

RESEARCH MISCONDUCT

Clinical Research Policy/Procedure	
Approved: October 2008	Next Review: October 2011

Purpose

To set forth the policy and procedures by which Swedish Medical Center (Swedish) seeks to ensure the integrity of the research conducted at Swedish. To establish a process for addressing allegations and charges of research misconduct in a fair, impartial, and confidential manner.

Responsible Persons

All persons engaged in the conduct of research at Swedish. Such persons include, but are not limited to, institutional officials, researchers, scientists, postdoctoral and other fellows, guest researchers, collaborators, technicians, research coordinators, research assistants, students, volunteers, trainees, and other staff participating in research at Swedish.

All persons, whether engaged in research or not, who have reason to believe research misconduct has occurred, or have information that may reasonably aid in a research misconduct proceeding.

Definitions

Allegation means a disclosure of possible research misconduct.

Charge means a formal written allegation of possible research misconduct that triggers the procedures set forth in this Policy/Procedure.

Complainant is a person who in good faith makes a charge of research misconduct.

Deciding Official (DO) is the institutional official who makes final determinations on charges of research misconduct and any responsive institutional actions. For purposes of this Policy/Procedure, the Chief Medical Officer is the DO for Swedish.

Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities as required by law. A committee member does not act in good faith if his/her acts or

omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

HHS means the U.S. Department of Health and Human Services.

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Notice means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the addressee.

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

Research Integrity Officer (RIO) is the institutional official responsible for: (1) assessing allegations and charges of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation or charge is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this Policy/Procedure. For purposes of this Policy/Procedure, the DO has appointed the Research Education & Compliance Officer to serve as the RIO for Swedish.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. *Fabrication* is making up data or results and recording or reporting them. *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. *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism does not include disputes about authorship or credit among collaborators.

Research misconduct does not include honest error or differences of opinion. Research misconduct is committed intentionally, knowingly, or recklessly, and represents a significant departure from accepted practices of the relevant research community.

See Addendum 1 for examples of research misconduct.

Research record means the record of data or results, both physical or electronic, that embody the facts resulting from scientific inquiry, or reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. Research records include but are not limited to, research proposals, grant or contract applications, research protocols, consent forms, research subject files or binders, source documents, medical charts, case report forms, laboratory notebooks, progress reports, notes, equipment use logs, laboratory procurement records, correspondence, videos, photographs, slides, biological specimens or materials, computer files or printouts, manuscripts, publications, abstracts, theses, oral presentations, internal reports, journal

articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.

Respondent is the person against whom a charge of research misconduct is directed or who is the subject of a research misconduct proceeding.

Retaliation means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation of research misconduct, or good faith cooperation with a research misconduct proceeding.

Policy

AUTHORITY

The U.S. Department of Health and Human Services (HHS) and institutions that apply for or receive Public Health Service (PHS) support for biomedical or behavioral research share responsibility for the integrity of the research process. HHS has ultimate oversight authority for PHS supported research, and for taking other actions as appropriate or necessary, including the right to assess allegations and perform inquiries or investigations at any time. Institutions and institutional members have an affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work, and primary responsibility for responding to and reporting allegations of research misconduct, as defined in this Policy/Procedure.

Swedish highly regards its responsibility and obligation to assure that research undertaken at Swedish are performed in accordance with applicable regulations and the utmost standards of scientific design, methodology and integrity.

RESEARCH INTEGRITY OFFICER

The Deciding Official (DO) has appointed a Research Integrity Officer (RIO) who has primary responsibility for implementation of the procedures set forth in this Policy/Procedure. As necessary, the RIO may appoint agents and committees to ensure a thorough and authoritative evaluation of the relevant evidence in research conduct proceeding. The RIO is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

DUTY

All Responsible Persons are obligated to report observed, suspected, or apparent **research misconduct** to the RIO. If a person is unsure whether a suspected incident falls within the definition of research misconduct, he or she may call the RIO to discuss the suspected misconduct informally. Representative case summaries of research misconduct are available at the U.S. Department of Health and Human Services – Office of Research Integrity website (see <http://ori.dhhs.gov/misconduct/cases/>).

All Responsible Persons, including those accused of research misconduct, are obligated to cooperate with the process set forth in this Policy/Procedure. Such cooperation shall include providing research records, evidence, and other relevant information to the DO, RIO, or their designees, and refraining from actions that are retaliatory or otherwise obstruct the process set forth in this Policy/Procedure.

PROCESS

Swedish will endeavor to respond to each allegation of research misconduct in a thorough, competent, objective and fair manner, including precautions to ensure that persons responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses.

CONFIDENTIALITY

Disclosure of the identity of complainants and respondents in research misconduct proceedings, and research subjects identifiable in research records, will be limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed or required by law.

CONFLICT OF INTEREST

At all stages of a research misconduct proceeding, all persons involved shall be vigilant to prevent any real, apparent, or perceived conflict of interest from affecting the outcome of the proceeding. Possible conflicts of interest may include personal or professional relationships, prior co-authorships, financial interests, or any other interest which potentially could bias judgment. All persons with a real, apparent, or perceived conflict of interest have a duty to disclose such interest. The DO has the authority to address and manage disclosed conflicts of interest as appropriate.

INTERIM PROTECTIVE ACTIONS

At any time during a research misconduct proceeding, Swedish maintains the right to take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the research process. Necessary actions may vary according to the circumstances of each case, but examples of actions that may be necessary include requiring administrative leave, delaying the publication of research results, limiting research privileges, providing for closer supervision of research, requiring approvals for actions related to research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

RETALIATION

Swedish will endeavor to take all reasonable and practical steps to protect the positions and reputations of those persons who, in good faith, make allegations of research misconduct and those who, in good faith, cooperate with a research misconduct proceeding. Persons should immediately report any alleged or apparent retaliation to the RIO.

ADMINISTRATIVE ACTIONS

Swedish maintains the right to take appropriate actions when allegations of research misconduct have been substantiated, up to and including termination of employment.

BAD FAITH

A person who makes an allegation of research misconduct in bad faith, or cooperates with research misconduct proceeding in bad faith, may be subject to sanctions or other administrative actions, up to and including termination of employment.

RESTORATION OF REPUTATIONS

Swedish will make diligent efforts, as appropriate, to restore the reputations of persons alleged to have committed research misconduct when such allegations are not confirmed.

ROLE OF COUNSEL

Swedish (including the RIO, DO, or any other person acting on Swedish's behalf in a research misconduct proceeding) may consult with legal counsel at any stage of the proceedings. A respondent may consult with legal counsel at his or her discretion and expense.

COOPERATION WITH FEDERAL AUTHORITIES

Swedish will cooperate fully and on a continuing basis with federal authorities during its oversight reviews of this institution and its research misconduct proceedings.

Procedure

- 1. Allegation; Charge.** An allegation of research misconduct may be put forward by anyone, whether associated with research at Swedish or not. An allegation may be made to the RIO, or to the DO or the Director of Swedish Research Center, who will refer the matter to the RIO. Upon being informed of an allegation, the RIO will consult informally with the complainant. Any consultation shall be confidential within the limits described in this Policy/Procedure. The consultation may help to distinguish whether the matter involves questions of research misconduct or may be better resolved by other deliberative proceedings. The RIO will inform the complainant of the rights and responsibilities set forth in this Policy/Procedure and the requirement for a complainant to file a formal written charge of research misconduct.

If the complainant files a written charge, the RIO makes an initial assessment whether the charge (1) falls within the definition of "research misconduct," as defined in this Policy/Procedure, and (2) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The assessment should be documented.

If a complainant does not file a written charge after consulting with the RIO, the matter will be dropped, unless the RIO believes there may be sufficient cause and evidence to warrant an inquiry. In such cases, the RIO will register a written charge.
- 2. Initiation of an inquiry.** If the RIO determines that the charge is sufficiently credible research misconduct, the RIO, in consultation with the DO, convenes an Inquiry Committee to conduct a preliminary information-gathering and fact-finding inquiry into the matter. The committee should be comprised of at least three (3) and no greater than five (5) members with appropriate expertise (e.g., scientific, human resources) and who do not have unresolved personal, professional, or financial conflicts of interest with those involved in the inquiry.
- 3. Inquiry.** An inquiry involves an initial review of evidence to determine whether an *investigation* should be conducted. The purpose of an inquiry is **not** to reach a final conclusion as to whether research misconduct has occurred or who was responsible.

 - a. Notice to respondents.** The RIO shall make a good faith effort to notify the presumed respondent (and subsequently-identified respondents) of the allegation and inquiry in writing.

- b. Sequestration of research records.** On or before the date the respondent is notified or the inquiry begins, whichever is earlier, the RIO shall promptly take all reasonable and practical measures to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific equipment shared by a number of users, custody may be limited to copies of the data or evidence on such equipment, so long as those copies are substantially equivalent to the evidentiary value of the equipment.
- ➔ **NOTE:** The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where it is established that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner.
- c. Information gathering.** The Inquiry Committee gathers information and facts by examining research records and interviewing the complainants, respondents, witnesses, and any other persons who have reasonably identified as having information regarding any relevant aspects of the inquiry.
- d. Documentation.** The Inquiry Committee ensures that investigation is thoroughly documented. Interviewees must be provided a recording or transcript of their interviews for correction before being entered into the record.
- e. Inquiry report.** The Inquiry Committee prepares a written inquiry report including: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) information relating to the PHS support (e.g., grant numbers, grant applications, contracts, and publications); and, (4) the basis for recommending that the alleged actions warrant an investigation.
- f. Opportunity to comment.** The Inquiry Committee provides the respondent a reasonable opportunity to review and comment on the inquiry report and attach respondent's comments to the report.
- g. Results of the inquiry.** Upon conclusion of the inquiry, the Inquiry Committee reports its findings to the respondents and the DO.
- h. Time to complete inquiry.** The inquiry must be completed within sixty (60) calendar days of its initiation unless a longer period is clearly warranted. If an inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period.
- 4. Initiating an investigation.** On the basis of the inquiry, the DO determines whether the inquiry warrants an investigation. To determine whether an investigation is warranted, the DO considers (1) whether there is a reasonable basis for concluding that the allegation falls within the definition of "research misconduct," as defined in this Policy/Procedure, and (2) whether the evidence from the inquiry indicates that the allegation may have substance. The determination to initiate an investigation (or not) must be documented. If an investigation is warranted, the DO convenes an Investigation Committee to conduct an investigation of the alleged research misconduct. The committee should be comprised of at least three (3) and no greater than five (5) members with appropriate scientific expertise and who do not have unresolved personal, professional, or financial conflicts of interest with those involved in the investigation.

- a. **Notice to respondents.** The Investigation Committee gives notice of the investigation to the respondent within a reasonable amount of time.
 - b. **Notice to ORI.** The Investigation Committee provides written notice to the Office of Research Integrity (ORI), U.S. Department of Health and Human Services, within thirty (30) days. The notice must include documentation as required by 42 CFR § 93.309.
 - c. **Time to initiate investigation.** The Investigation Committee initiates the investigation within thirty (30) days after determining the investigation is warranted.
5. **Investigation.** An investigation involves a comprehensive review of to determine whether research misconduct has been committed, by whom, and to what extent. The Investigation Committee takes measures to ensure an impartial and unbiased investigation. The Investigation Committee investigates the allegation facts by fully examining research records and interviewing the complainants, respondents, witnesses, and any other persons who have reasonably identified as having information regarding any relevant aspects of the investigation.
- a. **Information gathering.** The Investigation Committee gathers information and facts by examining research records and interviewing the complainants, respondents, witnesses, and any other persons who have reasonably identified as having information regarding any relevant aspects of the inquiry.
 - b. **Documentation.** The Investigation Committee ensures that investigation is thoroughly documented. Interviewees must be provided a recording or transcript of their interviews for correction before being entered into the record.
 - c. **Investigation report.** The Investigation Committee prepares a written investigation report including: (1) a general description of the allegations of research misconduct; (2) information relating to the PHS support (e.g., grant numbers, grant applications, contracts, and publications); (3) a specific description of the allegations investigated; (4) an identification and summary of the research records and evidence reviewed; and, (5) for each allegation investigated, a statement of finding as to whether the research misconduct did or did not occur.
- The Investigation Committee provides the respondent a reasonable opportunity to review and comment on the draft investigation report. If comments are submitted, the Investigation Committee considers and addresses the comments. The Investigation Committee provides the draft investigation report to the DO.
- d. **Findings; Administrative actions.** The Investigation Committee submits the draft investigation report to the DO. The DO makes a final determination whether to accept the draft investigation report and/or its findings, and what administrative actions, if any, are necessary. If the DO does not accept the investigation report and/or its findings, the DO clearly documents the rationale for his or her determination.
 - e. **Time to complete investigation.** The Investigation Committee must complete the investigation within one hundred twenty (120) calendar days of its initiation unless an extension is granted by ORI.
6. **Appeal.** Upon completion of an investigation and written request of the respondent, the DO may – but is not required to - authorize an appeal. If an appeal is authorized, the DO convenes an Appeals Committee of at least three (3) and no greater than five (5)

members with appropriate scientific expertise and who do not have unresolved personal, professional, or financial conflicts of interest with those involved in the investigation. The Appeals Committee members may not be comprised of any persons who have served on the Inquiry Committee or Investigation Committee for the same matter. The Appeals Committee may rely on the investigation's evidence and record. With respect to procedures, the appeals process mirrors the investigation process. The Appeals Committee must complete consideration of the appeal within one hundred twenty (120) calendar days of the appeals filing unless an extension is granted by ORI.

7. **Notice of findings and actions to ORI.** Upon completion of an investigation (and appeal), the DO provides to ORI: (1) the final investigation (and appeal) report; (2) a statement of findings and whether Swedish accepts the findings; and (3) a description of any pending or completed administrative actions. Notice must also be provided to ORI if an investigation is closed before completion (e.g., respondent admits misconduct, settlement, etc.).
 8. **Retention of records.** All records created or produced in the context of a research misconduct inquiry, investigation, or appeal must be retained in a secure manner for at least seven (7) years after completion of the proceedings.
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Forms

N/A

Supplemental Information

N/A

Expert Consultants

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Regulatory Requirement

42 CFR Part 93 – Public Health Service Policies on Research Misconduct

References

N/A

Addendum

N/A

pk:Research Misconduct. – v. 2.0.doc (10/13/08)