

SOP: CO 602 Version No.: 02 Effective Date: 7/1/08	SCIENTIFIC MISCONDUCT	Supercedes Document Dated: 12/18/03
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1. POLICY

The purpose of this policy is to establish policies and procedures for investigating and reporting alleged or apparent scientific misconduct in research studies that are funded by: agencies of the PHS that are being conducted at any Aurora Facility; federal agencies, which are not part of the PHS; and persons other than the federal government.

Specific Policies

The definitions of terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

1.1. Policies and Procedures for Scientific Misconduct in Research Studies That Are Funded by the PHS.

1.1.1. Inquiries.

A. Any allegation or other evidence of possible scientific misconduct shall be reported to the IRB Chair immediately.

B. Upon receiving a report of scientific misconduct, the IRB Chair, or his or her designee, shall immediately initiate an inquiry into an allegation or other evidence of possible scientific misconduct. The inquiry shall be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period of inquiry. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) who are the subject of the inquiry shall be given a copy of the report. If they comment on the report, their comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60 day period.

C. In all cases, the individual responsible for conducting the inquiry shall be a physician, or other individual with appropriate expertise, who is not in direct economic competition with the individual who is the subject of the Inquiry.

D. If the results of the inquiry indicate that an investigation is not warranted, no further action shall be taken and the IRB Chair, or his or her designee, shall prepare and maintain sufficiently detailed documentation of the inquiry to permit a later assessment of the reasons for determining that an investigation was not warranted. Such records shall be maintained in a secure manner for a period of at least three years after the termination of the inquiry, and shall, upon request, be provided to authorized personnel of DHHS.

E. All information gathered as part of the inquiry shall be maintained in a confidential fashion and shall not disclose the name of any person reporting apparent scientific misconduct.

F. If the results of the inquiry indicate that further investigation is warranted, the IRB Chair shall arrange for an investigation pursuant to section 1.1.2 of this policy.

1.1.2. Investigation.

A. If, after completion of the inquiry, the IRB Chair, or his or her designee, determines that the allegation of scientific misconduct warrants further investigation he or she shall consult with the Institutional-Official and the site administrator(s) of the Facility where the alleged scientific misconduct occurred.

B. If a determination is made to conduct an investigation, the IRB Chair shall notify the Director of the DHHS Office of Research Integrity (ORI) in writing on or before the date on which the investigation begins. The notification shall include the name of the individual(s) against whom the allegations have been made, the general nature of the allegations, and the PHS application or grant number(s) involved.

C. A committee shall be formed to conduct the investigation, which shall include: (i) the IRB Chair, or his or her designee; (ii) the site administrator of the Facility where the alleged scientific misconduct occurred, or his or her designee; and (iii) an independent physician, or other qualified individual, appointed by the IRB Chair. No person serving on the committee conducting the investigation shall be in direct economic competition with the individual who is the subject of the investigation.

D. The investigation shall include examination of all documentation, including, but not 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 should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigation file.

E. The committee conducting the investigation shall be responsible for:

(1) Securing the necessary and appropriate expertise to carry out a thorough and authoritative evaluation on the relevant evidence in an investigation.

(2) Taking precautions against real or apparent conflicts of interest on the part of those involved in the investigation.

(3) Preparing and maintaining the documentation to substantiate the investigation's finding. This documentation is to be made available to the Director of the ORI, who will decide whether that Office will either proceed with its own investigation or will act on the Aurora Facility's findings.

(4) Taking interim administrative actions, as appropriate, to protect PHS funds.

(5) Keeping the ORI apprised of any developments during the course of the Investigation that disclose facts that may affect PHS funding for the individual under investigation or that the PHS needs to know to ensure appropriate use of federal funds and otherwise protect the public interest.

(6) Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in scientific misconduct when allegations are not confirmed, and also undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

(7) Imposing appropriate sanctions on individuals when the allegation of scientific misconduct has been substantiated. (see section 1.1.3)

(8) Notifying the ORI of the final outcome of the investigation.

F. The investigation shall be completed and the first report submitted to ORI within 120 days. The report should describe how 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 scientific misconduct, as well as a description of any sanctions imposed by Aurora.

G. If the committee conducting the investigation decides to terminate the investigation prior to completion, it shall submit a report to the ORI describing the reasons for terminating the investigation.

H. The final report shall be maintained by the RSPP in a confidential manner for at least three years after the investigation is completed.

1.1.3. Sanctions.

After completion of the investigation and the allegations of scientific misconduct have been confirmed to a reasonable degree of certainty, the committee conducting the investigation may impose any sanctions on the affected individual permitted by law, this policy and the Aurora Health Care System Administrative Manual Disciplinary Policy.

1.1.4. Restoration of Reputation.

In consultation with the affected individual, the committee conducting the investigation shall make all reasonable efforts to restore the reputation of an individual alleged to have engaged in scientific misconduct when the allegations are not confirmed by the inquiry or the investigation.

1.1.5. Other ORI Notification Requirements.

A. Notwithstanding any other provision contained herein for conducting an inquiry or investigation, the IRB Chair shall be responsible for notifying ORI if any of the following conditions exist:

- (1) There is an immediate health hazard involved;
- (2) There is an immediate need to protect PHS funds or equipment;
- (3) There is an immediate need to protect the interests of the person(s) making the allegations or the interests of the individual who is the subject of the allegations, as well as his/her co-investigators and associates, if any;
- (4) It is probable that the alleged incident is going to be reported publicly; or
- (5) There is a reasonable indication of possible criminal violation. In that instance, the IRB Chair or the Institutional Official shall be responsible for informing the ORI of that fact within 24 hours of obtaining such information. ORI will immediately notify the DHHS Office of Inspector General (OIG).

B. The committee conducting an Investigation shall be responsible for notifying the ORI if it determines that it will not be able to complete the Investigation within 120 days. In this regard, the committee must submit to the ORI 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 of the report and other necessary steps to complete the investigation.

1.2. Policies and Procedures for Scientific Misconduct in Research Studies That Are Funded by Non-PHS Federal Agencies.

If an allegation or other evidence of scientific misconduct arises in research that is supported by a Federal Agency that is not part of the PHS, Aurora will comply with the misconduct policy of the supporting agency. Federal Agencies will be developing scientific misconduct policies in accordance with the requirements of 65 Federal Register, 75620 (Dec. 6, 2000).

1.3. Policies and Procedures for Scientific Misconduct in Research Studies That Are Funded by Persons/entities Other Than the Federal Government.

If an allegation or other evidence of scientific misconduct arises in research that is funded by persons other than the federal government, the IRB Chair, in consultation with the Institutional Official, may determine to conduct an inquiry and/or investigation in accordance with the policies and procedures set forth in section 1.1.2 of this policy. Notwithstanding the foregoing, Aurora and the Aurora IRB shall have no obligations to the ORI or any other Federal Agency.

2. SCOPE

This SOP applies to any scientific misconduct occurring in all research studies occurring at any Aurora Facility.

3. APPLICABLE REGULATIONS AND GUIDELINES

42 CFR §§ 50.103, 104

4. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
IRB Chair (or designee)	Initiate an inquiry into allegation of scientific misconduct. Appoint a subcommittee of at least 3 members to conduct an investigation if applicable. Prepare documentation of findings relative to inquiry or investigation as applicable.	
RSPP Manager	Report any allegations of scientific misconduct promptly to the IRB Chair.	
Human Protections Administrator	Responsible for notifying (within 120 days of the commencement of the investigation) the Director of ORI when an investigation into possible scientific misconduct is conducted and the results thereof. Ensuring that PHS funds are protected during the investigation.	