



## **Framework for Institutional Policies and Procedures to Deal With Fraud in Research**

**Association of American Universities  
National Association of State Universities and Land-Grant Colleges  
Council of Graduate Schools**

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### **Preface**

The "Framework for Institutional Policies and Procedures to Deal With Fraud in Research" was developed during the Summer and Fall of 1988 through the efforts of an interassociation working group. The working group included staff from the Association of Academic Health Centers (AAHC), the Association of American Medical Colleges (AAMC), the Association of American Universities (AAU), the American Council on Education (ACE), the American Society for Microbiology (ASM), the Council of Graduate Schools (CGS), the Council on Government Relations (COGR), the Federation of American Societies for Experimental Biology (FASEB), the National Association of College and University Attorneys (NACUA), and the National Association of State Universities and Land Grant Colleges (NASULGC). The document was revised to reflect the advice of a review group convened by the cooperating associations, a meeting of the AAAS/ABA National Conference of Lawyers and Scientists, the AAU, ACE, NASULGC Joint Committee on Health Policy, the AAU Executive Committee, and the AAU Biomedical Research Committee. The "Framework" will be revised again in the near future to take into account final PHS regulations on fraud and misconduct in research.

The existence of those regulations makes the issuance of this framework timely, but it would be necessary even if no regulations were forthcoming. This document grows out of the conviction that universities, not the sponsors of research, are responsible for the conduct of their faculty and staff. In order to fulfill that responsibility, they must have fair, workable and expeditious procedures for dealing with alleged transgressions of accepted standards.

We have chosen to offer guidance toward that end by the device of a "framework" rather than by a more prescriptive method. That is only appropriate, given the differing circumstances and existing policies and procedures among American Universities. An

acceptable process will require that all of the main elements of the framework be present, but there is and should be latitude for each institution to find the ways best suited to its condition.

The associations appreciate the financial support of the AAAS/ABA National Conference of Lawyers and Scientists, for the work of Lisa Poor, Administrative Fellow, Washington University School of Medicine, who worked with association staff in producing this document.

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**\*Revisions of this Document, required by the final PHS regulation, are in bold typeface.**

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### Introduction

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. Institution engaged in research 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 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 the ambiguities of interpretation that are inherent in the scientific process and are normally corrected by further research.

Many institutions have adopted and published policies to deal with these problems. The primary goal of this document is to assist institutions as they refine such policies or as they move to adopt new ones designed to assure careful and thorough handling of allegations of fraud. It expands upon the guidelines presented in two 1982 publications: "The Maintenance of High Ethical Standards in the Conduct of Research," by the Association of American Medical Colleges (AAMC), and the "Report of the Association of American Universities Committee on the Integrity of Research," by the Association of American Universities (AAU).

This document also has taken into consideration the 1986 Public Health Service (PHS) guidelines, "Policies and Procedures for Dealing with Possible Misconduct in Science"; and the 1987 regulations issued by the National Science Foundation (NSF), "Misconduct in Science and Engineering Research." The PHS guidelines and NSF regulations describe those agencies' preferred procedures for the institutional handling of allegations of research fraud. Those procedures normally have four stages:

- 1) an inquiry to determine whether the allegation or related issues warrant further investigation,
- 2) when warranted, an investigation to collect and thoroughly examine evidence,
- 3) a formal finding, and
- 4) appropriate disposition of the matter.

It is important to note that any new policies and procedures to deal with allegations of violations of the integrity of research must be incorporated into existing institutional policies and procedures for employment and academic conduct. Institutions must be vigilant to provide all parties with appropriate due process. It is reasonable to expect at different situations may require specific accommodations to insure the protection of the rights of all involved individuals. Institutions should be alert to possible harm to any parties throughout the process. An institution may choose, following an investigation, to refer any "findings" to its standing disciplinary procedures, or to develop processes specific to cases of fraud and misconduct in research.

The several stages of an institution's review process are discussed in detail in the remainder of this document. However, it seems useful to identify at the start the imperatives that should guide any institutional review process for dealing with allegations of fraud:

- Institutions should ensure that the process used to resolve allegations of fraud not damage science itself.
- Institutions should provide vigorous leadership in the pursuit and resolution of all charges.
- Institutions should treat all parties with justice and fairness and be sensitive to their reputations and areas of vulnerability.
- Procedures should preserve the highest attainable degree of confidentiality compatible with an effective and efficient response.
- The integrity of the process should be maintained by painstaking avoidance of real or apparent conflict of interest.
- The procedures should be as expeditious as possible leading to the resolution of charges in a timely manner.

- Institutions should document the pertinent facts and actions at each stage of the process.
  - After resolving allegations, institutions should discharge their responsibilities both internally--to all involved individuals--and externally--to the public, the sponsors of research, the scientific literature, and the scientific community, to the extent that is appropriate and allowable.
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## Definition of Research Fraud

Research fraud is a form of scientific misconduct involving deception. It should be distinguished from honest error, which can occur inadvertently in any enterprise. It is often difficult when confronted with an allegation to determine where along the spectrum from error to fraud a particular case will lie.

There is significant debate within the scientific community and in government about the appropriate scope of policies for dealing with the problem and about the definition of behaviors covered by such policies. Specifically, there is no agreement on the definitions of "fraud" or "misconduct". Until debate over appropriate scope and definition is resolved, institutions may wish to simply reference in their policies the definitions contained in federal regulation. The NSF defines misconduct as follows:

*(a) "Misconduct" means (1) fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from research; (2) material failure to comply with Federal requirements for protection of researchers, human subjects, or the public or for ensuring the welfare of laboratory animals; or (3) failure to meet other material legal requirements governing research.*

The PHS has published the following definition in its final rule:

*"Misconduct" or "Misconduct in Science" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.*

However, some institutions, feeling that these definitions are too broad, may wish to adopt a more precise definition of scientific fraud, such as that contained in the 1982 AAU policy statement. That definition includes the following:

- 1) *Falsification of data*---ranging from fabrication to deceptively selective 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) *Misappropriation of others' ideas*---the unauthorized use of privileged information (such as violation of confidentiality in peer review), however obtained.

In formulating such a definition of fraud, institutions should be aware of the need for policies and procedures address allegations relating to other forms of scientific misconduct. Examples of this kind of conduct would include inability to produce verifiable primary data supporting reported research results or violations of governmental or institutional rules and regulations regarding the conduct of research.

Some institutions may choose to consolidate in a single policy their procedures for dealing with all forms of alleged scientific misconduct. In such a case, the institution may wish to leave the determination of the point at which misconduct becomes fraud to ad hoc determination on the basis of the particular facts of each case. Such an approach permits the development of an institutional "common law" articulating acceptable scientific research standards. If an institution has separate policies and procedures for dealing with forms of misconduct other than fraud, it is suggested that the relevant sections be included in an appendix to the policies and procedures designed to address fraudulent behavior.

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## Process for Handling Allegations of Research Fraud

### **Assurances**

The final rule establishes specific requirements for institutional assurances of compliance. Each institution is required to establish an administrative process for reviewing, investigating, and reporting allegations of misconduct in science, and to comply with its established policy. Furthermore, each institution must submit its assurance to the Office of Scientific Integrity (OSI) on a form prescribed by the Secretary no later than January 1, 1990, and must update the assurance each year. In addition, an institution may be asked by the Secretary to submit aggregate information on allegations, inquiries and investigations along with its annual assurance. Although this section requires that institutions cooperate with OSI, it does not give the PHS authority to approve or disapprove institutional policies.

### **Initiation of an Inquiry**

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

In order to address all allegations of research fraud expeditiously, an institution should designate one or more senior administrators to whom allegations should be reported. Because universities are organized differently, they will choose to delegate this responsibility to meet the needs of their own organizational structure. The designated individual(s) could also:

- 1) provide education about fraud,
- 2) interpret the institution's fraud policy,
- 3) counsel staff, and
- 4) disseminate the policy.

The designated senior administrator(s) should pursue all allegations to resolution. If there is a conflict of interest, the case should be referred to an alternate senior administrator. To avoid unnecessary delays and confusion, it is advisable to predetermine the administrative alternate(s).

Institutional policies should state clearly that the senior administrator will counsel confidentially any individual who comes forward with an allegation of fraud. Some concerns brought to the senior administrator's attention may not fall within the scope of the policies and procedures developed to address fraud. Regardless of the nature of the concern, the senior administrator should seek to assist in its resolution through whatever institutional processes may be appropriate to the particular case, such as referral to the department chairman, the personnel office, or the faculty grievance procedure. If the senior administrator determines that the concern is properly addressed through policies and procedures designed to deal with fraud in research, the inquiry and investigation procedures should be discussed with the individual who has questions about the integrity of a research project. If the individual chooses not to make a formal allegation but the senior administrator believes there is sufficient cause to warrant an inquiry, the matter should be pursued; in such a case, there is no "complainant" for the purposes of this document.

Even if the respondent leaves the institution before the case is resolved, the institution has a responsibility to continue the examination of the allegations and reach a conclusion. Further, an institution should cooperate with the processes of other involved institutions to resolve such questions.

## **Inquiry Structure**

The inquiry process may be handled with or without a formal committee. Regardless of the approach chosen, it is the responsibility of the senior administrator to ensure that the inquiry is conducted in a fair and just manner. The inquiry phase is critical; institutions should consider whether more than one person should be involved in conducting the inquiry. If the committee method is utilized, the committee should be formed under the guidelines presented in the investigation section.

Individuals chosen to assist in the inquiry process should have no real or apparent conflicts of interest bearing on the case in question. They should be unbiased, and have appropriate backgrounds for judging the issues being raised.

Institutions should consult their own legal counsel to minimize the risk of liability for actions taken in the conduct of the inquiry and investigation. Institutions should also make clear any policies on providing legal counsel to complainants and respondents.

## **Purpose**

Whenever an allegation or complaint involving the possibility of fraud is made, the designated senior administrator should initiate an inquiry--the first step of the review process. **The PHS final rule specifies that allegations or suspicions must be followed up by an immediate inquiry.** In the inquiry stage, factual information gathered and expeditiously reviewed to determine if an 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.

## **Process**

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

Whether a case can be reviewed effectively without the involvement of the complainant depends upon the nature of the allegation and the evidence available. Cases that depend specifically upon the observations or statements of the complainant cannot proceed



without the open involvement of that individual; other cases that can rely on documentary evidence may permit the complainant to remain anonymous. While it may be desirable to keep the identity of the complainant confidential during the inquiry phase, local laws which provide for open access to certain records may make such confidentiality impossible. During the inquiry, confidentiality is desirable in order to protect the rights of all parties involved.

The senior administrator should assume responsibility for disseminating the information to the appropriate individuals. Normally notification should be made in writing and copies filed in the office of the senior administrator. The safety and security of all documents must be assured.

When the inquiry is initiated, the respondent should be reminded of the obligation to cooperate by providing material necessary to conduct the inquiry. Institutional policies should state clearly that uncooperative behavior may result in an immediate investigation and other institutional sanctions.

Each institution should develop policies regarding the role of legal counsel in this and other phases of these proceedings. Those responsible for conducting the inquiry must be aware of the institution's policies.

Due to the sensitive nature of allegations of fraud, institutions should strive to resolve cases expeditiously. Deadlines should be established to facilitate the process. **It is required that the inquiry phase be completed within 60 days of the initial written notification of the respondent.** If the committee or whatever body is convened anticipates that the established deadline cannot be met, a report, citing the reasons for the delay and progress to date, should be submitted for the record and the respondent and appropriately involved individuals should be informed.

## Findings

The completion of an inquiry is marked by a determination of whether or not an investigation is warranted. There should be written documentation to summarize the process and state the conclusion of the inquiry. The respondent should be informed by the senior administrator whether or not there will be further investigation. If there is a complainant, he or she should be likewise informed.

Allegations found to require investigation should be forwarded promptly to the investigative body. **In addition, the Director of OSI must be informed at this stage.** Federal regulation requires that the agency sponsoring the research also be notified at this point.

## **The Director of OSI must be informed of possible criminal violations within 24 hours so that OSI may inform the DHHS, Inspector General.**

If an allegation is found to be unsupported but has been submitted in good faith, no further formal action, other than informing all involved parties, including specifically the Director of OSI, should be taken. **However, the institution must maintain sufficient documentation (for 3 years) to allow for assessment of a decision not to pursue a formal investigation.** The proceedings of an inquiry, including the identity of the respondent, should be held in strict confidence to protect the parties involved. If confidentiality is breached, the institution should take reasonable steps to minimize the damage to reputations that may result from inaccurate reports. Policies should state that allegations that have not been brought in good faith may lead to disciplinary action.

The institution should seek to protect the complainant against retaliation. Younger, less senior people are particularly vulnerable. Individuals engaging in acts of retaliation should be disciplined in accordance with the appropriate institutional policies.

## **Investigation**

### **Purpose**

An investigation should be initiated when an inquiry issues a finding that investigation is warranted. The purpose of investigation 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 should be informed when significant new directions of investigations are undertaken. The investigation should focus on accusations of fraud as defined previously and examine the factual materials of each case.

### **Structure**

The investigative body may take any of several forms: an ad hoc committee to handle one specific case, a combination of standing committee and one-time-only appointed members, or a standing committee. Members of the investigative body may be chosen from within or outside of the institution.

Regardless of the structure chosen, conflicts of interest must be examined scrupulously and any relationship with parties to the matter must be fully disclosed. Those investigating the allegations should be selected in full awareness of the closeness of their professional or personal affiliation with the complainant or the respondent. Any member of a standing committee who has an unresolvable conflict of interest in a given

case should not be permitted to be involved in any aspect of the committee's handling of that case.

Whether a standing committee or an ad hoc committee is utilized, it is important that the committee have appropriate scientific expertise to assure a sound knowledge base from which to work.

## **Process**

Upon receipt of inquiry findings that an investigation is warranted, the senior administrator **must initiate investigation within 30 days**, and the complainant and respondent should be notified of the investigation. All involved parties are obligated to cooperate with the proceedings in providing information relating to the case. All necessary information should be provided to the respondent in a timely manner to facilitate the preparation of a response. The respondent should have the opportunity to address the charges and evidence in detail. The institutional procedures should address the role of legal counsel in the investigation.

Institutions may wish to adopt, as a matter of policy, a mechanism that would allow interim administrative action to be taken when justified by the need to protect the health and safety of research subjects and patients, or the interests of students and colleagues. Administrative action could range from slight restrictions to suspension of the activities of the respondent.

As previously noted, federal regulations require that the agency sponsoring a research project in which fraud is suspected should be notified as soon as the decision has been made to undertake an investigation. It is recommended that this practice be extended to include notification of all sponsors of research. The institution may wish, in turn, to seek assurances of the confidential treatment of this information. Significant developments during the investigation, as well as the final findings of the committee, should be reported to the sponsor. When the investigation is concluded, all entities initially notified of the investigation should be informed of its final outcome.

**Specifically, OSI must be informed of significant developments in the course of the investigation. The Director must be informed if an investigation is terminated before completion. Also, the Director must be informed of possible criminal violations within 24 hours so that OSI may inform the DHHS, Inspector General. Finally, OSI must be told about *"any development 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 the PHS needs to know to ensure appropriate use of Federal funds and other wise protect the public interest."***

An institution's policy should require that an investigation be conducted as expeditiously as possible. The adoption of a specific time period of 120 days for the completion of an investigation is recommended, to reflect the seriousness with which an institution views accusations of fraud and to be in compliance with the PHS guidelines and NSF regulations. However, an institution may choose to acknowledge formally in its procedures that the nature of some cases may render the time period difficult to meet. It should be noted that an institution's ability to complete an investigation within a specified time period will depend heavily upon factors such as the volume and nature of the research to be reviewed and the degree of operation being offered by the subject of the investigation. An institution may choose to specify interim reporting to monitor the progress of an investigation. If the deadline cannot be met, an interim report should be submitted to the senior administrator with a request for an extension.

## **Findings**

The findings of the investigative committee should be submitted in writing to the senior administrator. The respondent should receive the full report of the investigation. When there is more than one respondent, each shall receive all those parts that are pertinent to his or her role. All federal agencies, sponsors, or other entities initially informed of the investigation also must be notified promptly. The institution should retain the findings of the investigation in a confidential and secure file.

Investigations into allegations of fraud may result in various outcomes, including:

- 1) a finding of fraud;
- 2) a finding of serious scientific misconduct short of fraud;
- 3) a finding that no culpable conduct was committed, but serious scientific errors were discovered;
- 4) a finding that no fraud, misconduct or serious scientific error was committed.

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

If an investigation has been launched on the basis of a complaint, and no fraud or misconduct is found, no disciplinary measures should be taken against the complainant and every effort should be made to prevent retaliatory action against the complainant if the allegations, however incorrect, are found to have been made in good faith. If the

allegations are found to have been maliciously motivated, disciplinary actions may be taken against those responsible. **Furthermore, the final rule specifies that the institution must make "diligent efforts" to protect and to restore reputations of those accused wrongly.**

**The final rule also details information the institution must provide to OSI at the onset of an investigation (name of accused, general nature of allegation, and grant #) and provides assurances of confidentiality on behalf of OSI. Institutions are required to submit final reports to OSI describing institutional procedure, how and from whom information was obtained, the basis of findings, actual text or "accurate" summary of views of individual found to have engaged in misconduct, as well as any sanctions taken.**

**OSI reviews the information received from the institution and may request clarification, additional information and "if necessary perform its own investigation." In addition, the Department can levy its own sanctions upon the investigator or the institution.**

## **Appeal/Final Review**

Institutions may chose to provide respondents with an additional appeals process at this point through a written appeal of the investigative committee's decision. Appeals should be restricted to the body of evidence already presented, and the grounds for appeal should be limited to failure to follow appropriate procedures in the investigation or arbitrary and capricious decision making. New evidence may warrant a new investigation. The appeal should be filed promptly after a finding has been made. The institution should specify a senior administrative official (e.g., Provost) to hear the appeal. After an appeal is concluded, an institution may also wish to provide for a final review by its chief executive officer or designee. The institution should note that the decision of the review is final.

## **Disposition**

Responsibility for determining the nature and severity of disciplinary action should be specified in an institution's policy. This may, but need not necessarily, be done through the institution's regular faculty disciplinary or grievance procedures. Many actions may be available to the institution. Examples may include:

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

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

Consideration also should be given to formal notification of other concerned parties, not previously notified, such as:

- Sponsoring agencies, funding sources
  - Co-authors, co-investigators, collaborators
  - Editors of journals in which fraudulent research was published
  - State 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
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## Appendix

- Final PHS Regulations
- NSF Regulations
- 1982 AAMC Report
- 1982 AAU Report
- Descriptions of OSI and OSIR

Revised 11/4/88  
PFS/CRS/SC/dmm