Research Misconduct

Purpose

EDC is committed to principles of integrity in research and expects all employees to maintain the highest standard of conduct in research activities. As required by federal regulations and institutional policy, EDC will use the process outlined in this policy in response to an allegation of research misconduct.

I. Scope

This policy and review procedures apply to all EDC employees engaged in research regardless of the sponsor of the research.[1] This policy also applies to any institutional members, including people paid by, under the control of, or affiliated with EDC, such as independent contractors or consultants. Subcontractors and subrecipients will be required to have their own policy or agree to follow EDC's policy.

The policy and associated procedures will be followed when an allegation of possible misconduct in research is received by EDC unless particular circumstances in an individual case dictate variation from the normal procedure. Any change from the procedures described below must ensure fair treatment to the subject of the Inquiry or Investigation and will be approved in advance by the Research Integrity Officer (RIO).

For U.S. Public Health Service (PHS) funding, these policies and procedures apply only to research misconduct occurring within six years of the date the U.S. Department of Health and Human Services (HHS) or EDC receives an allegation of research misconduct, subject to the following exceptions:

- The six-year time limitation does not apply if the Respondent continues or renews any incident of alleged research misconduct that occurred before the six-year period through the use of, republication of, or citation to the portion(s) of the research record alleged to have been

[1] While this policy applies to all allegations of research misconduct, EDC is required to follow the procedures detailed in Section VIII when the implicated research is funded by the federal government, including the PHS.

fabricated, falsified, or plagiarized for the potential benefit of the Respondent ("subsequent use exception"). For alleged research misconduct that *appears* subject to this subsequent use exception but which EDC determines is *not* subject to the exception, EDC will document its determination that the subsequent use exception does not apply and will retain this documentation for the later of seven years after completion of the institutional proceeding or the completion of any HHS proceeding.

- For PHS funding, the six-year time limitation also does not apply if the Office of Research Integrity (ORI) or EDC, following consultation with ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public. These policies and procedures do not supersede or establish an alternative to the PHS regulation or any existing regulations for handling research misconduct involving non-PHS supported research. They do not replace the PHS regulation, and in the case of any conflict between this document and 42 CFR Part 93, the PHS regulation will prevail. Rather they are intended to enable EDC to comply with the requirements of the PHS regulation.

For non-PHS funding, the timeline period of the allegation will be reviewed on a case by case basis to determine whether the allegation falls within an appropriate timeframe.

II. Definitions

A. **Research misconduct** is defined as fabrication, falsification, or plagiarism, whether committed by an individual directly or through the use or assistance of other persons, entities, or tools, including artificial intelligence- (AI-) based tools, in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

B. **Research** means a systematic experiment, study, evaluation, demonstration, interview, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to any of the areas in which EDC works. Research can be qualitative or quantitative.

C. **Fabrication** is making up data or results and recording or reporting them.

D. **Falsification** is manipulating research materials, equipment, or processes. Falsification includes changing or omitting data or results such that the research is not accurately represented in the research record.

E. **Institutional Record**

The records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. The exact records required will vary depending on the specifics of the allegation and sponsor.

For PHS, the Institutional record comprises the following:

a. The records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include, but are not limited to:

i. Documentation of the assessment as required by § 93.306(c)

ii. If an Inquiry is conducted, the Inquiry report and all records (other than drafts of the report) considered or relied on during the Inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the Inquiry, information the Respondent provided to the institution, and the documentation of any decision not to investigate as required by § 93.309(c)

iii. If an Investigation is conducted, the Investigation report and all records (other than drafts of the report) considered or relied on during the Investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the Respondent provided to the institution

iv. Decision(s) by the Institutional Deciding Official, such as the written decision from the Institutional Deciding Official under § 93.314

v. The complete record of any institutional appeal consistent with § 93.315

b. A single index listing all the research records and evidence that the institution compiled during the research misconduct proceeding, except records the institution did not consider or rely on.

c. A general description of the records that were sequestered but not considered or relied on.

F. **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology. Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct. EDC considers plagiarism to be a serious offense. Please see EDC's Intellectual Property policy or contact the Office of the General Counsel for more information regarding plagiarism.

G. **Research record** means the record of data or results that embody the facts resulting from scientific Inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

H. **Research sponsor** means the agency, institution, or organization, if any, that funded the research that is the subject of an Inquiry or Investigation. This term includes the U.S.

Department of Health and Human Services (HHS) and its Office of Research Integrity (ORI) for research that is sponsored by any part of Health and Human Services.

I. **Respondent** means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the Inquiry or Investigation. There can be more than one Respondent in any Inquiry or Investigation.

J. **Whistleblower/Complainant** means a person who makes an allegation of research misconduct.

K. **Institutional member** means an individual (or individuals) who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, volunteers, subject matter experts, consultants, attorneys, or employees or agents of contractors, subcontractors, or sub-awardees.

L. **Research Integrity Officer (RIO)** refers to the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct.

M. **Institutional Deciding Official (IDO)** means the institutional official who makes the final determination on allegations of research misconduct and institutional actions. The same individual cannot serve as the IDO and the RIO.

III. Process Overview[2]

Allegation of research misconduct and review by the RIO:[3]

- Preliminary assessment by RIO: If there is evidence of research misconduct, the RIO initiates the Inquiry Phase.

Inquiry Phase:

- Inquiry Committee is appointed.
- RIO prepares Charge for Inquiry Committee.
- Inquiry Committee reviews Charge.
- Inquiry Report is issued.
- RIO and IDO review Inquiry Report and determine whether an Investigation is required.

[2] EDC's policy is designed to comply with the Public Health Service Policies on Research Misconduct—Federal Register :: Public Health Service Policies on Research Misconduct—PHS regulations found at 42 CFR Part 50 and 42 CFR Part 93 and the NSF Regulations found at 45 CFR Part 689.

[3] Sue Boucher, Director of Corporate Compliance, is EDC's Research Integrity Officer (RIO) and Christine Filosa, Senior Vice President and General Counsel, is EDC's Institutional Deciding Official (IDO).

Investigation Phase:

- Investigation Committee is appointed.
- Research Sponsor is notified as applicable.
- RIO prepares the Charge.
- Investigation Committee reviews the Charge.
- Draft Investigation Report is issued to the Respondent and Whistleblower, and their comments are included in the Final Investigation Report.
- IDO reviews the Final Investigation Report.
- Action(s) are taken as warranted by the findings.
- Final Investigation Report is sent to Research Sponsor.

IV. Rights and Responsibilities

A. Responsibility to Report Misconduct

All employees or individuals associated with EDC should report concerns of research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, they may call the RIO (617-618-2255) to discuss the suspected misconduct informally or go to EDC's third-party provider website Integrity Counts to file a complaint.

If the circumstances described by the individual do not meet the definition of research misconduct but may be in violation of other EDC policies, the RIO will refer the individual or allegation to the parties responsible for resolving the issue.

At any time, any individual covered by this policy may have confidential discussions regarding possible misconduct with the RIO, and they will be counseled about appropriate procedures for reporting allegations.

B. Research Integrity Officer

The RIO has primary responsibility for implementing the procedures set forth in this document. Specific responsibilities are detailed in the following sections. The RIO is also responsible for maintaining files of all documents and evidence and for the confidentiality and security of the files. In administering this policy, the RIO will be guided by the principle that disclosure of the identity of the Respondent and Whistleblower will be limited, to the extent possible, to those who need to know.

In consultation with the IDO, the RIO will appoint the committees defined in this policy. The RIO will also ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an Inquiry or Investigation of research misconduct.

C. Whistleblower/Complainant

The Whistleblower is responsible for making allegations in good faith based on reasonable grounds, maintaining confidentiality, and cooperating with an Inquiry or Investigation. Please refer to Section IV (E) below regarding protection of the Whistleblower. If EDC learns that an allegation was not made in good faith, the IDO will determine whether any administrative action should be taken against the Whistleblower. While EDC does not anticipate abuse of the process, any person who makes allegations that are proven to have been made maliciously (i.e., without a good faith basis for believing a violation has occurred) will be subject to discipline, which may include termination.

D. Respondent

The Respondent will be informed in writing of the allegations when an Inquiry is opened and notified in writing of the final determinations and resulting actions. The Respondent also will have the opportunity to be interviewed by, and present evidence to, the Inquiry and Investigation Committees, and to review the Draft and Final Inquiry and Investigation Reports.

The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an Inquiry or Investigation. If the Respondent is not found to have violated the Research Misconduct Policy, they may receive EDC's assistance in restoring their reputation (see Section X (B)).

E. Institutional Deciding Official

The IDO will receive the Inquiry Report, and after consulting with the RIO, will decide whether an Investigation is warranted. If warranted, the IDO will receive the Investigation Report and, after consultation with the RIO, decide the extent to which this institution accepts the findings of the Investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate.

F. Protecting those involved in the process

The RIO will monitor the treatment of the Whistleblower, Respondent, and others who participate in inquiries or Investigations. Employees must immediately report any concerns regarding retaliation to the RIO, as well as to the employee's manager and supervisor (unless either of them is the Respondent and/or alleged retaliator). The RIO will ensure that these persons are not retaliated against in the terms and conditions of their employment at EDC and will review allegations of retaliation for appropriate action.

EDC will protect the privacy of Whistleblowers, Respondents and those who participate in the process to the maximum extent possible. For example, if the Whistleblower requests anonymity, EDC will make an effort to honor the request during the allegation, assessment and Inquiry phases, subject to applicable regulations and laws. The Whistleblower will be advised that if the matter is referred to an Investigation Committee and the Whistleblower's testimony is required, anonymity may no longer be guaranteed.

G. Advisors

Participants may not be represented by legal counsel when they are participating in the process, but they are not prohibited from seeking legal advice. Subject to the confidentiality expectations, participants may also consult with a personal adviser (who is not a principal or witness in the case) and may bring the personal adviser to interviews or meetings. However, the advisor may not actively participate in interviews or meetings without approval of the RIO or committee chair.

H. Cooperation with Inquiries and Investigations

EDC employees and others governed by this policy are expected to cooperate with the RIO and others in the review of allegations and the conduct of inquiries and Investigations. EDC employees have an obligation to provide relevant evidence to the RIO or others on misconduct allegations.

V. The Process

A. Standard of Review

A finding of research misconduct requires the following:

- There be a significant departure from accepted practices of the relevant research community (i.e., the humanities, social sciences, or scientific research community)
- The misconduct be committed intentionally or knowingly or recklessly
- The allegation be proven by a preponderance of evidence

Evidentiary Standards:[4]

- Standard of proof. An EDC or HHS finding of research misconduct must be proved by a preponderance of the evidence.
- Burden of proof:
    - EDC or HHS has the burden of proof for making a finding of research misconduct. A Respondent's destruction of research records documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the Respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. A Respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the Respondent claims to possess the records but refuses to provide them upon request.
    - The Respondent has the burden of going forward with and proving, by a preponderance of the evidence, all affirmative defenses raised, including honest error or a difference of opinion.

[4] 2 CFR 93.105

- The Respondent has the burden of going forward with and proving, by a preponderance of the evidence, any mitigating factors relevant to a decision to impose administrative actions after a research misconduct proceeding.

B. Initial Review of Allegations – Institutional Assessment

Upon receiving an allegation of research misconduct, the RIO will promptly assess the allegation to determine (1) whether there is sufficient evidence to warrant an Inquiry, (2) whether federal regulations are implicated, and (3) whether the allegation falls under the definition of *research misconduct*.

If the RIO determines that the allegation provides sufficient information to allow specific follow-up, involves funded research, and falls under the definition of *research misconduct*, they will notify the IDO of the assessment and recommend initiation of an Inquiry.

After determining that an allegation falls within the definition of research misconduct, the RIO must ensure that all original research records and materials relevant to the allegation are immediately secured. The RIO may consult with the Research Sponsor for advice and assistance in this regard.

If the RIO determines that the allegations do not merit an Inquiry, they will document the decision in sufficient detail to allow the applicable ORI to understand why EDC elected not to conduct an Inquiry. These records will be maintained for seven years after the decision not to conduct the Inquiry has been made.

C. Appointment of the Inquiry Committee and Initiation of the Inquiry Process

The purpose of the Inquiry is to make a preliminary evaluation of the available evidence to determine whether there is sufficient evidence of research misconduct to warrant an Investigation. EDC will endeavor to complete the Inquiry within 90 days of initiating it unless circumstances warrant a longer period, in which case, it will sufficiently document the reasons for exceeding the time limit in the Inquiry Report.

At the time of or before beginning an Inquiry, the RIO must make a good faith effort to notify the Respondent in writing, if the Respondent is known. If the Inquiry subsequently identifies additional Respondents, they must be notified in writing.

The RIO, in consultation with the IDO, will endeavor to appoint an Inquiry Committee and committee chair within 10 days of the initiation of the Inquiry. The Inquiry Committee will consist of at least three persons, including the chair. The Inquiry Committee should consist of individuals who do not have real or apparent conflicts of interest in the matter, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation. The Inquiry Committee will interview the principals and key witnesses and conduct the Inquiry. These individuals may be subject matter experts, administrators, or other qualified persons, and they may be from inside or outside EDC.

The RIO will notify the Respondent of the proposed committee membership in 10 days. If the Respondent submits a written objection to any appointed member of the Inquiry Committee or expert—based on bias or conflict of interest—within 5 days of receiving the proposed membership, the

RIO will determine whether to replace the challenged committee member or expert with a qualified substitute.

The RIO will present the original allegation and any related issues that should be evaluated by the Inquiry Committee. At the committee's first meeting, the RIO will review the charge with the committee and will discuss the allegations, any related issues, and the appropriate procedures for conducting the Inquiry. The RIO also will assist the committee with organizing plans for the Inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the Inquiry to advise the committee as needed.

D. Inquiry Process and Report

The Inquiry Committee will interview the Whistleblower, the Respondent, and key witnesses and examine relevant research records and materials. Next, the Inquiry Committee will evaluate the evidence and testimony obtained during the Inquiry. After consultation with the RIO, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend an Investigation.

A written Inquiry Report will be prepared including the following information:

- The name and title of the Respondent, committee members and experts, if any
- A list of the allegations
- The name of the Research Sponsor
- A summary of the Inquiry process used
- A list of the research records reviewed
- Summaries of interviews
- A description of the evidence in sufficient detail to demonstrate whether an Investigation is warranted or not

The Inquiry Report will include the committee's determination as to whether an Investigation is recommended and whether any other actions should be taken if an Investigation is not recommended.

The Inquiry Report requires the following additional elements as described in 42 CFR 93.307 and 42 CFR 93.309:

1. The names, professional aliases, and positions of the Respondent and complainant(s)
2. A description of the allegation(s) of research misconduct
3. Details about the PHS funding, including any grant numbers, grant applications, contracts, and publications listing PHS support
4. The composition of the Inquiry Committee, if used, including name(s), position(s), and subject matter expertise
5. An inventory of sequestered research records and other evidence and a description of how sequestration was conducted
6. Transcripts of interviews, if transcribed
7. Inquiry timeline and procedural history

8. Any scientific or forensic analyses conducted
9. The basis for recommending that the allegation(s) warrant an Investigation
10. The basis on which any allegation(s) do not merit further Investigation
11. Any comments on the Inquiry Report by the Respondent or the Whistleblower/Complainant(s)
12. Any institutional actions implemented, including internal communications or external communications with journals or funding agencies
13. Documentation of potential evidence of honest error or difference of opinion

The Inquiry Committee will complete the Inquiry and submit its report in writing to the RIO no more than 60 calendar days following its first meeting, unless the RIO approves an extension for good cause. In addition to factual findings, the Inquiry Committee will recommend whether or not an Investigation of the allegations of research misconduct is warranted. If the RIO approves an extension, the reason for the extension will be entered into the records of the case and the report. The Respondent also will be notified of the extension.

The RIO will notify the Respondent whether the Inquiry found an Investigation to be warranted, provide the Respondent with a copy of the Draft Inquiry Report for comment and rebuttal, and provide the Whistleblower (if they are not anonymous) with portions of the Draft Inquiry Report that address the Whistleblower's role in the Inquiry and the institution's policies and procedures on research misconduct. After reviewing the draft report, the Respondent may elect, but is not required, to admit to any of the allegations of misconduct and the Whistleblower may elect, but is not required, to withdraw any of the allegations made. The RIO will establish reasonable conditions for review to protect the confidentiality of the Draft Report.

Within 14 calendar days of their receipt of the Draft Inquiry Report, the Whistleblower and Respondent will provide any written comments to the Inquiry Committee. Comments submitted by the Whistleblower or Respondent will become part of the Final Inquiry Report and record. Based on the comments, the Inquiry Committee may revise the report as appropriate. The RIO will transmit the Final Inquiry Report and any comments to the IDO, who, within 10 days after receipt of the report will make the determination of whether findings from the Inquiry provide sufficient evidence of possible research misconduct to justify conducting an Investigation or whether the committee's findings or comments received from the Respondent and/or the Whistleblower resolve any of the allegations of misconduct. The Inquiry is completed when the IDO makes this determination. Any extension of this period will be based on good cause and recorded in the Inquiry file.

The RIO will notify both the Respondent and the Whistleblower in writing of the IDO's decision. The RIO will also notify all appropriate staff of the IDO's decision.

For PHS funding, if the Inquiry Committee, RIO, or other designated institutional official determines one of the following:

- **An Investigation is warranted**: EDC must (a) within a reasonable amount of time after this decision, provide written notice to the Respondent(s) of the decision to conduct an Investigation of the alleged misconduct, including any allegations of research misconduct not

addressed during the Inquiry, and (b) within 30 days of determining that an investigation is warranted, provide ORI with a copy of the Inquiry Report.

- **The Investigation is not warranted**: EDC will keep sufficiently detailed documentation to permit a later review by ORI of why the institution did not proceed to an Investigation, store these records in a secure manner for at least seven years after the termination of the Inquiry, and provide them to ORI upon request.

VI. Investigation Phase

A. Purpose of the Investigation and Timeline

The Investigation includes a formal development of the factual record, pursuit of leads, examination of that record by the Investigation Committee and a recommendation regarding the disposition of the case. The Investigation begins within 30 days after the determination that an Investigation is warranted. All aspects of the Investigation will be completed within 180 days unless an exception is granted.

B. Notifying the Respondent and Sequestration of the Research Records

EDC will notify the Respondent in writing of the allegations within 30 days of determining that an Investigation is warranted and before the Investigation begins. The RIO must also give the Respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the Inquiry or in the initial notice of the Investigation.

If the Inquiry Committee recommends a full Investigation, the RIO will take all reasonable and practical steps to obtain custody of and sequester any additional pertinent research records that were not previously sequestered during the Inquiry. Sequestration of additional records may occur for several reasons, including EDC's decision to investigate additional allegations not raised during the Inquiry stage or the identification of records during the Inquiry process had not been secured previously.

C. Appointment of the Investigation Committee

The RIO IDO will appoint an Investigation Committee and the committee chair within 10 days of the notification to the Respondent that an Investigation is planned. The Investigation Committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case; are unbiased; and have the necessary expertise to (1) evaluate the evidence and issues related to the allegations, (2) interview the principals and key witnesses, and (3) conduct the Investigation. These individuals may be administrators, subject matter experts, or other qualified persons, and they may be from inside or outside EDC. Individuals who served on the Inquiry Committee may also serve on the Investigation Committee. The RIO will notify the Respondent of the proposed committee membership within 5 days. If the Respondent submits a written objection to any appointed member of the Investigation Committee or expert, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Investigation Committee, Process, and Reports

The RIO will define the subject matter of the Investigation in a written charge to the Investigation Committee that describes the allegations and related issues identified during the Inquiry. The charge will also define the research misconduct and identify the Respondent. The charge will state that the committee is to evaluate the evidence and testimony of the Respondent, Whistleblower, key witnesses, and relevant facts. The committee will be instructed to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to identify who was responsible. During the Investigation, if additional information becomes available that substantially changes the scope of the potential misconduct or identifies additional allegations or potential Respondents, the committee will notify the RIO, who will notify the Respondent of the new subject matter or provide notice to additional Respondents.

The RIO will convene the first meeting of the Investigation Committee to review the charge, the Inquiry Report, and the prescribed procedures and standards for the conduct of the Investigation, including the necessity for confidentiality and for developing a specific Investigation plan. The Investigation Committee will be provided with a copy of these instructions and, where federal funding is involved, the appropriate regulation.

The first meeting of the Investigation Committee will take place no more than 20 days after the committee is appointed. The Investigation normally will involve examination of all documentation. Whenever possible, the committee should interview the Whistleblower(s), the Respondents(s), and other individuals who might have information regarding aspects of the alleged misconduct. Interviews of the Respondent(s) and others who appear before the committee should be (or for PHS, *must be*) transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared and provided to the interviewed party for comment or revision. The summary and any comments or proposed revisions will be included in the investigatory file and institutional record. The Investigation Committee will follow the process described below and will issue a Final Investigation Report that may include recommendations for sanctions or other remedial actions.

At the conclusion of its Investigation, the Investigation Committee will issue a Draft Investigation Report. The Draft Investigation Report and Final Investigation Report must (a) be in writing and describe the nature of the allegations, including the identification of the Respondent; (b) identify the Research Sponsor support (if any); (c) describe the specific allegations; (d) describe the policies and procedures under which the Investigation was conducted; (e) describe how and from whom information relevant to the Investigation was obtained, including identification and summary of the research records and evidence reviewed; (f) identify any evidence taken into custody but not reviewed; (g) state the findings; and (h) explain the basis for the findings.

For PHS funding, the report must contain the following items as described in 42 CFR 93.313:

1. Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.
2. Description and documentation of the PHS support, including any grant numbers, grant applications, contracts, and publications listing PHS support. This documentation includes

known applications or proposals for support that the Respondent has pending with PHS and non-PHS federal agencies.

3. Description of the specific allegation(s) of research misconduct for consideration in the Investigation of the Respondent.
4. Composition of the Investigation Committee, including name(s), position(s), and subject matter expertise.
5. Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on. This inventory will include manuscripts and funding proposals that were considered or relied on during the Investigation. The inventory will also include a description of how any sequestration was conducted during the Investigation.
6. Transcripts of all interviews conducted.
7. Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that contain the allegedly falsified, fabricated, or plagiarized material.
8. Any scientific or forensic analyses conducted.
9. A copy of these policies and procedures.
10. Any comments made by the Respondent and complainant(s) on the Draft Investigation Report and the Investigation Committee's consideration of those comments.
11. A statement for each separate allegation of whether the committee recommends a finding of research misconduct

If the Investigation Committee recommends a finding of research misconduct for an allegation, the Investigation Report will present a finding for each allegation. These findings will (a) identify the individual(s) who committed the research misconduct; (b) indicate whether the misconduct was falsification, fabrication, and/or plagiarism; (c) indicate whether the misconduct was committed intentionally, knowingly, or recklessly; (d) identify any significant departure from the accepted practices of the relevant research community and that the allegation was proven by a preponderance of the evidence; (e) summarize the facts and analysis supporting the conclusion and consider the merits of any explanation by the Respondent; (f) identify the specific PHS support; and (g) state whether any publications need correction or retraction.

If the Investigation Committee does not recommend a finding of research misconduct for an allegation, the Investigation Report will provide a detailed rationale for its conclusion.

In either case, the Investigation Committee should also provide a list of any current support or known applications or proposals for support that the Respondent has pending with PHS and non-PHS federal agencies.

The Final Investigation Report should ordinarily be submitted to the IDO within 60 days after the first meeting of the Investigation Committee.

The RIO will provide the Respondent with a copy of the Draft Investigation Report for comment and rebuttal. The Respondent will be allowed 30 days from the date they receive the Draft Investigation

Report to review and comment. The Respondent's written comments will be attached to the Final Investigation Report.

The RIO will provide the Whistleblower (if they are not anonymous) with those portions of the Draft Investigation Report that address the Whistleblower's allegations and any testimony provided. The Whistleblower will be allowed 30 days from the date they received the draft report to review and comment. The Final Investigation Report will include the written comments of the Whistleblower.

In distributing the Draft Investigation Report, or portions thereof, to the Respondent and Whistleblower, the RIO will inform the recipient of the confidentiality under which the draft is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may request the recipient to sign a confidentiality statement or to come to the RIO's office to review the report.

The Investigation Committee will only issue a finding of research misconduct if a preponderance of the evidence demonstrates that to be the case.

After comments have been received and the necessary changes have been made to the Draft Investigation Report, the Investigation Committee will transmit the Final Investigation Report (including its findings and any recommendations) with attachments to the RIO and the IDO.

VII. Institutional Review and Decision

Based on a preponderance of the evidence standard, the IDO will make the final determination in writing whether to accept, reject, or modify the Final Investigation Report and any actions recommended by the Investigation Committee. Depending on the recommended actions, the IDO may consult with Human Resources, Finance, or the Office of Sponsored Programs. The IDO may meet with the Investigation Committee and RIO to discuss any of the findings or recommended actions. The IDO may also return the report to the Investigation Committee with a request for further fact finding or analysis. The IDO's determination and the Investigation Committee's report constitute the Final Investigation Report for purposes of the Federal Research Sponsor review.

If the IDO determines that the alleged misconduct is substantiated by the findings, they will decide on the appropriate actions to be taken after consultation with the RIO. The actions may include (1) withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found and (2) removal of the responsible person from the particular project, a letter of reprimand, the monitoring of future work, probation, suspension, salary reduction, demotion, termination of employment and/or restitution of funds, or any other action appropriate to the research misconduct.

When a final decision has been reached, the RIO will notify both the Respondent and the Whistleblower in writing. In addition, if research misconduct has been found, the IDO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the Respondent, or other relevant parties should be notified of the findings. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

EDC will complete all aspects of the Investigation within 180 days, including the following:

- Conduct the Investigation
- Prepare the Draft Investigation Report for each Respondent
- Provide the opportunity for Respondents to comment
- Document the IDO's final decision
- Transmit the institutional record, including the Final Investigation Report and IDO's decision, to Research Sponsor

If the Investigation takes more than 180 days to complete, EDC will ask the Research Sponsor in writing for an extension and document the reasons for exceeding the 180-day period in the Investigation Report.

VIII. Requirements for Reporting to Federal Research Sponsor

EDC's decision to convene an Investigation Committee must be reported in writing to the applicable Research Sponsor within 30 calendar days of finding that an Investigation is warranted and before the Investigation is commenced. The notification will include a copy of the Inquiry Report (including any comments by the Respondent or Whistleblower), the name of the Respondent, a description of the allegation, and the Research Sponsor's application or grant number. For PHS notice to ORI requirements, see 42 CFR 93.309 and 42 CFR 93.310.

The federal Research Sponsor will also be given a copy of the Investigation Report and the final outcome of the Investigation within the 180-day period for completing the Investigation. The federal Research Sponsor must also be notified if the IDO rejected any finding or recommendation of the Investigation Committee or proposed alternative or additional findings. The IDO's actions must be consistent with the definition of *research misconduct*, EDC's policies and procedures, and the evidence reviewed and analyzed by the Investigation Committee. Any significant variations from the provisions of EDC policies and procedures must be explained to the Research Sponsor. For PHS transmittal of the institutional record to ORI requirements, see 42 CFR 93.316.

For PHS funding, if a Respondent appeals an institution's finding(s) of research misconduct or institutional actions, EDC will promptly notify ORI. If the Respondent filed an appeal, the complete record of any institutional appeal also becomes part of the institutional record. EDC will wait until the appeal is concluded to transmit the institutional record to ORI. After the IDO has made a final written determination, and any institutional appeal is complete, EDC will transmit the institutional record to ORI.

If EDC plans to terminate an Inquiry or Investigation for any reason without completing all relevant requirements of the federal Research Sponsor's regulations, the RIO will submit a report of the planned termination to the Research Sponsor including the reasons for the proposed termination.

If EDC determines that it will not be able to complete the Investigation according to any deadlines by the Research Sponsor's regulations, the RIO will submit a written request for an extension to the Research Sponsor. The request will explain the delay, report on the progress to date, estimate the

date of completion of the report, and describe other necessary steps to be taken. If the request is granted, the RIO will file periodic progress reports as requested by the Research Sponsor.

When the Research Sponsor funding or applications for funding are involved and the Respondent admits to research misconduct, the RIO will contact the Research Sponsor for consultation and advice. The individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. **When the misconduct involves Research Sponsor funds, EDC cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an Investigation without prior approval from the Research Sponsor.**

At any stage of the Inquiry or Investigation, the RIO will notify the Research Sponsor within 24 hours for any of the following:

1. There is an immediate public health or safety risk involved, including an immediate need to protect human or animal subjects.
2. There is an immediate need to protect federal resources, reputation, or other interests.
3. There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is(are) the subject of the allegations as well as their co-investigators and associates, if any.
4. It is probable that the alleged incident is going to be reported publicly.
5. Research activities should be suspended.
6. There is a reasonable indication of possible civil or criminal violation.

EDC will enforce any HHS administrative action imposed on institutional members and will take the appropriate interim administrative actions to protect the integrity of the research process.

At the completion of an Investigation, the RIO will provide the Research Sponsor with (1) the Final Investigation Report with attachments; (2) a statement of whether research misconduct was found, and if so, by whom; (3) a statement of whether EDC accepts the Investigation's findings; and (4) a description of any pending or completed administrative actions against the Respondent.

IX. Federal Regulations

Public Health Service Policies and Guidance on Research Misconduct:

- Federal Register :: Public Health Service Policies on Research Misconduct
- eCFR :: 42 CFR Part 93 – Public Health Service Policies on Research Misconduct
- New ORI Final Rule Guidance Documents Released | ORI - The Office of Research Integrity:
    - Institutional Record Guidance_final.pdf
    - Research Records Guidance_final.pdf
    - Multiple Institutions Guidance_final.pdf
- Guidance Documents | ORI – The Office of Research Integrity:
    - Honest Error Guidance_final.pdf
    - Admissions Guidance_final.pdf

- Pursuing Leads Guidance_final.pdf
- Subawardee Assurances Guidance_final_0.pdf
- Institutional Assessments Guidance_final.pdf

National Science Foundation Policy on Research Misconduct:

- eCFR :: 45 CFR Part 689 – Research Misconduct

National Aeronautics and Space Administration Policy on Research Misconduct:

- eCFR :: 14 CFR Part 1275 – Research Misconduct (FAR Part 1275)

United States Department of Agriculture: Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct:

- eCFR :: 2 CFR Part 422 – Research Institutions Conducting USDA-Funded Extramural Research; Research Misconduct

X. Other Considerations

A. Termination of Respondent's Employment or Resignation Prior to Completing Inquiry or Investigation

EDC will complete its review of alleged research misconduct regardless of the Respondent's employment status when the allegations are made.

If the Respondent refuses to participate in the process after resignation, the applicable committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the Respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

If EDC finds no misconduct and the Research Sponsor concurs, after consulting with the Respondent, the RIO will undertake reasonable efforts to restore the Respondent's reputation. Depending on the particular circumstances, the RIO should consider notifying those individuals aware of or involved in the Investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunging all reference to the research misconduct allegation from the Respondent's personnel file. Any EDC actions to restore the Respondent's reputation must first be approved by the IDO.

C. Interim Administrative Actions

EDC will take interim administrative actions as necessary to protect federal funds and ensure that the purposes of the federal awards are carried out.

XI. Record Retention

After completion of a case and all related actions, the RIO will prepare a complete file for the institutional record, including the records of any initial review, Inquiry, or Investigation, and copies of

all documents and other materials furnished to the RIO or committees. The RIO will keep the file for seven years after EDC's final disposition of the case or any PHS proceedings involving the allegations, whichever comes later, unless custody has been transferred to HHS in accordance with 2 CFR 93.318. The Research Sponsor's personnel will be given access to the records upon request.

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