



FRIENDS RESEARCH INSTITUTE, INC.
1040 Park Avenue, Suite 103
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Subject: Scientific Misconduct
Division: Research
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SCIENTIFIC MISCONDUCT POLICY

Introduction

Scientific misconduct undermines the integrity of scientific research. Because FRI is concerned about the possible effect scientific misconduct may have upon our work, this policy was developed to prevent, detect, and address issues regarding scientific misconduct. This policy attempts to establish an environment that balances the need to deal firmly and effectively with allegations of possible misconduct with the need for openness and creativity in the scientific enterprise.

Policy Statement

In all of its research activities, FRI requires the highest standards of professional conduct. The enterprise of scientific research relies upon the trust and confidence of both the scientific community and the public at-large in the integrity of the scientific process. Unethical behavior represents a breach of the confidence among scientists that is central to the advancement of knowledge. It also undermines the confidence that the public has in the reliability of science. For these reasons, FRI considers misconduct in science a betrayal of fundamental scientific principles and shall deal with all instances of possible misconduct firmly.

FRI attempts to maintain the highest ethical standards in research and shall thoroughly investigate and resolve promptly, fairly, and confidentially all instances of alleged or apparent scientific misconduct. Many grants supporting research projects are conducted and administered by FRI. The President of FRI has the responsibility and final authority for assuring that ethical standards are applied.

Principles

Authorship shall not be accepted on papers or abstracts unless the investigator has had a genuine involvement in the conduct of the research. Any investigator accepting authorship formally accepts responsibility for the quality of the work being reported in the publication. The first author will have the ultimate responsibility for the quality of the work reported (for more information, please refer to FRI's *Authorship Guidelines*).

All research results shall be maintained in a computer database or any other commonly accepted form, and all research data shall be retained by the investigator for at least five years beyond the date of publication, or in compliance with federal guidelines regarding record maintenance in clinical trials, whichever is greater.

Members of the scientific staff bear the responsibility for adhering to the ethical standards of their profession and maintaining the intellectual honesty of research conducted at FRI. The President of FRI and the Chairperson and members of the Institutional Review Board (IRB) accept primary responsibility for setting the ethical tone, professional conduct, and for assuring the integrity of the research conducted at FRI.

The rights and reputations of all parties involved in an instance of alleged scientific misconduct shall be respected and protected, including the individuals who report possible misconduct in good faith. This policy provides for the confidential treatment, prompt and thorough investigation, and the opportunity for all involved parties to respond to all allegations and/or findings. While confidentiality has a high priority, allegations must be investigated and there may be situations in which confidentiality cannot be guaranteed.

Accusations of falsifying or misrepresenting data or authorship are among the most serious charges that can be lodged against an investigator. Any person contemplating such accusations should fully consider the gravity of the accusation and its consequences and should make every reasonable effort to avoid lodging charges that prove to be devoid of merit. Frivolous or false accusations may result in disciplinary action up to and including termination.

If allegations of misconduct are substantiated after investigation, FRI shall impose appropriate sanctions, including termination of employment.

During any stage of proceedings of possible misconduct, FRI shall take appropriate administrative action to protect federal or other research-sponsored funds, including immediate cessation of funding of any related activities.

For every instance of verified misconduct, FRI is obligated to report the facts and conclusions of its investigation to (1) the current or potential funding agency or agencies involved, (2) Office of Research Integrity (ORI), (3) past or potential publishing agencies involved in reporting the data, and (4) past or present collaborators.

All proceedings shall comply with applicable policies and contractual obligations of FRI.

A legal representative may accompany all individuals meeting with an inquiry or investigating committee. That representative may participate only in an advisory capacity and may not participate in the process. FRI may also have a legal representative present for advice.

Definition of Scientific Misconduct

Misconduct in research is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community. This does not include honest error or honest differences in interpretation or judgment of facts.

Allegations of noncompliance or of protocol violation are also considered to be scientific misconduct. To the extent possible, every effort is made to maintain confidentiality regarding the identity of the person who submits the allegation. If the allegations suggest that research participants are at immediate risk, the IRB has the authority to suspend the study and to obtain research records including raw data. In most cases, upon receipt of the allegation, no formal action will be taken until an inquiry is conducted and the review is concluded as in any other situation involving allegations of scientific misconduct.

Procedures

The procedures described herein represent the general approach that FRI will employ during investigations of possible scientific misconduct since no policy can anticipate every possible issue that shall arise in the course of an investigation. The President of FRI is responsible for implementing (and/or modifying) these procedures, as necessary, to ensure adherence to the policy and principles outlined above.

1. Prevention

FRI shall encourage intellectual honesty in all endeavors by maintaining open communication, submitting work for peer review, avoiding conflict of interest and committing to self-regulation.

FRI employees will sign this policy acknowledging that have been informed of and agree to comply with FRI ethical standards and accept the policies and resolutions stated under this policy.

FRI shall periodically evaluate its policies and procedures for acquainting staff with appropriate ethical standards and assess whether additional efforts in this regard are necessary.

2. Allegations

Charges of scientific misconduct shall be brought to the Executive Management Committee (EMC) consisting of the President, Medical Director, Vice President, and Chief Operating Officer. In the event that any member of this Committee is involved in allegations of misconduct, that member shall recuse him/herself from the Committee to avoid a conflict of interest.

If the charges, either written or verbal, are determined to have merit, an initial inquiry shall be instituted immediately and may proceed to complete investigation.

Instances of possible scientific misconduct that depend upon the observation or statements of the complainant cannot proceed without the open involvement of that individual. Instances that can rely on documentary evidence may permit the complainant to remain anonymous. The President of FRI shall determine whether an inquiry can proceed effectively without the direct involvement of the complainant.

When an inquiry is initiated, the respondent(s) shall be reminded of the obligation to cooperate in providing the material necessary to conduct the inquiry. Uncooperative behavior shall be considered unacceptable and may result in immediate implementation of a formal investigation and appropriate administrative action.

The process of dealing with allegations of possible misconduct raises difficult and sensitive issues for those making allegations, those suspected of misconduct, and those responsible for the investigation. All proceedings shall be conducted with care and sensitivity. The privacy of those who in good faith report possible misconduct shall be protected to the maximum extent possible. Appropriate administrative action shall be taken when retaliation is perpetrated by or against any party involved in an inquiry or investigation of possible scientific misconduct. In those cases where, despite efforts to maintain confidentiality, allegations become public, diligent efforts shall be undertaken, as appropriate, to restore the reputation of persons alleged to have engaged in misconduct when allegations are not confirmed.

3. Initial Inquiry

An inquiry is defined as information gathering and initial fact-finding to determine whether an allegation of suspected misconduct warrants an investigation.

- a. The President of FRI shall advise the subject of the allegations and discuss the matter with the other members of the EMC. All deliberations and proceedings of the EMC shall be handled in a discreet and confidential manner. Legal counsel shall advise the EMC, if necessary.

- b. The EMC shall conduct separate and private sessions to hear the complainant, the subject of the allegations, and others as determined necessary. All evidence that is produced, which bears directly upon the charges, shall be reviewed and secured.
- c. The EMC shall make an initial written report and recommendation within 30 days after being informed of the charges. Sufficient documentation shall be provided to permit assessment of the reasons for determining whether a full investigation should proceed or whether such an investigation is not warranted.
- d. Three basic recommendations may follow this initial inquiry: (1) the allegations are without merit; or (2) no culpable conduct was committed but serious scientific errors were discovered, necessitating appropriate administrative action; or (3) the allegations have sufficient substance to warrant further investigation. If the EMC concludes that the allegations are without merit, sufficient documentation shall be available to permit an assessment of the reasons for determining that an investigation was not warranted.
- e. The President with the EMC's input will decide whether to request a complete investigation, as described below, and/or to take any other appropriate action pursuant to FRI policies or contractual agreements. This decision shall be delivered in writing to the subject of the allegations, the complainant, and the Chairperson of the IRB.

4. Investigation

Investigation is defined as the formal examination and evaluation of all relevant facts to determine if misconduct has occurred. If misconduct has already been confirmed, an investigation may nevertheless be conducted to determine the extent of any adverse effects resulting from the misconduct.

- a. The President shall determine whether sponsored research is involved and whether the supporting agency shall be notified that an investigation is underway. If the research is conducted with Public Health Service (PHS) funds, the President shall inform the Office of Research Integrity (ORI) that an investigation is warranted on the basis of an initial inquiry.
- b. The EMC shall conduct a complete investigation of the allegations and will commence the investigation within 30 days of the completion of the inquiry. All deliberations and proceedings of the EMC shall be handled in a discreet and confidential manner and only shared with those on a need-to-know basis. Legal counsel shall advise the EMC, if necessary.
- c. The investigation shall be prompt and thorough and provide an opportunity for the subject to fully respond to all allegations.
- d. The EMC shall be empowered to review all primary evidence associated with the alleged misconduct including but not limited to: relevant research data and proposals, publications, and correspondence and memoranda of telephone calls and email. Wherever possible, interviews shall be conducted with all individuals involved in lodging allegations or participating in the alleged misconduct, as well as other individuals who might have information regarding key aspects of the allegations. Complete summaries of interviews shall be prepared and included as part of the investigatory file.
- e. Necessary support (e.g., clerical, information gathering, involvement of witnesses, organizational, security, record keeping, and maintenance of confidentiality) shall be arranged by the EMC.

- f. The EMC shall conduct private and separate sessions to hear the complainant, the subject of the allegations, and others as determined necessary. All evidence that is produced that bears directly upon the charges shall be reviewed and secured. Interviews with any individuals may be recorded for the sole use of the EMC.
- g. The EMC shall maintain a written report of its proceedings, findings, evidence, conclusions, and recommendation with all other pertinent documentation. Affected individuals shall have the opportunity to comment on allegations and findings and provide their written comments as part of the investigation report.
- h. The President of FRI may appoint an External Committee of Investigators, members and/or administrators from another institution or institutions to provide written comment regarding findings, conclusions, and recommendations.
- i. The President shall review the recommendations and supporting rationale from the EMC and deliver his final decision regarding the investigation in writing to the subject of the allegations, the complainant, and the Chairperson of the IRB.
- j. With the advice of legal counsel, if needed, the President shall impose appropriate sanctions under applicable policies and contractual agreements such as:
 - (i) Alteration of employment status or termination of employment of those individuals whose misconduct was substantiated.
 - (ii) Withdrawal of all pending abstracts and papers deemed to include affected research and notification of editors of journals in which previous abstracts and papers containing these research results were published.
 - (iii) Notification of and, if required, restitution to the sponsoring agency.
 - (iv) Notification of collaborators regarding any substantiated scientific misconduct related to their research.
 - (v) Notification of institutions and sponsoring agencies with which the individual has been affiliated, if reason exists to believe the validity of previous research might be questionable.

The President shall deliver the decision to impose sanctions in writing to the subject of the allegations, the complainant, and the Chairperson of the IRB.

- k. At any time that scientific misconduct, as defined herein, or significant errors are substantiated in any sponsored or reported research, the President shall notify the sponsoring agent or publisher in writing. If the research is conducted with PHS funds, the ORI shall be informed of the final outcome of the investigation. The final 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, the actual text or an accurate summary of the views of any of the individual(s) found to have engaged in misconduct and a description of the sanctions taken by FRI.
- l. If scientific misconduct is not substantiated, the President shall undertake immediate efforts to restore the reputations of those who made allegations in good faith as well as those under

investigation by notifying the Chairperson of the IRB as well as any sponsoring agency or publisher of the results of the investigation in writing.

- m. FRI shall take any actions necessary, at any stage during this process, to protect the integrity of a project or the continuity of research.
- n. The investigation process, including preparation of a written report and notification to ORI, shall be completed within 90 days.

5. Challenges to the Decision of the President

An individual who is the subject of allegations may challenge the decision of the President. If the subject is not satisfied with the decision of the President, a written request for the opportunity to challenge the decision of the President shall be made to the Chairperson of the Board of Directors of FRI.

- a. The individual(s) shall state the reasons for requesting FRI Board review of the decision. The reasons shall be based on factual evidence of such significance that the outcome would be changed.
- b. The Chairperson will contact the Board members as soon as possible, if he/she determines Board review is warranted.
- c. If warranted, a meeting will be scheduled as soon as a quorum can be achieved.
- d. All evidence available at the time of the review will be presented to the Board. A representative may accompany all individuals providing evidence during the review.
- e. Legal counsel shall advise the Board, if necessary. Following the review, the Board will determine whether to continue or suspend further investigation of possible misconduct.
- f. The individual(s) will be notified in writing of the Board's decision within 15 working days of the review. The decision of the Board shall be final and binding.

6. Reporting and Recordkeeping

- a. Before an investigation begins, a written report containing the name of the person(s) against whom the allegations have been made, the general nature of the allegations and PHS application or grant number(s) involved, shall be prepared and provided to ORI.
- b. If FRI plans to terminate an inquiry or investigation without completing all the relevant requirements, a report describing reasons for such termination shall be made to ORI.
- c. IF FRI determines an investigation will not be completed within 90 days, a written request for extension shall be submitted to ORI, which explains the reason(s) for delay, describes the progress to date and provides an estimated date of completion. If an extension is granted, FRI shall file periodic progress reports as requested by ORI.
- d. FRI shall maintain detailed documentation and records for at least three (3) years.
- e. All records related to any part of this process shall be considered confidential and appropriate protection shall be provided.

- f. The President shall apprise the Chairperson of the IRB of any developments during an investigation, which discloses facts that affect PHS funding.
- g. The President shall notify the IRB if he ascertains at any stage of inquiry or investigation that:
 - (i) There is an immediate health hazard involved.
 - (ii) There is an immediate need to protect any individual.
 - (iii) The alleged incident is to be reported publicly.
 - (iv) There is an immediate need to protect Federal funds or equipment.
 - (v) There is reasonable indication of possible criminal violation. In this instance, FRI shall inform ORI within 24 hours of obtaining that information.



FRIENDS RESEARCH INSTITUTE, INC.

Receipt of Scientific Misconduct Policy

I understand that my signature below indicates that I have received, read, and understand FRI's Scientific Misconduct Policy and agree to comply with FRI ethical standards and accept the policies and resolutions stated under this policy.

Employee's Printed Name

Employee's Signature

Date