

Policies and Procedures on Ethical Practices in Research

Introduction

The School hereby affirms its commitment to the highest ethical standards in the conduct of scientific research, the promotion of original research of high quality, and the importance of academic freedom. It also acknowledges that unethical conduct in research is extremely serious and threatens these principles. The School is, therefore, committed to preventing unethical conduct in research from occurring and, should it occur, to dealing with it swiftly, fairly, and thoroughly.

The School expects each faculty member to do his or her part to maintain and further standards of ethical practices in research. As part of the commitment to intellectual honesty and integrity, each faculty member and employee involved with research is responsible for promoting an environment that emphasizes open publication and discussion, high quality research, appropriate supervision, accurate and complete research records, and appropriate attribution of credit and responsibility. Faculty must ensure that everyone involved in their research adheres to federal and institutional policies governing the conduct of research. Further, if faculty and/or staff observe unethical practices in research, it is their obligation to report this information to the Research Integrity Officer (RIO) for review and investigation as provided for below.

The identity of individuals who bring concerns of unethical practices to the RIO will be protected to the extent consistent with the needs of an inquiry or investigation. Individuals who provide information in good faith about questionable conduct will be protected against reprisals.

The policy provides a framework to ensure that unethical practices in research are investigated and corrected as appropriate. It is further intended to satisfy the requirements of the Office of Research Integrity for allegations of research misconduct as that term is specifically defined.

Definitions

1. **Research** for purposes of this policy, "research" is defined as anything that is or purports to be "a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." [Federal Policy _____.102 Cd).].
2. **Unethical Practices in Research** as it is used in these guidelines, "unethical practices in research" refers to the intentional, knowing or reckless disregard for ethical practices in the conduct of research. The definition is broader than the definition of "research misconduct" used by the Office of Research Integrity ("ORI") and encompasses, but is not limited to: activities that compromise the integrity of the research results such as fabrication, falsification, manipulation of data or results; plagiarism; failure to comply with the guidelines for handling misconduct in research; seriously deviating from the School of Medicine's policies concerning human or animal research subjects; or other practices that significantly deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. The guidelines apply to all research conducted under the auspices of the School of Medicine and to anyone who participates in such research regardless of position, including all members of the faculty regardless of employment status or worksite, house staff, fellows, students, guests, volunteers, and technical support staff.

"Unethical practices in research" as used in these guidelines does not encompass disagreements between authors and/or collaborators regarding manuscript submission, e.g. relative contributions of involved parties and order of authorship. The School Policy On Responsibilities of Authors and Data Retention (<http://preview.mountsinai.org/sites/mssm/default/about/faculty-resources/handbook/institutional>) and the Guidelines for Reporting Research Results provide information on authorship. Authorship disputes should be resolved at the department level unless the case involves unethical practices as defined in this policy.

3. **Research Misconduct** is based on the ORI definition and encompasses: 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. Research misconduct does not include honest error or differences of opinion.
4. **Deciding Official (Dean)** means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Dean will serve as the deciding official.
5. **Research Integrity Officer (RIO)** is responsible for (1) overseeing inquiries and investigations; and (2) the other responsibilities described in this policy.
6. **Research Integrity Committee (RIC)** is responsible for assessing allegations of unethical practices in research to determine if they fall within the definition of research misconduct **AND/OR** are covered by 42 CFR Part 93, and/or warrant further action by existing institutional committees. The RIC may direct the RIO to engage one of the three methods of investigation detailed in this policy.
7. **Good Faith Allegation** is an allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.
8. **Inquiry** means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR §§ 93.307-93.309.
9. **Investigation** means the formal development of a factual record and the examination of that record leading to a decision whether to recommend a finding of research misconduct and/or other appropriate actions, including administrative actions. An investigation shall follow the procedures of 42 CFR SS 93.310-316.

Responsibilities of Research Integrity Officer and Research Integrity Committee

Research Integrity Officer -- The Dean will appoint the RIO who will have primary responsibility for implementation of the institution's policies and procedures on unethical practices in research. The RIO has general responsibility for overseeing the investigation of all allegations of unethical conduct in research and shall be available to:

- Consult confidentially with persons uncertain about whether to submit an allegation of unethical research practices and if the allegations do not involve unethical practices in research, refer the individual to other offices with responsibility for resolving the issue.
- Receive allegations of suspected unethical research practices and work with the RIC to determine and pursue the appropriate method for investigating and resolving these allegations.

For research misconduct proceedings, the RIO also has specific responsibilities including but not limited to:

- Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receiving allegations of suspected research misconduct;
- As necessary, taking interim action and notifying the ORI of special circumstances, in accordance with this policy;
- Directing and organizing the sequestration of research data and evidence pertinent to the allegation of research misconduct in accordance with this policy.
- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Overseeing the processes for notifying the respondent and providing opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports;
- Overseeing the processes for informing respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;
- Keeping the Research Integrity Committee and Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;

- Ensuring that ORI receives necessary notifications and reports as required by 42 CFR Part 93;
- Taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
- Overseeing the maintenance of records of the research misconduct proceeding and making them available to ORI.

Responsibilities of the RIC

The RIC will be appointed by the Dean. The committee will consist of at least three members and may include 1) Dean for Translational Biomedical Research, 2) Dean of Basic Sciences and the Graduate School of Biological Sciences, 3) the Research Integrity Officer, and 4) a representative from the Compliance Office. A representative from the Office of the General Counsel will serve as counsel to the Committee. The committee will be chaired by the Dean for Translational Biomedical Research and have the following duties:

- Receive and review reports from the RIO and other committee members regarding alleged unethical practices in research, misconduct evaluations and conclusions. The RIC retains the option of requesting additional information or pursuing additional courses of action with regard to the status of any investigation or corresponding action.
- The RIC may direct the RIO to pursue one of the following three methods of investigation detailed below.

Inquiries and Investigations

Based on the nature of the allegations and the review by the RIC, alleged unethical practices in research will be classified as either:

1. Allegations of Substantive Noncompliance with Regulations and Institutional Policies
2. Allegations of Financial Misappropriation
3. Research Misconduct as defined by 42 CFR Part 93

Each of these three categories has its own review process as described below.

I. Allegations of Substantive Noncompliance with Regulations and Institutional Policies

Often, unethical practices in research involve noncompliance with regulatory policies including but not limited to human subject research, animal research or biosafety. These allegations should be reviewed with the RIC for confirmation that the alleged failure to comply with federal, state or institutional regulations may be assessed and managed by the primary regulatory entity within MSSM (Program for the Protection of Human Subjects, The Institutional Animal Care and Use Committee, the Institutional Biosafety Committee or the HIPAA Oversight Committee) according to the standard policies and procedures. The RIC and RIO are available for consultation regarding proper management and resolution of specific cases.

All findings that appear to require reporting to regulatory bodies must be communicated to the RIC through the RIO prior to submission. All cases in which the internal auditors are requested to perform an audit for cause will be reported to the RIC.

Findings that fall within grounds for disciplinary action as defined in the Faculty Handbook will be reported to the RIC and the Dean. The findings shall constitute prima-facie evidence of the facts contained therein in any subsequent adjudicatory proceeding held under the Medical Staff By-laws, the Faculty Handbook or the Mount Sinai Personnel Policy.

If an allegation is not substantiated, the RIO shall oversee diligent efforts by the institution to restore fully the reputation of the researcher and any others whose reputation may have been injured. The RIO will consult with the Dean regarding taking appropriate action against any complainant or witness who did not act in good faith when making unfounded allegations and/or refused to cooperate with the Investigation.

II. Allegation of Financial Misappropriation

Unethical practices in research may involve misuse of research funds. At the discretion of the Chief Financial Officer of MSSM, failure to comply with federal, state or institutional financial controls may be assessed and managed by the CFO with the assistance of the Compliance, Grants and Contracts and Legal offices as appropriate. The RIC and RIO are available for consultation as regarding proper management and resolution of specific cases.

All findings that appear to require reporting to regulatory bodies must be communicated to the RIC through the RIO prior to submission. All cases in which the internal auditors are requested to perform an audit for cause will be reported to the RIC.

Findings that fall within grounds for disciplinary action as defined in the Faculty Handbook will be reported to the RIC and the Dean. The findings shall constitute prima-facie evidence of the facts contained therein in any subsequent adjudicatory proceeding held under the Medical Staff By-laws, the Faculty Handbook or the Mount Sinai Personnel Policy.

If an allegation is not substantiated, the RIO shall oversee diligent efforts by the institution to restore fully the reputation of the researcher and any others whose reputation may have been injured. The RIO will consult with the Dean regarding taking appropriate action against any complainant or witness who did not act in good faith when making unfounded allegations and/or refused to cooperate with the Investigation.

III. Research Misconduct as Defined by 42 CFR Part 93

Allegations of research misconduct that are reported to the RIO or referred to the RIC within the MSSM will be managed by the process set forth below. This process is intended to comply with the regulatory requirements set forth in 42 CFR Part 93.

1. The Inquiry

1.1. An allegation of research misconduct should be reported immediately to the relevant Department Chairperson or Institute Director, or the RIO. The Chair or Institute Director shall report it to the RIO immediately. This low threshold at the initial review is to ensure that the departmental /center review is swift and that any allegation requiring further review is appropriately forwarded to the RIO's Office.

1.2. In the event the Department Chairperson is the subject of the allegation the matter should be reported directly to the RIO.

1.3. If the RIO concludes that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified, the RIO shall refer the matter immediately to the RIC.

1.4. Upon determination that a matter requires review pursuant to this process, the RIC shall constitute a standing panel to conduct an inquiry (the "Panel") and the representative from the Office of General Counsel shall serve as counsel to the Panel. The RIC shall use its discretion to appoint additional members with appropriate scientific expertise when necessary to evaluate technically related allegations. The Panel shall consist of no fewer than three faculty members and shall be staffed by the Dean's Office. Any committee member who has any involvement in the alleged wrongdoing must be excluded from any involvement in the conduct of the inquiry. The faculty member accused of misconduct may object in writing to the RIC regarding the composition of the Panel based upon personal, professional or financial conflict of interest. The decision of the RIC to change or not change the composition of the Panel is final. As part of this inquiry and before the faculty member is informed of the specific allegations, the RIO shall secure the relevant research records and evidence. The RIO will provide the faculty member under investigation access to the records unless such access would impede the investigation or be otherwise inappropriate.

1.5. The Panel will promptly conduct an initial inquiry into the alleged wrongdoing for the purpose of determining whether a full scale investigation should be initiated.

1.6. The Panel must complete its inquiry within 60 calendar days of initiation of the Inquiry, unless circumstances clearly warrant a longer period, in which case the record of the Panel shall include documentation of the reasons for extending the 60 day period.

1.7. At the conclusion of its inquiry, the Panel must issue a written report to the Dean with recommendations as to whether to pursue an investigation or close the inquiry. The report must include the name and position of the subject of the inquiry; a description of the allegations of research misconduct; any PHS support that triggers ORI oversight; a summary of the evidence reviewed, and the basis for the recommendations of the Panel.

1.8. The RIO shall provide a draft of the Panel's inquiry report to any individual who has been a subject of the inquiry. Such subject will be given an opportunity to comment on the allegations and conclusions of the Panel and any written comments shall be made part of the final report. If the accused faculty member admits to the allegations of research misconduct during the inquiry stage, then the inquiry panel may recommend a finding of misconduct without the need to continue to the investigation stage. If the research involves PHS support, the Dean in consultation with the RIC shall consult with ORI to determine the next steps and the appropriate resolution of the matter.

1.9. After the subject(s) have submitted their responses, the final report shall be provided to the Dean. The Dean will make a written determination whether to accept the Panel's recommendations whether an investigation is warranted or not. The inquiry shall be deemed complete when the Dean makes this determination. If the Dean has further questions regarding the Panel's recommendations, the Dean may send the inquiry back to the Panel for further consideration.

1.10. If the Dean decides that an investigation is warranted and if the research involved PHS funds, he/she shall notify ORI within 30 days of the issuance of this decision and provide ORI with his a copy of his written decision and the Final Report.

1.11. If the Dean decides to close the Inquiry, the RIO shall ensure that the documentation of the inquiry is retained for seven years. These documents will be provided to ORI upon request

2. The Investigation

2.1. In the event the Dean determines that the allegation may have substance, the RIC shall appoint an Ad Hoc Committee ("Committee") for the purpose of conducting a fact finding review. To ensure appropriate peer review, the Ad Hoc Committee will be composed of a sufficient number of research scientists, at least one of whom shall have expertise in the subject matter of the investigation, and, if appropriate, other experts, such as an attorney or an expert in ethics in science. The RIC may also appoint others, such as individuals from outside of the institution, to serve on the Ad Hoc Committee. The Ad Hoc Committee will be advised by the General Counsel's office. The Dean's Office will supply such staff and other resources to the Ad Hoc Committee as may be necessary. In no event may any individual who is selected to serve on the Ad Hoc Committee have any prior involvement in the research project that is the subject of the inquiry.

2.2. The RIO shall notify in writing any individuals who are the subject of the Committee's investigation and provide the individuals with notice of any new allegations of research misconduct that were not addressed in the inquiry or arose as part of the Investigation.

2.3 The RIO shall ensure that any additional research records or evidence not previously secured during the inquiry are properly sequestered for the duration of the Investigation. Any individual against whom an allegation is made shall be apprised of the composition of the Ad Hoc Committee and may object to any member of the Ad Hoc Committee based upon personal, professional or financial conflict of interest. The objection should be made in writing to the RIC and must state the reasons for the objection. The decision of the RIC to change or not change the composition of the Ad Hoc Committee is final.

2.4. The Ad Hoc Committee will commence a thorough investigation within 30 days of a determination by the Dean that an investigation should be conducted. The Ad Hoc Committee must complete the investigation and submit its report to the Office of Research Integrity (ORI) (if the research involved PHS funds) within 120 days. If the Ad Hoc Committee believes it is unable to complete its report within 120 days, the Ad Hoc Committee Chairman must make a written request for an extension to ORI and comply with ORI's decision.

2.5. The Ad Hoc Committee review shall encompass all significant issues identified during the course of the investigation and, depending on its findings, the Ad Hoc Committee should consider reviewing all of the research in which the accused individual was involved. The Ad Hoc Committee must review all relevant documents and interview each person who has been reasonably identified as having relevant information, including the researcher under investigation. Transcriptions of all interviews must be provided to the interviewee for correction and then made part of the record.

2.6. The Ad Hoc Committee must issue a written report to the Dean outlining its conclusions and recommendations and setting forth in detail the basis for them. The Committee shall determine whether research misconduct occurred, whether the misconduct was a significant departure from accepted practices of the pertinent practices of the community and whether the subject of the allegation committed the research misconduct intentionally, knowingly or recklessly. The Committee shall use the preponderance of the evidence standard for reaching these conclusions.

2.7. The content of the report must include at a minimum the elements set forth in 42 CFR Section 93.313, including but not limited to: 1) a description of the allegations of research misconduct; 2) summary of the research records and evidence reviewed; 3) any findings of misconduct separately delineated and the supporting basis for each of these findings. Furthermore, for every finding of misconduct, the Report shall identify the following: 1) the form of misconduct, 2) whether it was committed intentionally, knowingly, or recklessly, 3) the specific PHS support if any, 4) whether any publications need correction or retraction and 5) whether there is any non-PHS current or pending support. Before it is finalized, a draft of the report, or relevant portions of it, shall be sent to each researcher accused of misconduct in research and to any collaborators or supervisors who may have been involved. These individuals will also be given access to all the underlying evidence to comment on the report and all their comments to the Ad Hoc Committee will be considered in preparing the report for presentation to the Dean and shall be made a permanent part of the record. In no event shall any report by the Ad Hoc Committee be approved by less than a majority of the Ad Hoc Committee membership.

2.8 The Dean in consultation with the RIC may accept the Ad Hoc Committee's report as final or may request that the Ad Hoc Committee reopen its investigation to address any additional issues. The Dean must complete the review process and determine in writing whether to accept the Final Report within 120 days of the commencement of the Investigation or the time frame specified by ORI.

3. Implementation of the Report Findings

3.1. If the Final Report substantiates a finding of misconduct in research, the Dean together with the RIC shall be responsible for carrying out the following:

- a. withdrawing any pending abstracts or papers containing false information and notifying the co-authors;
- b. if there are published papers or abstracts containing false information, notifying the editors of the journals in which abstracts and papers appeared and notifying all co-authors and giving them the opportunity to retract their names from the publication and;
- c. if there is reason to question the validity of previous research, notifying any institution or sponsoring agency with which the individual is or has been affiliated, and any other co-authors;
- d. instructing the General Counsel's office to take appropriate action concerning any pending or issued patents; and
- e. taking other appropriate action including disciplinary action against those individuals who engaged in misconduct in research. The Final Report shall constitute prima-facie evidence of the facts contained therein in any subsequent adjudicatory proceeding held under the Medical Staff By-laws, the Faculty Handbook or the Mount Sinai Personnel Policy.

3.2. If the alleged misconduct in research is not substantiated, the RIO shall be responsible for overseeing that:

- a. diligent efforts are made by the institution to restore fully the reputation of the researcher and any others whose reputation may have been injured. Specifically, any agency or individual which has been informed of the investigation will be notified that the allegations have been reviewed and not substantiated;
- b. appropriate action is taken against any complainant, or witness who did not act in good faith when making unfounded allegations of scientific misconduct and/or refused to cooperate with the Investigation.

4. Notification to the Office of Research Integrity (ORI) for all Inquiries and Investigations of Research Misconduct involving PHS funds.

4.1. The RIO shall ensure compliance with the ORI reporting requirements set forth in 42 CFR Section 93.315, including but not limited to the following:

- a. Notification to ORI on or before the date on which an Ad Hoc Committee investigation is commenced and providing ORI with a copy of the Panel's report within 30 days.
- b. Notification of the outcome of any Ad Hoc Committee investigation, including a copy of the Ad Hoc Committee's Final Report;
- c. Immediate notification if the School has reason to believe that any of the following conditions exist:
 - o if there is an immediate health hazard;
 - o if there is an immediate need to protect federal funds or equipment;
 - o if there is an immediate need to protect the individual making the allegation, the individual who is accused of the allegation or his or her investigators; or
 - o if it is probable that there will be a public report of the allegations;
 - o if the faculty admits to the research misconduct;
 - o if there has been possible criminal or civil violation of the law.
 - o if the School reaches a settlement of the allegations with the accused faculty member.

5. Record Retention

All documents relating to each research misconduct proceeding must be maintained for at least seven years after the final conclusion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The documents shall also be made available upon request to authorized ORI personnel.

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