

MANUAL ON
RESPONDING TO
ALLEGATIONS OR EVIDENCE OF
POSSIBLE RESEARCH MISCONDUCT

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I. GENERAL PROVISIONS.

A. Introduction and Rule of Interpretation. This manual contains policies and procedures for responding to allegations or evidence of possible of research misconduct in a thorough, competent, objective, and fair manner. This manual applies to all persons of the University community and all research conducted under the auspices of the University. This manual is intended to comply with the requirements contained in 42 CFR Part 93 and is to be interpreted consistent with protecting the health and safety of the public, protecting the integrity of research, and conserving funds entrusted to the University regardless of their original source. Questions about this manual should be directed to the Research Integrity Officer in the Office of Research Integrity.

B. Confidentiality.

1. Disclosure of the identity of respondents and complainants in research misconduct proceedings is 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 by law. The University must disclose the identity of respondents and complainants to ORI and NIH pursuant to federal regulations and as provided in this manual.
2. Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.

C. Protect / Restore Reputations. Reasonable and practical efforts will be taken and all persons are required to cooperate in these efforts that are taken:

1. to protect the positions and reputations of good faith complainants, witnesses and committee members; and
- 2.. to restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

D. Protect from Retaliation. Reasonable and practical efforts will be taken and all persons are required to cooperate in these efforts that are taken to protect against and counter potential or actual retaliation against good faith complainants, witnesses, and committee members.

E. Records Retention. The following records must be kept in a secure manner for a period of 7 years after the completion of the last relevant process contained in the manual or, if applicable, completion of the final action by ORI, whichever is later:

1. The records that were obtained and secured during the assessment, inquiry, and/or investigation phases explained in this manual, except to the extent those records were subsequently determined and documented that those records were not relevant to the proceeding or that the records duplicated other records that are being retained;
2. The documentation of the determination of irrelevant or duplicate records;
3. The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate;
4. The investigation report and all records (other than drafts of the report) in support of that report, including written investigation findings and the recordings or transcriptions of each interview conducted; and
5. The final decision by the University and all records in support of that decision.

F. Sanctions for Noncompliance. Violations of this manual could result in sanctions by the University, up to and including termination. Because many parts of this manual reflect requirements imposed by federal regulations, violations may also result in sanctions imposed by the federal government.

G. Definitions. Appendix A contains definitions of terms used in this manual.

II. OBLIGATION TO REPORT POSSIBLE RESEARCH MISCONDUCT.

A. All members of the University community have the responsibility and obligation to report what is believed, in good faith, to be observed, suspected, or apparent research misconduct to the Research Integrity Officer in the Office of Research Integrity or the Executive Vice President for Research.

B. As an alternative, reports may be made to the Office of Compliance directly or through EthicsPoint, Inc., using its toll-free number (800-254-0460) or URL (<http://rosalindfranklin.ethicspoint.com>), which allows anonymity.

C. Once a report of possible research misconduct is made, it shall be forwarded to the Executive Vice President for Research so that an initial assessment may be made, as further described in Section III of this Manual.

III. INITIAL ASSESSMENT PROCESS. The purpose of the initial assessment process is to assess each report of research misconduct in order to determine whether to conduct an inquiry process. Therefore, this initial assessment need not (and normally would not) include a fact-gathering process other than possibly seeking clarification or more details from the complainant about the report. The initial assessment does not involve determining whether the allegation is actually true or not.

A. Responsible Person. The Executive Vice President for Research has the responsibility for conducting the initial assessment of the report.

B. Timing for Completion. Normally, the initial assessment is made within a week of receipt of the report.

C. Criteria. This initial assessment involves determining:

1. whether the report contains an allegation of research misconduct and
2. whether the specifics contained in the report are sufficiently detailed to enable identifying potentially relevant evidence in a fact-gathering process.

D. Consequence of Initial Assessment.

1. If both criteria listed in paragraph III.C are met, the Executive Vice President for Research must make a written determination to initiate the inquiry process and promptly take all reasonable and practical steps to:

- a. obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding,
- b. inventory the records and evidence, and
- c. sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

2. If the criteria listed in paragraph III.C are not met, the matter will be addressed as deemed appropriate by the Executive Vice President for Research (*e.g.* seek additional information from the complainant, closed without further action, handled pursuant to some other relevant University policy, or referred to another office for action).

IV. INQUIRY PROCESS. The purpose of the inquiry process is to conduct an initial review of the research records and evidence to determine whether to conduct an investigation and to prepare an Inquiry Report documenting this process. Therefore, an inquiry does not require a full and thorough review of all the evidence related to the allegation.

A. Responsible Person. The Executive Vice President for Research has the responsibility to ensure the timely accomplishment of this inquiry process and to make the determination whether an investigation is warranted.

B. Timing for Completion. The Executive Vice President for Research must make the determination whether an investigation is warranted within 60 days of the initiation of this inquiry process unless circumstances clearly warrant a longer period. If all of the procedures take longer than 60 days to complete, the Inquiry Report must include documentation of the reasons for exceeding the 60-day period.

C. Formal Notification to Respondent. The first formal step of the inquiry process is a formal notification to the respondent(s). A good faith effort will be made to notify in writing the presumed respondent(s), if any, that an inquiry will be conducted into the allegation(s) of research misconduct. If the inquiry subsequently identifies additional respondents, those additional respondents will be notified in writing.

D. Obtain Custody of Research Records and Evidence. Continue efforts to promptly take all reasonable and practical steps to:

1. Obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding,
2. Inventory the records and evidence, and
3. Sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

Note: Whenever possible, custody of records and evidence should take place:

- a. Before or at the time the respondent receives notification; and
- b. Whenever additional items become known or relevant.

E. Inquiry Committee Review and Recommendation. Normally, an Inquiry Committee will be appointed and the following will be accomplished by that committee; however, the Executive Vice President for Research may choose to conduct these steps personally in lieu of appointing a committee.

1. Appointment of Members. The Executive Vice President for Research will appoint two or more members to an Inquiry Committee and provide to each member a copy of this manual. No member appointed to this Inquiry Committee may have any unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses. The appointment letter will set forth:

- a. the date or number of days for completion of the committee's inquiry and delivery of the Inquiry Report to the Executive Vice President for Research;
- b. the specific allegation(s) of research misconduct;
- c. the purpose of the inquiry (which is to conduct an initial review of the evidence in order to provide a recommendation to the Executive Vice President for Research regarding whether or not an investigation is warranted and to produce an Inquiry Report documenting that process; it is not to determine whether research misconduct definitely occurred);
- d. the criteria to be used to make this recommendation (as described below);
- e. the authority of the committee to seek additional evidence through the testimony of the respondent, complainant, and key witnesses as deemed useful for the committee to reach its recommendation using the established criteria (as described below); and
- f. the requirement to comply with this manual.

2. Criteria. The recommendation of the Inquiry Committee is based on the following determinations:

- a. whether there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and
- b. whether the records and evidence indicate that the allegation may have substance.

3. Consequences of Review by Inquiry Committee. If both criteria listed in paragraph IV.E.2 are met, the Inquiry Committee will recommend that the Executive Vice President for Research determine that an investigation is warranted.

4. Inquiry Report. The Inquiry Committee will prepare and deliver a written Inquiry Report to the Executive Vice President for Research. That report will contain:

- a. The name and position of the respondent;
- b. The specific allegation(s) of research misconduct;
- c. A copy of the formal written notification to the respondent;
- d. A copy of the appointment letter of the Inquiry Committee;
- e. If applicable, the PHS support, including, for example, grant numbers, grant listing PHS support;
- f. A recommendation for each allegation whether an investigation is warranted or not; and
- g. The basis for each recommendation regarding whether an investigation is or is not warranted (which normally would include a brief summary of the relevant evidence).

F. Written Notification to Respondent and Opportunity for Comment. Upon receipt of the Inquiry Report, the Executive Vice President for Research will provide written notification to the respondent(s) of the completion of the review and opportunity for comment. This written notification will include:

1. A statement that the Inquiry Committee has completed its review and prepared an Inquiry Report;
2. As an enclosure, a copy of the Inquiry Report;
3. A statement that the respondent has the opportunity to provide comments about the Inquiry Report within 10 days of the date of the notice and that any comments received within those 10 days will be attached to and thereafter considered part of the Inquiry Report (due diligence will be exercised to deliver the notice in a timely manner); and
4. As an enclosure, a copy of this manual.

G. Optional Notice and Opportunity to Comment for Complainant. The Executive Vice President for Research may, but is not required to, provide the complainant a copy of the Inquiry Report or relevant portions of that report for an opportunity to comment. The comments of the complainant, if any, must be submitted within 10 days of the date on which the complainant received the Inquiry Report or relevant portions of it.

H. Additional Attachments to the Inquiry Report. The following will be attached to and will be thereafter considered part of the Inquiry Report:

1. A copy of the written notification made to respondent of the completion of the review and opportunity for comment described in paragraph IV.F;
2. Any comments made in a timely manner by the respondent(s) described in paragraph IV.F; and
3. Any comments made in a timely manner by the complainant described in paragraph IV.G.

I. Formal Finding Whether an Investigation is Warranted.

1. The final formal step in the inquiry process is a written finding made by the Executive Vice President for Research whether or not an investigation is warranted and, if so, the specific allegations of research misconduct to be investigated.
2. This written finding will be based on the Inquiry Report (which will include the additional attachments described in paragraph IV.H) and applying the same criteria used by the Inquiry Committee, as described in paragraph IV.E.2, which are:
 - a. whether there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and
 - b. whether the records and evidence indicate that the allegation may have substance.
3. Documentation of this final formal step of the inquiry process as described in paragraph IV.I.1 will be attached to and will be thereafter considered part of the Inquiry Report.

V. INVESTIGATION PROCESS. The purpose of the investigation process is to explore the allegations and examine the evidence in a thorough, competent, objective and fair manner in order to develop a factual record and prepare an Investigation Report, which will include specific investigation findings relating to each allegation of research misconduct and upon which final decision(s) will be made by the University.

A. Responsible Person. The Executive Vice President for Research has the responsibility to ensure the timely accomplishment of this investigation process and to make the final decision on behalf of the University (and forward that final decision to ORI, if applicable).

B. Timing for Completion.

1. All aspects of the investigation process must be accomplished within 120 days of its initiation. This includes conducting the investigation, preparing the Investigation Report, providing a copy of that report for comment, and making (and forwarded to ORI, if applicable) the final decision of the University.

2. For cases within the applicability of 42 CFR Part 93 (see definitions in Appendix A), if unable to complete the investigation in 120 days, the Executive Vice President for Research must ask the Office of Research Integrity (ORI) for an extension in writing.

C. Obtain Custody of Research Records and Evidence. Continue efforts to promptly take all reasonable and practical steps to:

1. Obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding,

2. Inventory the records and evidence, and

3. Sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

Note: Whenever possible, custody of records and evidence should take place:

- a. Before or at the time the respondent receives notification; and
- b. Whenever additional items become known or relevant to the investigation.

D. Initial Notifications. Within 30 days of the formal finding by the Executive Vice President for Research that an investigation is warranted for certain specified allegations of research misconduct but before the investigation actually begins, the following notifications must be accomplished:

1. Office of Research Integrity (ORI). For cases within the applicability of 42 CFR Part 93 (see definitions in Appendix A), the Executive Vice President for Research must notify ORI in writing of the decision to begin an investigation and provide a copy of the Inquiry Report (including its attachments as described in Section IV).
2. NIH Office of Extramural Research - Research Integrity (OER-RI). For cases involving NIH-supported research, consistent with Notice Number NOT-OD-19-020 released October 17, 2018, the Executive Vice President for Research must notify and work with the NIH Extramural Research Integrity Officer to assess the effect on the ability to continue the project, as originally approved by NIH. If the University determines that a change of scope or a change of PD/PI or other senior/key personnel is required, the University must promptly obtain approval from the NIH funding Institute or Center Grants Management Officer.
3. Formal Notification to Respondent. The first formal step of the investigation process is a formal notification to the respondent. The Executive Vice President must notify the respondent in writing of the specific allegations of research misconduct that will be investigated. Additional written notifications are required within a reasonable amount of time for any new allegations of research misconduct that were identified within the investigation process but that were not previously addressed during the inquiry or in the initial notice of investigation.

E. Investigation Committee. Normally, an Investigation Committee will be appointed and the following will be accomplished by that committee; however, the Executive Vice President for Research may choose to conduct these steps personally in lieu of appointing a committee.

1. Appointment of Members. The Executive Vice President for Research will appoint two or more members to an Investigation Committee and provide to each member a copy of this manual. Due diligence will be exercised to ensure participation of persons with appropriate scientific expertise and that no member appointed to this Investigation Committee has any unresolved personal, professional or financial conflicts of interest with the complainant, respondent or

witnesses. Individuals appointed to the investigation committee may have also served on the inquiry committee. The appointment letter will set forth:

- a. the date or number of days for completion of the committee's investigation and delivery of the Investigation Report to the Executive Vice President for Research;
- b. the specific allegations of research misconduct to be investigated;
- c. the purpose of the committee (which is to explore the allegations and examine the evidence in a thorough, competent, objective and fair manner in order to develop a factual record and an Investigation Report, which will include specific investigation findings relating to each allegation of research misconduct);
- d. the expectation of the committee to carry the investigation through to completion and to pursue diligently all significant issues; and
- e. the requirement to comply with this manual.

2. Requirements During Investigation. The investigation committee must:

- a. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations;
- b. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including ensuring the recusal of any member with any unresolved personal, professional, or financial conflicts of interest with those involved with the investigation;
- c. Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and
- d. Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

3. Investigation Findings.

a. For each allegation of research misconduct, the Investigation Committee shall make an investigation finding, by majority vote, whether research misconduct did or did not occur.

Note: A finding of research misconduct requires that—

- * There be a significant departure from accepted practices of the relevant research community;
- * The misconduct be committed intentionally, knowingly, or recklessly; and
- * The allegation be proven by a preponderance of the evidence.

The University has the burden of proof for making a finding of research misconduct by a preponderance of the evidence. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the University establishes by a preponderance of the evidence 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 and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

In determining whether University has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

b. For each investigation finding that research misconduct did occur, the following additional information must accompany that finding:

- (1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
- (2) Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
- (3) If applicable, identify the specific PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support;
- (4) Identify whether any publications need correction or retraction;
- (5) Identify the person(s) responsible for the misconduct; and

(6) List any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies.

4. Investigation Report. The Investigation Committee will prepare and deliver a written Investigation Report to the Executive Vice President for Research. That report will contain:

- a. The name and position of the respondent;
- b. The specific allegation(s) of research misconduct;
- c. A copy of the formal written notification to the respondent that began the investigation process as described in paragraph V.D.2;
- d. A copy of the appointment letter of the Investigation Committee as described in V.E.1;
- e. If applicable, a description of the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support; and
- f. A statement that the Investigation Committee conducted its investigation consistent with this manual;
- g. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
- h. The investigation findings and, for each finding that research misconduct did occur, the additional information to accompany the investigation findings, as described in V.E.4.

F. Opportunity to Comment on Investigation Report.

1. Respondent. The Executive Vice President for Research must give the respondent a copy of the Investigation Report for an opportunity to comment and, concurrently, provide a copy of, or supervised access to, the evidence on which the report is based. The comments of the respondent on the Investigation Report, if any, must be submitted within 30 days of the date on which the respondent received the investigation report. These comments may include any mitigating factors that are relevant to a decision to impose institutional action in response to a final decision on the findings by the University.

2. Complainant. The Executive Vice President for Research may, but is not required to, provide the complainant a copy of the investigation report or relevant

portions of that report for an opportunity to comment. The comments of the complainant, if any, must be submitted within 30 days of the date on which the complainant received the investigation report or relevant portions of it.

3. Attach to Investigation Report. Any comments received pursuant to the above provisions will be attached to and will be thereafter considered part of the Investigation Report.

G. Final Decision of University.

1. The Executive Vice President for Research will decide on behalf of the University and document:

a. Whether or not to accept the written investigation findings in total or in part. If this decision is anything other than a total acceptance of the investigation findings, include a detailed explanation the basis for rendering a decision that differs from the investigation findings.

b. The appropriate institutional action in response to the decision on those investigation findings. Such action may relate, consistent with other relevant University policies:

(1) to pending or published abstracts and papers emanating from the research;

(2) to the authority to continue in the specific research project or engage in future research under the auspices of the University; and/or

(3) to various individual sanctions such as letter of reprimand or loss/reduction of salary, rank, or employment status.

2. For cases within the applicability of 42 CFR Part 93 (see definitions in Appendix A), the Executive Vice President for Research must notify in writing and provide to the Office of Research Integrity (ORI) of the following:

a. Copy of the Investigation Report (including all attachments as described in paragraph V.F).

b. The final decision of the University (as described in paragraph V.G.1) and include any pending or completed administrative actions against the respondent.

POSSIBLE RESEARCH MISCONDUCT
- Appendix A -

Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication.

Applicability of 42 CFR Part 93 means to allegations of research misconduct and research misconduct involving:

- (i) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information;
- (ii) PHS supported biomedical or behavioral extramural or intramural research;
- (iii) PHS supported biomedical or behavioral extramural or intramural research training programs;
- (iv) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks or the dissemination of research information; and
- (v) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.

Complainant means a person who in good faith makes an allegation of research misconduct.

Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

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 under this part. 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.

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.

Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

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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.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, 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 means the person against whom an allegation 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) A good faith allegation of research misconduct; or
- (b) Good faith cooperation with a research misconduct proceeding.