information relating to the case. The Investigative Committee will secure necessary and appropriate expertise to carry out the thorough and authoritative evaluation of relevant evidence in an investigation. 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 shall be conducted of all individuals involved either in making the allegation or against whom the allegation is made as well as other individuals who might have information regarding key aspects of the allegations. Complete summaries of these interviews will be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

All necessary information shall be provided in writing to the respondent in a timely manner to facilitate the preparation of a response. The respondent shall have the opportunity to address the charges and evidence in detail.

If warranted, the Foundation shall take interim administrative actions to protect Federal funds, the health and safety of research subjects and patients, or the interests of students and colleagues. Such actions may range from slight restrictions to suspension of the activities of the respondent. Interim administrative actions shall be taken in full awareness of how they might affect the respondent and HCMC and HHRI's ongoing research.

Significant developments during the investigation, as well as the final findings of the Committee, shall be reported to the sponsor. In the case of PHS-supported research, the OSI shall be kept apprised of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services 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. When the investigation is concluded, all entities initially notified of the formal investigation shall be informed of its final outcome.

An investigation shall be conducted as expeditiously as possible and generally shall be completed within 120 days. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation and submitting the report to the OSI. If they can be identified, the person(s) who raised the allegation shall be provided with those portions of the report that address their role and opinions in the investigation.

The nature of some investigations may render the 120-day time period difficult to meet. If, after thoughtful consideration of the need for a thorough and rigorous examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter, the 120-day deadline cannot be met, an interim report

shall be submitted by the Investigative Committee to the President, accompanied by a request for an extension. The Foundation will then submit to the OSI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion. If the request for an extension is approved by the OSI, the Foundation shall file any periodic progress reports that are requested by the OSI. The Foundation recognizes that if satisfactory progress is not made in its investigation, the OSI may undertake an investigation of its own.

#### D. Findings of the Investigation

The Investigative Committee shall provide a draft report to the respondent for comment before a final report is filed. The findings of the Investigative Committee shall be submitted in writing to the President. The respondent shall also receive the final, full report of the investigation. When there is more than one respondent, each shall receive those parts of the draft and final reports that are pertinent to his/her role.

The final report along with documentation to substantiate the investigation's findings will be submitted to the OSI. This report shall 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.

The Foundation recognizes that upon receipt of the final report of the investigation and supporting materials; the OSI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The Foundation shall respond promptly to any requests from the OSI for clarification or additional information. The Foundation understands that the OSI, if necessary, will perform its own investigation.

### III. RESOLUTION

The investigation into allegations of scientific misconduct may have any number of outcomes, including: that fraud was committed; that scientific or scholarly misconduct short of fraud was established; there was no culpable conduct, but serious scientific, scholarly, or artistic errors were discovered in the course of the investigation; errors that were less than serious were discovered; that no fraud, misconduct or scholarly error was committed.

Thus, an investigation of scientific misconduct may disclose evidence that requires further action, even in those cases in which no fraud is found.

#### A. No Finding of Fraud

When the investigation finds no support for allegations of fraud, all entities, initially informed of the investigation shall be notified promptly as outlined above. HCMC and HHRI shall retain the findings of the investigation and accompanying documentation in a confidential and secure file for a period of at least three years.

If the Investigative Committee determines that the allegations of scientific misconduct were maliciously motivated, this information will be reported to the individual's Department Chief for appropriate disciplinary action. If the allegations, however incorrect, are found to have been made in good faith, no disciplinary measures shall be taken and efforts shall be made to prevent retaliatory actions.

**B. Serious Scientific Error if Found**

Even when no culpable misconduct has occurred, HCMC and HHRI shall consider means to correct the scientific record.

**C. Findings of Fraud**

All entities initially informed of the investigation shall be notified promptly of the findings of fraud.

If an individual is found guilty of fraud, the President, in conjunction with the individual's Department Chief and the Chairman of the HCMC Board of Governors, shall determine the disciplinary action to be taken. (See examples of possible disciplinary action under V.B. below.)

The Foundation recognizes that in addition to sanctions it may decide to impose, the Department of Health and Human Services also may impose sanctions of its own upon investigators or institutions based upon authorities it possesses or may possess, if such action seems appropriate.

**IV. APPEAL/FINAL REVIEW**

The respondent may file a written appeal of the Investigative Committee's decision. Appeals shall be restricted to the body of evidence already presented, and the grounds for appeal shall be limited to failure to follow appropriate procedures in the investigation or arbitrary and capricious decision making. The appeal shall be filed within 30 days of the issuance of the report of findings and presented to the original Inquiry Committee for review of the appeal. The report of the appeal process shall be concluded within 30 days. Before an appeal is concluded, HCMC and HHRI may request a final review of the report by the Medical Director of the Hennepin County Medical Center and/or the Chairman of the Board of HCMC and/or the Dean of the Medical School or his/her designee and/or the cognate head of the University Department or his/her designee. The decision of the Appeals Committee is final. New evidence, however, may warrant a new investigation.

**V. DISPOSITION**

**A. Notification**

The complainant and other concerned parties, as set forth in the following illustrative, but not exhaustive, list, shall be notified of the disposition of the investigation:

- Sponsoring agencies, funding sources
- Co-authors, co-investigators, collaborators

- Editors of journals in which fraudulent research was published with appropriate retraction or correction

Under appropriate circumstances any of the following bodies may be informed of the outcome of these deliberations:

- Professional licensing boards
- Editors of journals or other publications, other institutions, sponsoring agencies, and funding sources with which the individual has been affiliated
- Professional societies
- Where appropriate, criminal authorities

#### B. Institutional Disciplinary Action

The HHRI and HCMC may take disciplinary action for its employees and recommend such action for non-employees and members as warranted by the circumstances of each case. Action may include:

- Removal from particular project
- Letter of reprimand
- Special monitoring of future work

HHRI employees:

- Probation
- Suspension
- Salary reduction
- Rank reduction
- Termination of employment

Non-Foundation employees may be banned from use of HHRI and HCMC facilities and participation in HHRI and HCMC research activities.

### **VI. POLICY REVIEW**

The President will be responsible for reviewing these policies and procedures on an annual basis.

### **VII. ANNUAL SUBMISSION OF ASSURANCES TO PHS**

The President will be responsible for updating the Foundation's assurance on an annual basis on a date specified by the OSI.