

INDIANA STATE UNIVERSITY POLICIES AND PROCEDURES FOR DEALING WITH MISCONDUCT IN RESEARCH

INTRODUCTION

Researchers at Indiana State University (ISU) are engaged in a vast array of projects which hold remarkable promise for the health and well-being of mankind. Key elements of this process are the objective and accurate reporting of data accumulated in the course of experimentation and verification of research findings to assure valid conclusions. In addition, generally-sanctioned standards of conduct and propriety, when followed, not only assure the integrity of the scientific profession, but engender public support for, and lend credibility to, the scientific endeavor as a whole. Although an uncommon event relative to the large scientific literature, violations of accepted standards inevitably appear in this as in all human pursuits. Institutions 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 scientific misconduct.

In dealing with this problem, it is important to maintain an atmosphere of openness and creativity. Good and innovative science cannot flourish in an atmosphere of oppressive regulation. Moreover, it is particularly important to distinguish misconduct from the honest error and the ambiguities of interpretation that are inherent in the scientific process and are normally corrected by further research.

The stages of ISU'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 guide ISU's review process for dealing with allegations of misconduct or fraud:

1. ISU will ensure that the process used to resolve allegations of fraud does not damage science itself.
2. ISU will provide vigorous leadership in the pursuit and resolution of all charges.
3. All parties will be treated with justice and fairness and with due concern for reputations and vulnerabilities.
4. Procedures will preserve the highest attainable degree of confidentiality compatible with an effective and efficient response.
5. The integrity of the process will be maintained by painstaking avoidance of real or apparent conflict of interest.
6. The procedures will be as expeditious as possible, leading to the resolution of charges in a timely manner.

7. Pertinent facts and actions will be documented at each stage of the process.
8. After resolving allegations, ISU will, to the extent that it is appropriate and allowable, discharge its responsibilities both internally--to all involved, and externally--to the public, to the sponsors of research, to the scientific literature, and to the scientific community.

DEFINITION OF MISCONDUCT IN RESEARCH

There is significant debate within the scientific community and in government about the appropriate scope for policies dealing with and defining Misconduct in Research. ISU will adopt the following definition of Misconduct in Research based on the definitions used by the Public Health Service (PHS) and the National Science Foundation (NSF).

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- (a) Fabrication is making up data or results and recording or reporting them.
- (b) 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.
- (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- (d) Research misconduct does not include honest error or differences of opinion.

PREVENTION OF MISCONDUCT IN RESEARCH

While the primary focus of this document is on procedures for investigating allegations of research fraud and misconduct, the ultimate goal must be to create and maintain an environment in which there is a pervasive attitude of high ethical standards. This climate should serve to eliminate, or at a minimum reduce, dishonest behavior. Policies which deter or prevent misconduct include:

1. Notification to the whole academic community of ISU's policies on standards of conduct and sanctions for failure to meet these standards by incorporating these standards into written policy, the student and faculty handbook, and contractual agreements.
2. Definition of the roles of officials and faculty who have special responsibilities for the prevention of research fraud and misconduct. The director of a laboratory, for example, must have clearly defined responsibilities for reviewing standards with personnel, students, and junior investigators; for ensuring proper practices for well-designed experimental protocols; and for recording, retaining, and storing research or scholarly research data.

3. Acceptance by all study authors of full responsibility for the work published, at least for that portion of the research for which they were responsible. Validation of the role of each author should be required.
4. Maintenance of professional relationships among investigators to assure open discussion of data and research results and freedom of expression leading to an enhanced climate of integrity and objectivity and the avoidance of secrecy and undue competition.
5. Encouragement of the incorporation of formal course work--for example, seminars of bio-ethics--into the curriculum, making this subject an integral part of the research and educational experience.

PROCESS FOR HANDING ALLEGATIONS OF MISCONDUCT IN RESEARCH

INITIATION OF AN INQUIRY

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

The Director of Sponsored Programs is the senior official to whom allegations should be reported. If for some reason this is not practical or there is a conflict of interest, the alternative senior official will be appointed by the Provost. These designated individuals also (1) provide education about scientific misconduct, (2) interpret ISU's misconduct policy, (3) counsel staff, and (4) disseminate the policy. This designated senior official will pursue all allegations to resolution.

The senior official will counsel confidentially any individual who comes forward with an allegation of misconduct. Some concerns brought to the senior official's attention may not fall within the scope of the policies and procedures developed to address misconduct. Regardless of the nature of the concern, the senior official should seek to assist in its resolution through institutional processes appropriate to the particular case, such as referral to the department chairperson, the personnel office, or the faculty grievance procedure. If the senior official determines that the concern is properly addressed through policies and procedures designed to deal with misconduct in research, the inquiry and investigation procedures should be discussed with the individual who has questioned the integrity of a research project. If the individual chooses not to make a formal allegation but the senior official believes there is sufficient cause to warrant an inquiry, the matter

will be pursued; in such a case, there is no "complainant" for the purposes of the document.

Even if the respondents(s), or subject(s) of the allegation, leave(s) ISU before the case is resolved, ISU has a responsibility to continue the examination of the allegations and reach a conclusion. Further, the institution should cooperate with the process of other involved institutions to resolve such questions.

INQUIRY

Purpose

Whenever an allegation or complaint involving the possibility of scientific misconduct is made, the designated senior official should initiate an inquiry--the first step of the review process. In the inquiry stage, factual information is 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.

Structure

The inquiry process will be conducted by an ad hoc committee composed of two (2) faculty members and chaired by the senior official. It is the responsibility of the senior official to make every effort to ensure that the inquiry is conducted in a fair and just manner.

Individuals chosen to assist in the inquiry process must not have real or apparent conflicts of interest bearing on the case in question. They must be unbiased and have appropriate backgrounds for judging the issues being raised.

The committee will consult the legal counsel for ISU to minimize the risk of liability for actions taken in the conduct of the inquiry and investigation. ISU will not at any time provide legal counsel to the complainant(s) or respondent(s).

Process

Upon initiation of an inquiry, the senior official is responsible for notifying the respondent(s) within five (5) working days of the charges and the process that will follow. The committee members will be appointed and convened during this time.

Whether a case can be reviewed effectively without the involvement of the complainant(s) depends upon the nature of the allegation and the evidence available. Cases that depend specifically upon the observations or statements of the complainant(s) cannot proceed without the open involvement of that individual; other cases that can rely on documentary evidence may permit the complainant(s) to remain anonymous. While it

may be desirable to keep the identity of the complainant(s) 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 official has the responsibility for dissemination of the facts of the case to the appropriate individuals. Normally notification should be made in writing and copies filed in the office of the senior official. The safety and security of all documents must be assured. The senior official, accompanied by the appropriate department chairperson and an officer from safety and security, will hand deliver the written notification of the inquiry and, at that time, take possession of all pertinent records such as, but not limited to, laboratory notes, computer files, and research reports.

When the inquiry is initiated, the respondent(s) should be reminded of the obligation to cooperate by providing material necessary to conduct the inquiry. Uncooperative behavior may result in an immediate investigation and other institutional sanctions.

This inquiry is not a legal proceeding. Observers may be permitted to attend the inquiry at the discretion of the committee, with prior approval. Each party to the dispute may choose one (1) advisor and may confer with that advisor before answering a question during the hearing. Neither observers nor advisors may be attorneys.

Due to the sensitive nature of allegations of scientific misconduct, ISU will strive to resolve cases expeditiously. The inquiry phase will be completed within sixty (60) days or less of the initial notification of the respondent(s). A sixty (60) day period is consistent with the 2005 PHS guidelines and the 2002 NSF regulations. If the committee 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(s) and appropriately involved individuals should be informed. For any inquiry that finds sufficient basis for conducting an investigation, records will be maintained in the Office of Sponsored Programs for four (4) years and will be made available to authorized PHS or NSF personnel.

Findings

The completion of an inquiry is marked by a determination of whether or not a formal investigation is warranted. The committee shall prepare written documentation to summarize the process and state the conclusion of the inquiry. The respondent(s) will be informed by the senior official whether or not there will be further investigation. Any complainants(s) will also be informed. Allegations found to require investigation will be forwarded promptly to the investigative body. Federal regulation requires that the agency sponsoring the research also be notified at this point.

If an allegation is found to be unsupported but has been submitted in good faith, no further formal action will be taken, other than informing all involved parties. The proceedings of an inquiry, including the identity of respondent(s), will be held in strict

confidence to protect the parties involved. If confidentiality is breached, the institution will take reasonable steps to minimize the damage to reputations that will result from inaccurate reports. Allegations that have not been brought in good faith will lead to disciplinary action.

ISU will seek to protect the complainant(s) against retaliation, including protecting anonymity whenever possible. Those early in their careers, with less authority, are particularly vulnerable. Individuals engaged in acts of retaliation will be disciplined in accordance with the appropriate institutional policies.

INVESTIGATION

Purpose

An investigation will be initiated within thirty (30) days when an inquiry determines that it is warranted. The purpose of an investigation is to explore further the allegations and determine whether misconduct has been committed. In the course of the investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations. The respondent(s) will be informed when significant new directions of investigation are undertaken. The investigation will focus on accusations of misconduct and examine the factual materials of each case.

Structure

The investigative body (consisting of three (3) to five (5) members not involved in the inquiry and the senior official), will be an ad hoc committee created to investigate each specific case. Members of the investigative body will be chosen from within or outside of the institution, as circumstances dictate.

Conflicts of interest must be examined scrupulously and any relationship with parties to the matter must be fully disclosed and made visible to all those involved and having an interest in the investigation. Those investigating the allegations will be selected in full awareness of the closeness of their professional affiliation with the complainant(s) or the respondent(s). 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. 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 official will initiate an investigation within thirty (30) days, and the complainant(s) and respondent(s) should be notified of the investigation. All involved parties are obligated to cooperate with the proceedings by providing information relating to the case. All necessary information will be provided to the respondent(s) in a timely manner to facilitate the

preparation of a response. The respondent(s) will have the opportunity to address the charges and evidence in detail.

Interim administrative action, ranging from restrictions to suspension of the activities of the respondent(s), will 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. In conformance with guidelines contained in the Indiana State University Handbook, any suspensions during the proceedings will be with pay unless legal considerations forbid it. Additionally, necessary actions will be undertaken to protect grantor funds and ensure that the purpose of the financial assistance are being carried out.

Sponsors of a research project in which misconduct is suspected shall be notified as soon as the decision has been made to undertake a formal investigation including the Office of Scientific Integrity if PHS is a grantor, or the Office of Inspector General if NSF is a grantor. ISU will seek assurances of the confidential treatment of this information by such sponsors. Significant developments during the investigation, particularly reasonable indications of criminal violations, as well as the final findings of the committee, will be reported to the sponsor. When the investigation is concluded, all entities initially notified of the investigation shall be informed of its final outcome.

The investigation will be conducted as expeditiously as fairness and thoroughness permit. Every attempt will be made to conclude the investigation within a period of one hundred and twenty (120) days of the initiation of the notification of the respondent(s). However, the nature of some cases may render the time period difficult to meet. The 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 cooperation being offered by the subject of the investigation. If the deadline cannot be met, an interim report should be submitted to the senior official with a request for an extension.

Findings

The findings of the investigative committee must be submitted in writing to the Director of Sponsored Programs. The respondent(s) will 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 promptly notified of the findings. The findings of the investigation will be retained in a confidential and secure file in the Office of Sponsored Programs for at least (4) years after the completion of the hearing.

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

1. A finding of misconduct
2. A finding that no culpable conduct was committed, but serious scientific errors were discovered
3. A finding that no fraud, misconduct, or serious scientific errors was

committed

Thus, an investigation of misconduct may disclose evidence that requires further action even in those cases in which no fraud or misconduct 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 complainants. In addition, every effort should be made to prevent retaliatory action against the complainant(s) 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 will be taken against those responsible.

APPEAL/FINAL REVIEW

The findings of the committee may be appealed by writing the Director of Sponsored Programs. Only lack of due process or discovery of relevant new information after the conclusion of the hearing are justified reasons for an appeal. The Director of Sponsored Programs shall review the appeal and make a decision on the validity or the request.

The appeal shall be decided upon after an examination of the record of the hearing and any relevant information discovered after the hearing. The review by the Director of Sponsored Programs shall be limited to determining whether proper procedures were followed in the original hearing and reviewing any relevant information obtained after the conclusion of the hearing. The Director of Sponsored Programs may recommend a new hearing or other appropriate action. The decision of the Director of Sponsored Programs is final.

DISPOSITON

The investigation committee will recommend appropriate disciplinary action to the Vice President for Academic Affairs. Examples include:

- Removal from a particular project
- Letter of reprimand
- Special monitoring of future work
- Probation
- Suspension
- Salary reduction
- Rank reduction
- Termination of employment

Consideration also will be given to formal notification of other concerned parties not previously notified as to the outcome of the case.

These parties may include:

- Sponsoring agencies
- Co-authors, co-investigators, and collaborators
- Editors of journals in which fraudulent research was published
- State professional licensing boards
- Editors of journals or other publications, other institutions, and sponsoring agencies, with which the individual has been affiliated
- Professional societies
- Where appropriate, criminal authorities

The possibility exists that, during the course of the investigation, the individual involved may resign from employment. In this instance, the investigation will continue to its full conclusion. Also, once dismissed or resigned from an institution, an individual found guilty of scientific misconduct may move on and engage in dishonest activities elsewhere. Thus, it is an institutional responsibility to check thoroughly the references, licensing, and accreditation status of all new faculty and clinical staff.

As for grantees, federal regulations are already in place to identify individuals who have been debarred or suspended from receiving federal grant or contract funds.

Any appeal of disciplinary action is subject to the faculty grievance procedure outlined in the Indiana State University Handbook.

CONCLUSION

Federal regulations governing the handling of cases of scientific misconduct are still in a process of evolution. Thus, this document, and institutional policies, must change over time to conform to the evolving regulatory environment. Regardless of these patterns of change, it is imperative that research institutions treat allegations of scientific misconduct seriously and not only develop, but implement policies and procedures to provide for fair and expeditious handling of these accusations. Though many, and perhaps most, of the allegations will be ungrounded, all suspected cases of misconduct must be brought to light for what they are if public confidence in the integrity and value of scientific research is to be preserved.