Guidelines and Procedures for Responding to Allegations of Research/ Scientific Misconduct

January 1, 2026

I. Introduction

A. General Policy

The University of Colorado Denver I Anschutz Campuses, herein referred to as the "University", has the responsibility to foster a research environment that promotes the responsible conduct of research, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

To fulfill its obligations and ensure the public trust, the University must prevent, identify, and investigate research misconduct. The University's obligations arise under Article V of the Laws of the Regents, *University of Colorado Administrative Policy Statement on Misconduct in Research and Authorship* and the requirements of federal agencies, including the National Institutes of Health/Public Health Service and the National Science Foundation.

The leadership of the schools and colleges of the University have a responsibility to identify faculty to serve on research misconduct committees to fulfill its obligation of investigating allegations of research misconduct. These Guidelines and Procedures are intended to provide guidance with respect to the manner in which the University will carry out these responsibilities.

Nothing in these Guidelines and Procedures is intended to override or contradict provisions of other regulations or policies of the University of Colorado or the applicable funding agencies.

Although these Guidelines and Procedures set forth the presumptive time frames for the conduct of proceedings, these time frames are not absolute and may be modified as necessary for the Research Integrity Officer ("RIO") and/or the applicable committees to adequately perform their functions. Failure to complete an inquiry, investigation, or other process within these time frames shall not be grounds for dismissal of an allegation of research misconduct, but any undue delay may be considered by the RIO or other appropriate official when reviewing the relevant committee's findings and recommendations.

While every effort will be made to follow the proscribed procedures, unanticipated situations including but not limited to the nature of the allegation and events related to its investigation may necessitate reasonable changes in our approaches to obtaining a fair and timely decision.

B. Scope

These Guidelines and Procedures apply to:

1. Any person who, at the time of the alleged research misconduct, was employed by, was an agent of, and/or was affiliated by contract or agreement with the University of Colorado Denver I Anschutz Campuses.
2. Any person who is alleged to have committed research misconduct prior to his or her employment, agency or affiliation with the University of Colorado Denver | Anschutz Campuses, provided the RIO determines that such allegations of research misconduct may violate University policies and impact the reputation of the

University in coordination with the applicable external institution.

The University has academic dishonesty procedures but such policies do not take precedence over these policies and procedures for allegations involving alleged research misconduct in student course work.

In the event that potential research misconduct is alleged to have occurred in the course of federally-funded research, the RIO shall attempt to comply with both these Guidelines and Procedures and the funding agency's requirements for the investigation of research misconduct. In any such case, the RIO shall refer to the requirements delineated by each federal agency, including, for example, the Public Health Service requirements contained in 42 C.F.R. 93 and the National Science Foundation requirements described in Section 930 of the NSF Grant Policy Manual. In the event that these Guidelines and Procedures materially conflict with the requirements of any funding agency, the RIO will apply the requirements of the funding agency. Any allegation brought forward after the effective date listed on this policy and procedure document must be managed in accordance with this document. The institution notes that these policies and procedures have been amended to align when applicable with the latest amendments to PHS regulations 42 C.F.R. 93 effective January 1, 2026.

There is no time limitation for bringing forward an allegation of research misconduct at CU Denver I Anschutz to trigger review in accordance with this process as outlined in this document.

II. Definitions

A. Research

The University broadly defines "research, scholarship and creative activities" to include all forms of scholarship and creative activities within the responsibilities of faculty, staff, or students that are designed as original works or are intended to contribute to generalizable knowledge in a field of academic inquiry. The terms "research" and "research, scholarship and creative activities" are used interchangeably throughout this document.

PHS 42 CFR 93.232 defines research to mean a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating, or confirming information or underlying mechanisms related to biological causes, functions, or effects; diseases; treatments; or related matters to be studied.

B. Misconduct in Research

Misconduct in research includes the following and means:

1. **Fabrication**, **falsification**, **plagiarism** and other forms of misrepresentation of ideas, and other serious deviations from accepted practices in proposing, carrying out, reviewing, or reporting results from research. Research misconduct does not

include honest error or differences of opinion.

The following definitions apply:

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.

a) Plagiarism includes the unattributed 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.

b) Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes and former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the PHS definition of research misconduct.

2. Failure to comply with established standards regarding author names on publications;

3. Retaliation of any kind against a person who, in good faith, reported or provided information about suspected or alleged research misconduct. 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; b) Good faith cooperations with a research misconduct proceeding.

Research misconduct does not include honest error or honest differences in opinion, or differences in interpretations or judgments of data.

However, where a person's conduct otherwise constitutes research misconduct, the burden of proof lies with that person to establish by a preponderance of the evidence that his or her conduct represents honest error or differences in interpretation.

A finding of research misconduct requires that:

- The conduct in question is found to meet the definitions of fabrication, falsification and/ or plagiarism;
- There is a significant departure from accepted practices of the relevant research community; and
- The misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation be proven by a preponderance of the evidence.

To act **Intentionally** means to act with the aim of carrying out the act.

To act **knowingly** means to act with awareness of the act.

To act **recklessly** means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification or plagiarism.

Accepted Practices of the relevant research community means those practices established by regulation and by PHS or other funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive federal awards.

Good faith:

As applied to a complainant or witness means having a reasonable belief in the truth of one's allegation or testimony 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 knowledge of or reckless disregard for information that would negate the allegation or testimony.

As applied to an institutional or committee member means cooperating with the research misconduct proceedings by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under this document. An institutional or committee member does not act in good faith if their acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional or financial conflicts of interest with those involved in the research misconduct proceedings.

If, in the course of an investigation, it is determined that the allegations of research misconduct relate to federally-funded research and the federal funding agency's definition of research misconduct is more limited than the definition set forth in these Guidelines and Procedures, the federal funding agency's definition of research misconduct shall apply for determining whether such research misconduct shall be reported to the federal funding agency or other appropriate authority. The University's definition of research misconduct, however, shall continue to apply for the University's internal administrative purposes, including the imposition of discipline against any person who is determined to have engaged in conduct that meets the University's definition of research misconduct.

C. Public Health Service Office of Research Integrity (PHS/ORI)

As used in these Guidelines and Procedures, PHS/ORI refers to the Office of Research Integrity within the Public Health Service of the National Institutes of Health (NIH). This office oversees research misconduct investigations involving research funded by the NIH. PHS support means PHS funding, or applications or proposals for PHS funding, for biomedical or behavioral research, biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: funding for PHS intramural research; PHS grants, cooperative

agreements, or contracts; subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

III. Roles and Responsibilities

A. Research Integrity Officer

The Vice Chancellor for Research shall appoint the RIO. The RIO is the institutional official who has primary responsibility for implementing these Guidelines and Procedures.

The RIO's duties are described in Appendix A, but generally include:

Advising any person who is considering whether to submit an allegation of research misconduct about the requirements of these Guidelines and Procedures;

Receiving allegations of research misconduct, assessing allegations of research misconduct to determine if they fall within the definition of research misconduct and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified;

Overseeing inquiries and investigations;

Administering these Guidelines and Procedures to provide timely notice and an opportunity to respond to any person alleged to have engaged in research misconduct;

Providing timely notifications of research misconduct inquiries and investigations to appropriate University and federal agency officials;

Notifying the Office of Grants & Contracts of any requirements of funding organizations concerning research misconduct; and

Acting as liaison between the appropriate dean, vice chancellor, or other University official if that party is required to communicate with the funding agency on research matters.

B. Scientific Research Integrity Officer

The Scientific Research Integrity Officer (SRIO) is a member of the faculty whose role is to support the RIO. The basic responsibilities of the RIO and SRIO are to promote exemplary ethical standards of research conduct, to publicize the Guidelines and Procedures for reporting research misconduct, and ensure that the procedures are appropriately followed and documented.

C. Deciding Official

The Deciding Official (DO) is the institutional official who receives the investigative report and makes the final determinations on allegations of research misconduct and determines

the appropriate institutional response. The University has designated the Vice Chancellor for Research as the DO. The DO shall not be the same person as the RIO. To the extent possible, the DO should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment; the fact that the DO received an allegation of research misconduct or referred such an allegation to the RIO shall not constitute direct prior involvement.

If the Vice Chancellor for Research is conflicted or is otherwise unable to render a decision regarding the referred matter, then the RIO should consult with the University's leadership to determine, as early as practicable in the process, an appropriate individual to serve as the DO. In the event of such a conflict, or if the Vice Chancellor for Research is unable to render a decision, the designated DO will be either the Provost or the Dean of the appropriate School or College, depending on the nature of the allegation.

D. Complainant

The Complainant is the individual who brings forward an allegation (preferably in writing) of misconduct in research to the RIO. The University requires any person who makes an allegation of research misconduct to make allegations in good faith, maintain confidentiality, and cooperate with the inquiry and investigation. Most anonymous complaints will not be investigated. As a matter of good practice, the complainant should be initially interviewed by the RIO and/or SRIO.

E. Respondent

The Respondent is the person against whom an allegation of research misconduct has been made or who is the subject of a research misconduct proceeding. The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation.

If an institution identifies additional respondents during an inquiry or investigation, the institution is not required to conduct a separate inquiry for each new respondent. However, each additional respondent must be provided separate notice of and an opportunity to respond to the allegations, Each respondent should also receive a separate determination and report at inquiry and/or investigation.

As further described in these Guidelines and Procedures, the Respondent has rights that the RIO and the committees shall attempt to preserve during the inquiry and investigation processes. In the event the RIO or the committees fail to provide the rights identified in these Guidelines and Procedures, the DO may consider any such failure when determining the appropriate institutional response to an allegation of research misconduct.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

University employees have an obligation to report observed or suspected research misconduct to the RIO or SRIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact the RIO to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, but are appropriately addressed to another University entity or third party, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem. Except to the extent necessary to comply with reporting requirements or state law or to defend any legal action which might be asserted against the University, the RIO will maintain confidentiality of any such discussions or consultations regarding concerns of possible research misconduct.

Allegations of suspected research misconduct that are brought by faculty or staff to their supervisor or University leadership must be immediately forwarded to the RIO for evaluation. The applicable school, college, or department shall not undertake any level of internal review regarding the allegation(s). This is important to protect the chain of evidence and ensure the investigation is conducted in accordance with applicable federal regulations.

B. Cooperation with Research Misconduct Proceedings

In accordance with the University of Colorado Administrative Policy Statement on Misconduct in Research and Authorship, members of the University community are obligated to cooperate with and provide evidence relevant to a research misconduct allegation to the RIO, and other institutional officials. Any member of the University community who fails or refuses to cooperate with the inquiry or investigative processes shall be reported to the appropriate dean or vice chancellor; such non-cooperation may constitute the basis for disciplinary action. Nothing herein will be interpreted in such a way as to infringe on an employee's, or, when applicable, a student's right to invoke the protection of the Fifth Amendment to the U.S. Constitution with regard to self-incrimination.

During both inquiry and investigation, the RIO and the SRIO shall elicit the cooperation of the Complainant, the Respondent, and any other persons who have knowledge of the alleged research misconduct. Any person's failure to provide such cooperation, however, shall not preclude the University's investigation of potential research misconduct.

C. Confidentiality

The RIO, the SRIO, and the appropriate committee members shall take reasonable steps to maintain the confidentiality of an allegation of research misconduct through the inquiry and investigative stages. The RIO, the SRIO, and the committees shall request that the Complainant, the Respondent, and any other involved persons maintain confidentiality during the inquiry and investigative processes, including requiring signature to

confidentiality agreements.

During the course of the inquiry and investigative stages, the RIO, and the appropriate committees, may disclose information related to an allegation of research misconduct through the inquiry and investigative stages to the extent required by law.

The RIO or the committee may also disclose information related to the inquiry and investigative processes if the seriousness of the alleged research misconduct warrants disclosure prior to the outcome of the inquiry or the investigation.

Without limitation such instances include where the disclosure is necessary:

(1) To prevent an immediate health hazard;

(2) To protect the University's resources or reputation;

(3) To protect the interests of the academic community;

4) To protect any person's resources or reputation;

(5) To comply with the University's obligations to any state or federal agency, or

(6) To correct misinformation made available to the public about the alleged research misconduct and the University's response.

To the extent possible, the RIO, SRIO, and/or the committee shall limit disclosure of the identity of the Complainant, Respondent, or witnesses in the inquiry and investigative processes. For example, unless the circumstances merit direct identification of the participants in their reports and other documents, the committees should refer to the participants as "Complainant," "Respondent," and "Witness 1." In the event that the committees refer to individuals using generic identifiers, it should also include a confidential appendix containing those persons' identities.

The DO may disclose the final inquiry report and/or investigative report and /or DO memo as necessary for it to meet its obligation of discouraging research misconduct in the University community, to remediate the harm caused by research misconduct, as necessary to comply with the requirements of funded research or to comply with the Colorado Open Records Act, C.R.S. §§ 24-72-201 to 206. In the event that the DO finds that a Respondent has not engaged in research misconduct, the DO may disclose the final inquiry report and investigative report as necessary to protect the reputation of the Respondent.

Notwithstanding any other provision in these Guidelines and Procedures, the University, the RIO, the DO, and the committees shall disclose any information reasonably necessary for it to comply with state or federal law.

D. Non-Retaliation

Members of the University community or the Respondent(s) may not retaliate in any way against Complainants, witnesses, or committee members for their participation in an investigation of Research Misconduct. Institutional members should immediately report any

alleged or apparent retaliation to the RIO or to the CU Ethics Line. The RIO shall review the allegation of retaliation and, if warranted, make all reasonable and practical efforts to redress any retaliation that has already occurred and to prevent any further retaliation.

All parties involved in an allegation of research misconduct should continue, whenever feasible, maintain business as usual until such times as findings are made unless a party has a concern for their safety, wellbeing or productivity.

E. Interim Administrative Actions and Notifying PHS/ORI of Special Circumstances

Throughout the research misconduct inquiry and investigation, the RIO will monitor the proceedings to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the federally-supported research process. In the event of such a threat, the RIO will, in consultation with other Institutional officials and the funding agency, take appropriate interim action to protect against any such threat.

Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results, delaying publication, or notifying appropriate persons of errors in published research.

The RIO shall, at any time during a research misconduct proceeding, notify PHS/ORI or NIH, if applicable under NOT-OD-19-20, immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed. This requirement may include contacting editors/journals regarding existing publications.

The RIO will also ensure that any individual involved in the process, including the Complainant, Respondent, and committee members, is referred to the appropriate resources on campus that can provide additional support during an Inquiry and/or

Investigation, including but not limited to, the CARE Team, FAST Team, and/or the Office of Professionalism for concerns relating to:

- Supporting parties to continue to work productivity;
- Address how to interact on campus; and
- Field questions by colleagues related to the situation.
- Handle stress related to the process

V. The Scientific Research Integrity Officer

A. Appointment .

The Deciding Official appoints the Scientific Research Integrity Officer (SRIO) in consultation with the RIO.

B. Meeting Schedule

The RIO and SRIO shall meet at least twice each academic year or more frequently as needed to address research integrity concerns involving the institution.

C. Role of the University Counsel

As it deems necessary, the RIO and the constituted committees may seek advice and assistance from the Office of the University Counsel. In this role, University Counsel is representing the University, and not any individual involved in any part of the process. Complainant, Respondent, and witnesses may retain their own counsel to represent their interests during any part of the proceedings.

The Office of the University Counsel shall be notified of any allegations that are brought forward and are deemed to trigger these policies and procedures. University Counsel may send a representative to attend the proceedings of any inquiry or Investigation committee appointed if the University Counsel considers that such attendance is in the best interests of the University.

D. Amendments to the Guidelines and Procedures

Amendments may be proposed by the RIO, SRIO or University Counsel and approved by the DO.

E. Education of the Academic Community

Deans, directors, chairs and graduate advisors shall be reminded annually of the University

of Colorado Administrative Policy on *Research Misconduct and Authorship* and of these Guidelines and Procedures. The University shall also inform all faculty, students, and staff of (1) the need for integrity in research performance and (2) the role of the RIO in considering allegations of research misconduct.

Training with regard to Responsible Conduct of Research is the responsibility of all faculty, mentors and trainers who conduct research. The RIO is responsible for ensuring that appropriate training and educational opportunities are made available.

VI. Conducting an Assessment & Inquiry

A. Procedures for Making Allegations

All persons having knowledge of research misconduct or having reason to believe that such misconduct may have occurred, should connect with the Research Integrity Officer (RIO) and/or the SRIO. An allegation means a disclosure of possible research misconduct through any means of communication and brought directly to the attention of the responsible institutional official ie, RIO or SRIO.

Individuals who are uncertain about whether to file an allegation may consult with the RIO prior to filing a written complaint. Except as described in the section of these Guidelines and Procedures detailing confidentiality, the RIO will maintain confidential any such discussions or consultations regarding concerns of possible research misconduct.

B. Initial Review and Assessment

Upon receiving a written allegation of research misconduct, the RIO, in collaboration with the SRIO, will immediately assess the allegation to determine whether it (a) is sufficiently credible and specific so that potential evidence of research misconduct may be identified, and (b) the substance of the complaint, if it is assumed true, meets the definition of research misconduct described under these Guidelines and Procedures or under any federal standard applicable to the research. The RIO may utilize available resources such as the SRIO, University Counsel and/or other experts in making the determination.

The assessment period should be sufficiently robust to make an assessment. In conducting the assessment, the RIO may, but is not required to, interview the Complainant, or other witnesses. The RIO need not conduct any research or gather any data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently specific so that a potential instance of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation.

Should multiple complaints about the Respondent be received, the RIO in collaboration with the SRIO shall determine how best to proceed. Generally, multiple complaints will be handled as follows:

1. If an *inquiry* is already in process, the new complaint will be forwarded to the current Inquiry Committee. The current Inquiry Committee may recommend to the RIO that the new complaint be included as part of the ongoing inquiry, that a new Inquiry Committee be formed to explore the new complaint, or that the new complaint be rejected as being duplicative with the allegations already being reviewed.
2. If an *investigation* is underway when a new complaint arrives, the RIO will confer with the chair of the Investigative Committee to determine if the new complaint is most appropriately included in a revised charge to the Investigative Committee, or whether it should be referred to an Inquiry Committee.
3. If a complaint is received after an Investigation has been *completed*, the RIO will determine whether the new complaint merits an Inquiry or is redundant with the prior complaint(s) that have already been investigated.
4. If the Inquiry or Investigation Committee identifies new areas of concern as part of their process, then the appropriate committee may notify the Respondent verbally during the interview process or in writing of any additional concerns. If the new allegations involve new Respondents, then the new Respondents should be notified in writing of the allegations against them.

The assessment of the allegation must be sufficiently documented. If the RIO in collaboration with the SRIO determines that the Complainant has stated a possible instance of research misconduct, the complaint will be referred for inquiry as described below. If the RIO or designee determines that requirements for an inquiry are not met, they must keep sufficient documentation of the assessment and rationale for external review as needed. Such documentation must be available for seven years after the assessment. If not, the RIO and/or Chair shall notify the Complainant, the Respondent (if appropriate) and the DO of the decision not to pursue the allegations. Such decisions may be over-ruled by the DO. The DO's decision is final, and cannot be appealed.

C. Confidentiality

Disclosure of the identity of respondents, complainants, and witnesses while conducting the research proceedings is limited, to the extent possible, to those who need to know, as determined by the institution, consistent with a thorough, competent, objective and fair research misconduct proceedings.

Those that may need to know may include institutional review boards, journals, editors, publishers, sponsors, co-authors and collaborating institutions.

This limitation no longer applies once an institution has made a final determination of research misconduct findings. An appropriately redacted copy of the final investigation report and/or the Deciding Officials determinations may be made available under a CORA request or its equivalent. All other documentation related to the review process with be managed as confidential by the institution unless required by law.

D. Conduct of Inquiry

1. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

Note certain funding agencies require to be notified at this stage in the proceedings. The RIO should consult with the Office of Grants and Contracts to complete any such obligations.

2. Sequestration and Protection of Evidence

The institution has a duty to obtain, inventory, and securely sequester evidence that extends to whenever additional items become known or relevant to the inquiry or investigation. The RIO shall, on or before the date on which the Respondent is notified of the allegation, take all reasonable and practical steps to obtain the original or substantially equivalent copies of all records and evidence necessary to conduct the inquiry unless the Respondent can provide a reasonable explanation of the allegation. The RIO shall inventory and, in collaboration with the Office of Information Technology (OIT) Security Officer or delegate, sequester all such records and evidence. The RIO shall confer with the Respondent to identify the records and evidence needed for the inquiry and the best means of preserving and maintaining the integrity of the records and evidence. Whenever feasible, three (3) forensic copies of all sequestered data will be made and stored by OIT. All physical notebooks, slides or other physical evidence will be logged on a custody form and stored in the RIO's custody lockers. All sequestered documents should be retained for seven years.

Where the 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. The RIO may consult with NIH/PHS/ORI or other similar parties for advice and assistance in this regard.

3. Notice to Respondent

The Respondent is normally not informed of an allegation until an Inquiry Committee has completed Phase I and determined that the inquiry procedure should proceed. Once this

determination has been made, the RIO, must make a good faith effort to notify the Respondent in writing, that an allegation(s) of research misconduct has been raised against them, the relevant research records have been sequestered, and an inquiry will be conducted to decide whether to proceed with an investigation. The Respondent will be informed of the specifics of the allegation and will be provided with University rules and procedures governing the inquiry process; in the case of funded research, the RIO will provide Respondent with the relevant federal regulations. If additional allegations are raised, the institution will notify the respondent(s) in writing. When appropriate, the institution will give the respondent(s) copies of, or reasonable supervised access to, the sequestered materials.

The Respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO, the Deciding Official may terminate the Institution's review of an allegation that has been admitted. In the case of allegations that fall under the purview of the Public Health Service, the institution's acceptance of the admission and any proposed settlement must be approved by PHS/ORI. NIH must be informed of Respondent's admission of research misconduct if the study is funded by NIH. [See page 33 for more details]

If additional respondents are identified, the RIO will provide written notification to the new respondent(s). All additional respondents will be given the same rights and opportunities as the initial respondent. Only allegations specific to a particular respondent will be included in the notification to that respondent.

If the Inquiry Committee, as part of its Phase I inquiry, determines that a complaint should not be pursued, it will so advise the RIO. If the RIO concurs, the Respondent may be informed of the complaint and the reasons for not pursuing it but only if the RIO determines such an approach is appropriate.

4. Inquiry Process – General Requirements

The RIO, in consultation with the SRIO Chair and other institutional officials as appropriate, shall appoint the Inquiry Committee and Inquiry Committee chair as soon after the initiation of the inquiry as possible.

In lieu of a committee, the institution may task the RIO or another designated institutional official to conduct the inquiry, provided this person utilizes subject matter experts as needed to assist in the inquiry

The Inquiry Committee may include the SRIO but must also consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with either the Complainant or Respondent. The Inquiry Committee members should also have the appropriate scientific or related subject matter expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses and conduct the inquiry. Each member of the Inquiry Committee must sign a confidentiality agreement prior to reviewing any information related to Complainant's allegations. The RIO will ensure that all inquiry committee members understand their commission, keep the identities of respondents, complainants, and witnesses confidential, and conduct the research misconduct proceedings in compliance with the PHS regulation or this document.

The RIO will prepare a charge for the inquiry committee that:

- Sets forth the timeline for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: 1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and 2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the Inquiry Committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of these guidelines and procedures.

The inquiry is a two-stage, fact-finding, non-adversarial proceeding intended to provide an initial review of the evidence so that a preliminary evaluation can be made as to whether there is sufficient evidence of research misconduct to warrant full investigation. The inquiry is intended only to provide a means of initially evaluating the merits of the allegations of research misconduct to identify and dismiss non-meritorious allegations. Consequently, because of the limited nature of the inquiry proceedings, an inquiry does not require the Inquiry Committee to fully review all of the evidence related to the allegation.

The RIO will provide copies of all documentation and interview summaries obtained as part of the preliminary assessment to the Inquiry Committee members. This material may be sufficient for the Inquiry Committee to make a determination. If the inquiry committee decides additional information is needed, then the Inquiry Committee shall request confidentiality from all participants in the inquiry committee process. Each participant will be asked to sign a confidentiality agreement and be provided with a summary of their rights and responsibilities with regard to the inquiry. Each interested party shall be interviewed separately. Any person—whether a Complainant, Respondent, or witness—may have an advisor or attorney present at any interview of such person to act as such person's personal

advisor. Such advisors may assist in the presentation of information but may not speak for these persons or conduct cross-examinations. The inquiry proceedings may be recorded, although the members of the Inquiry Committee may also take informal written notes during the proceedings.

The inquiry shall be initiated and conducted as expeditiously as possible. The inquiry, including preparation of the final inquiry report and the decision on whether an investigation is warranted, shall be completed within **ninety (90) calendar days** of the initial written notification of the Respondent unless the RIO or Inquiry Committee determine that circumstances warrant a longer period. If a time extension is granted, the final report of the Inquiry Committee must include the reasons for the extension.

D. Inquiry Procedures

1. Stage One

The Inquiry Committee begins its proceedings by reviewing the written allegations of research misconduct and the supporting materials, if any, to determine whether to pursue further investigation. This stage of the inquiry is intended to allow the Inquiry Committee to identify baseless and groundless allegations of research misconduct.

The Inquiry Committee, in extraordinary cases where it is unable to form an opinion whether the written allegations are baseless or groundless, may interview additional witnesses, but shall conduct the interviews in a manner designed to protect the confidentiality of the inquiry process, including, to the extent possible, the Respondent's identity.

Upon a majority vote of the members of the Inquiry Committee determining that some or all of the allegations of research misconduct are potentially meritorious, the Inquiry Committee shall notify the RIO of its intention to proceed to the second stage of the inquiry.

The members of the Inquiry Committee may by majority vote may also recommend that the RIO dismiss any baseless and groundless allegations before proceeding to the second stage of the inquiry. If the Inquiry Committee votes to recommend dismissal of some or all of the allegations, the Inquiry Committee shall submit its written recommendation and reasons to the DO. The RIO shall review the Inquiry Committee's recommendation and decide whether to accept it.

If the RIO accepts the Inquiry Committee's recommendation of dismissal of some or all of the allegations, the inquiry shall be deemed concluded as to those allegations, and the RIO shall inform the Respondent of the determination and the bases for its determination. If the RIO determines that some or all of the Complainant's allegations were made without reasonable basis in fact and with malicious intent, the RIO may refer the Complainant to appropriate entities within the University or other institutions to properly address the matter.

If the RIO rejects the Inquiry Committee's recommendation of dismissal, in whole or in part, s/he shall return the allegations that s/he did not dismiss to the Inquiry Committee for the

second stage of the inquiry.

2. Stage Two

If the Inquiry Committee or the RIO decide, after Stage One is complete, that some or all of the allegations of research misconduct are potentially meritorious, the RIO shall notify the Complaint in writing of this determination after all relevant data has been sequestered.

The RIO shall inform the Respondent in writing about the nature of the research misconduct allegations, including a copy of the written allegations and any supporting materials. The Inquiry Committee shall request that the Respondent provide a written response to the allegations of research misconduct within fourteen (14) calendar days, but the Inquiry Committee may grant reasonable extension of this deadline at its discretion in consultation with the RIO/SRIO.

After receiving and reviewing the Respondent's written response to the allegations of research misconduct, or if the Respondent does not respond within the allowed period of time, the Inquiry Committee may invite the Respondent for a personal interview to discuss the details of the alleged misconduct. This interview shall be fact-finding rather than adversarial. If the Respondent declines a personal interview, or in addition to such a personal interview, the Inquiry Committee may also interview the Respondent by telephone or through solicited responses to questions or other methods.

The Inquiry Committee, at its discretion, may interview other individuals to obtain information pertinent to the inquiry. Any such interviews may be conducted in person, by telephone, or through solicited responses to written questions, or other methods. Additional sources of information, such as documents and physical evidence, may be considered by the Inquiry Committee.

3. Decision of Inquiry Committee

The inquiry should be completed within **ninety (90) calendar days** of its initiation unless circumstances warrant a longer period. If the inquiry takes longer than **ninety (90) days** to complete, the inquiry report must include documentation of the reasons for exceeding the ninety (90)-day period. Upon concluding its inquiry, the Inquiry Committee shall decide by recorded simple majority vote whether a full investigation of any or all of the allegations is needed.

The inquiry committee will not determine if research misconduct occurred, nor assess whether the alleged misconduct was intentional, knowing, or reckless; such a determination is not made until the case proceeds to an investigation.

The criteria for warranting an investigation are met if the following findings can be made:

- There is a reasonable basis for concluding that the allegation(s) fall within the definition of research misconduct; and
- Preliminary information-gathering and preliminary fact-finding from the inquiry

indicates that the allegation may have substance

E. The Inquiry Report

At the conclusion of the inquiry, regardless of whether an investigation is warranted, the inquiry committee, RIO, or other designated institutional official will prepare a written inquiry report.

1. Content of Inquiry Report

The contents of a complete inquiry report will include:

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 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 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.

2. Solicitation of Comments

Before the Inquiry Committee submits its report to the RIO under Stage Two, the

Institution's legal counsel shall review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the Inquiry Committee. The RIO shall provide a copy of its proposed report to the Respondent for review. This report may include suggestions to broaden the scope for the Investigation process. If the Respondent wishes to submit any comments on the proposed report to the DO, the RIO shall include those comments with the final report that is transmitted to the DO. The Respondent's comments shall be received by the RIO within ten (10) days after the Respondent's receipt of the proposed report.

Upon receipt of comments by the Respondent, the Inquiry Committee may modify its proposed report before submitting a final report to the RIO to provide to the DO. The Inquiry Committee is not required to provide the Respondent with its modifications before submitting the final report to the RIO. Such comments do not constitute an appeal of the DO's decision after the Inquiry proceeding, which is final.

The Complainant will not review the final Inquiry report unless the RIO or Inquiry Committee determines that it is appropriate.

The RIO will transmit the final inquiry report and any comments to the DO.

F. DO Review of Inquiry Report and Determination

Upon review of the Inquiry Committee's report, the DO may:

(a) Dismiss some or all of the allegations of research misconduct. The inquiry shall be deemed concluded as to any dismissed allegation. The RIO shall inform the Complainant and the Respondent of the DO's determination and the bases for his/her determination. If the DO determines that some or all of the Complainant's allegations were made without reasonable basis in fact and with malicious intent, the DO may refer the Complainant to appropriate entities within the University or other institutions, as appropriate to address the matter.

(b) Initiate a full investigation of some or all of the allegations of research misconduct. The DO shall refer any appropriate allegations for investigation to the Investigation Committee.

1. Documentation of Decision Not to Investigate

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI, or the appropriate funding agency, as required, of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

2. Notification to Complainant and Respondent

The RIO shall inform the Complainant and the Respondent of the determination and the bases for its determination. The RIO will provide the Respondent with a copy of the final Inquiry report.

The RIO may, but is not required to, provide a copy of the Inquiry report to the Complainant. The RIO shall not provide the Complainant with a copy of the report unless the Complainant agrees to be bound by a confidentiality agreement preventing disclosure of the contents of the report. The RIO is required to take the same notification action for all complainants in cases where there is more than one complainant.

3. Notification to PHS (including NIH)/ORI (if applicable)

If applicable, within **thirty (30) calendar days** of the decision by the DO that an investigation is warranted, the RIO will so inform PHS/ORI and provide PHS/ORI with a copy of the inquiry report.

The RIO will provide the following information to PHS/ORI upon request:

(1) the institutional policies and procedures under which the inquiry was conducted;

(2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and

(3) the charges to be considered in the investigation.

The RIO will also review the requirements of other funding agencies to comply with other reporting requirements. The RIO will also notify those institutional officials who need to know of the DO's decision.

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by PHS/ORI of the reasons why an investigation was not conducted. These documents must be provided to PHS/ORI or other authorized HHS personnel upon request.

VII. Investigative Phase

A. Initiation and Purpose

The purpose of an investigation is to formally develop a factual record, pursue leads, examine the record, and recommend finding(s) to the DO, who will make the final decision, based on a preponderance of evidence, on each allegation and any institutional actions. As part of its investigation, the institution will pursue diligently all significant issues and relevant

leads, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

Unless the DO determines otherwise, due to extraordinary circumstances, the investigation phase must begin within 30 calendar days after the determination by the DO that an investigation is warranted. The ultimate purpose of the investigation is to determine whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. Such expansion of the allegation is not consider a new allegation but is instead managed as part of the current Investigation.

B. Notifying ORI (or PHS, if applicable) and Respondent; Sequestration of Research Records

The RIO will notify the respondent(s) of the allegation(s) within 30 days of determining that an investigation is warranted and before the investigation begins. If any additional respondent(s) are identified during the investigation, the institution will notify them of the allegation(s) and provide them an opportunity to respond consistent with the PHS regulation or this document.

If the institution identifies additional respondents during the investigation, it may choose to either conduct a separate inquiry or add the new respondent(s) to the ongoing investigation.

The institution will obtain the original or substantially equivalent copies of all research records and other evidence, inventory these materials, sequester them in a secure manner, and retain them for seven years after its proceeding or any HHS proceeding, whichever is later.

C. Appointment of Investigative Committee

As soon as possible after the DO decides to pursue an investigation, the RIO, in consultation with the SRIO, appropriate vice chancellor or dean, will appoint an ad hoc committee of three to five members, including a chair, from the broader research community depending on the nature of the allegation to serve as an Investigative Committee. Scientists external to the institution should be considered if there is any concern of potential or perceived conflict of interest with the local research community or institution. The investigational committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee or can be members from outside the institution. The Investigative Committee is charged with conducting a thorough and unbiased investigation of the allegations of misconduct.

The RIO shall notify the Respondent and Complainant of the names of potential

Investigative Committee members, to ensure that Investigative Committee members do not have a bias or conflict of interest in considering the case. If a potential member's impartiality is questioned, the RIO will determine whether the potential member should be excluded from the Investigation Committee. If, during the course of an investigation, a member's impartiality is questioned, the RIO, in consultation with legal counsel, will determine whether the potential member should be removed and replaced.

D. Charge to the Investigative Committee

The RIO will convene the first meeting of the Investigative Committee at which the RIO will review with the Investigation Committee the charge, the inquiry report, and these Guidelines and Procedures. The RIO will inform the members of the Investigative Committee of the confidentiality requirements of these Guidelines and Procedures and obtain the members' agreement to these requirements. The RIO shall provide each member with these Guidelines and Procedures, as well as any federal standards applicable to the investigation. The RIO will be available throughout the investigation to advise the Investigative Committee as needed and provide administrative support.

The RIO will provide the Investigation Committee with a written charge that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the Respondent(s);
- Informs the committee that it must conduct the investigation as prescribed in these Guidelines and Procedures;
- Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the committee that the Respondent(s) has the burden of proving **by a preponderance of the evidence** any affirmative defenses raised, including honest error or a difference of opinion. Preponderance of the evidence means proof by evidence, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not;
- Informs the committee that in order to determine that the respondent committed research misconduct it must find on a preponderance of the evidence, research misconduct occurred it must find that a preponderance of the evidence establishes that:

    1) research misconduct, as defined by this policy occurred;

    2) the research misconduct is a significant departure from accepted practices of the relevant research community;

    3) the respondent committed the relevant research misconduct intentionally, knowingly, or recklessly.

- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and, if applicable, 42 CFR § 93.313.

E. Investigative Process

The investigation committee will conduct interviews, pursue leads, and examine all research records and other evidence relevant to reaching a decision on the merits of the allegation(s). The institution will use diligent efforts to ensure that the investigation is thorough, sufficiently documented, and impartial and unbiased to the maximum extent practicable. The institution will notify the respondent in writing of any additional allegations raised against them during the investigation.

The Investigative Committee has the responsibility for conducting a thorough and unbiased investigation. Legal Counsel is available to provide legal advice. In accordance with this mandate, the investigation committee and the RIO must:

1. Begin its proceedings by studying the information and evidence collected by the Inquiry Committee and/or RIO.
2. Determine what additional evidence the Investigative Committee needs to make an informed determination as to whether research misconduct has occurred, including interviews of witnesses (including witnesses already interviewed by the Inquiry Committee and/or RIO) and review of additional evidence.
3. 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 each allegation;
4. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
5. 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;
6. Pursue diligently all significant issues and material leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.
7. Provide the Respondent with copies of or reasonable supervised access to the research records that are sequestered, as appropriate.
8. Provide the Respondent with an opportunity to provide oral or documentary evidence related to the allegations and/or research misconduct.
9. Provide the Respondent with an opportunity to identify witnesses (internal and/or

external) with knowledge in the area of the alleged research misconduct.

10. Provide the Respondent with an opportunity to review and respond to any evidence that the Investigative Committee relies upon in making its determinations.
11. Preserve the evidence that it relies upon in making its determinations.

The Investigation Committee will interview each respondent, complainant(s), 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. The institution will number all relevant exhibits and refer to any exhibits shown to the interviewee during the interview by that number. The institution will record and transcribe interviews during the investigation and make the transcripts available to the interviewee for correction. The institution will include the transcript(s) with any corrections and exhibits in the institutional record of the investigation. The respondent will not be present during the witnesses' interviews, but the institution will provide the respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality.

The Chair of the Investigative Committee shall control the proceedings and determine the admissibility of evidence. The Investigative Committee shall not be bound by the Colorado Rules of Evidence and may admit any evidence that the Chair deems reasonably related to the allegations of research misconduct. The Chair shall have the ability to limit the presentation of irrelevant or repetitious evidence.

Any party appearing before the committee may have an advisor present, who may be an attorney. The advisor may assist the party in the presentation of information but may not speak on the party's behalf.

F. Evidentiary Standard

An institutional finding of research misconduct must be proved by a preponderance of the evidence.

The institution 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 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 whether 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. In determining whether the institution has 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.

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.

G. Time for Completion

The Investigational Committee will complete all aspects of the investigation within 180 days. The institution will conduct the investigation, prepare the draft investigation report for each respondent, and provide the opportunity for respondents to comment. The institution will document the DO's final decision and transmit the institutional record (including the final investigation report and DO's decision) to ORI. If the investigation takes more than 180 days to complete, the institution will ask ORI in writing for an extension and document the reasons for exceeding the 180-day period in the investigation report. If applicable, the RIO may inform NIH of any extension of the Investigation process.

VIII. The Investigation Report

A. Decision by the Investigative Committee

When it considers that its task has been completed, the Investigation Committee shall determine by majority vote whether the allegations of misconduct are supported by a preponderance of evidence. The Investigation Committee shall reach one of the following decisions as to each allegation of research misconduct:

1. A finding of research misconduct (as defined in this document or applicable regulation) as well as a determination of the level of intent;
2. A finding of no culpable research misconduct, but serious research error; or
3. A finding of no misconduct and no serious research error.

B. Draft Investigation Report

The investigation report for each respondent will include:

Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.

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.

Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.

Composition of investigation committee, including name(s), position(s), and subject matter expertise.

Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on.156 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.

Transcripts of all interviews conducted.

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.

Any scientific or forensic analyses conducted.

A copy of these policies and procedures.

Any comments made by the respondent and complainant(s) on the draft investigation report and the committee's consideration of those comments.

A statement for each separate allegation of whether the committee recommends a finding of research misconduct.

If the 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.

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

C. Comments on the Investigative Report and Access to Evidence

1. Respondent

The RIO will give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the research records and other evidence that the investigation committee considered or relied on. The respondent will submit any comments on the draft report to the institution within 30 days of receiving the draft investigation report.

2. Complainant

At their discretion, the RIO may, but is not required to, provide the Complainant with a copy of the investigation report, or relevant portions of it, for Complainant's response. The RIO shall not provide the Complainant with a copy of the report unless the Complainant agrees to be bound by a confidentiality agreement preventing disclosure of the contents of the report. If the RIO allows the Complainant to receive the report, the Complainant will be allowed thirty (30) days from the date he/she received the final investigation report to provide the RIO with his/her written response to the final investigation report.

D. Other Procedures and Special Circumstances

1. Multiple Institutions and Multiple Respondents

If the alleged research misconduct involves multiple institutions, CU Denver and/or Anschutz may work closely with the other affected institutions to determine whether a joint research misconduct proceeding will be conducted. If so, the cooperating institutions will choose an institution to serve as the lead institution. In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution. If the alleged research misconduct involves multiple respondents, CU Denver and/or

Anschutz may either conduct a separate inquiry for each new respondent or add them to the ongoing proceedings. The institution must give additional respondent(s) notice of and an opportunity to respond to the allegations.

It is preferential to document in writing the collaboration plan between the institutions.

2. Respondent Admissions

CU Denver and/or Anschutz will promptly notify ORI (if under their jurisdiction) in advance if at any point during the proceedings (including the assessment, inquiry, investigation, or appeal stage) it plans to close a research misconduct case because the respondent has admitted to committing research misconduct or a settlement with the respondent has been reached. If the respondent admits to research misconduct, the institution will not close the case until providing ORI with the respondent's signed, written admission. The admission must state the specific fabrication, falsification, or plagiarism that occurred, which research records were affected, and that it constituted a significant departure from accepted practices of the relevant research community. The institution must not close the case until giving ORI a written statement confirming the respondent's culpability and explaining how the institution determined that the respondent's admission fully addresses the scope of the misconduct.

3. Other Special Circumstances

At any time during the misconduct proceedings, CU Denver and/or Anschutz will immediately notify ORI if any of the following circumstances arise:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

2. HHS resources or interests are threatened.

3. Research activities should be suspended.

4. There is reasonable indication of possible violations of civil or criminal law.

5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.

6. HHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.

IX. Disposition by the RIO

Upon receipt of the Investigation Committee's final investigation report and the responses

thereto, if any, from the Respondent or Complainant, the RIO shall review the same and create a final RIO report. The final RIO report is not intended to be a separate investigation of the allegations. Rather, it shall include recommendations based on the findings included in the Investigative Committee Report regarding:

- Possible disciplinary action, policy changes, or other actions that might ensure that similar misconduct does not occur in the future.
- Steps to correct or ameliorate the effects of the misconduct.
- Steps to be taken to prevent retaliation against the Complainant or other persons providing information in the investigation and to restore the positions and reputations of persons who have made allegations in good faith.
- Whether the Respondent's reputation has been unjustly damaged by the investigation and, if so, what steps might be taken to repair that damage.
- Whether any allegation is judged to have been made without reasonable basis in fact and with malicious intent.

The final report of the RIO, along with the final report of the Investigation Committee, shall be submitted to the Deciding Official.

X. Final Disposition

A. Decision by the DO

The DO will review the investigation report and make a final written determination of whether the institution found research misconduct and, if so, who committed the misconduct. In this statement, the DO will include a description of relevant institutional actions taken or to be taken.

The DO will determine in writing:

(1) whether the University accepts the investigation report, its findings, and the RIO's recommendations; and

(2) set forth the institution's actions in response thereto.

If this determination varies from the findings of the investigation committee and/or the recommendations of the RIO, the DO will, as part of his/her written determination, explain the basis for the decision. Alternatively, the DO may return the report to the Investigation Committee with a request for further fact-finding or analysis.

B. Communication of Decision

When the DO has reached a final decision on the case, the DO will so notify both the Respondent and the Complainant in writing.

The DO, in consultation with the RIO and the Office of University Counsel, will determine whether other university officials, PHS/ORI, NIH, law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the Respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

As a public entity of the state of Colorado, the University is subject to the Colorado Open Records Act (CORA). If an individual submits a request seeking the Investigation Report or any other materials considered a public record and related to the Investigation, the University may be required to produce the records relevant to the request. Any University response to a CORA request must be processed by the Office of University Counsel in consultation with the relevant University stakeholders.

C. Other Issues

During the Inquiry and/or Investigation process, other issues may be discovered or identified that should be addressed by the University, or the applicable school, college, or department. In such situations, the responsible party in the University should be informed of the recommendations of the DO, RIO and / or Investigational Committee. It is the responsibility of the responsible party to ensure that any issues are appropriately addressed.

D. Possible Institutional Administrative actions

If the DO determines that research misconduct as defined under these guidelines and procedures is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;

- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;

- Restitution of funds to the grantor agency as appropriate;

- Revocation of a degree awarded to the Respondent from the University; and

- Other action appropriate based on the nature of the research misconduct.

E. Appeals

Any disciplinary or personnel action taken as a result of a finding of Research Misconduct may be appealed in accordance with existing University policy.

F. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI, or, if applicable, the NIH in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy

G. Notice to PHS/ORI or Other Funding Agencies of Institutional Findings and Actions

After the DO has made a final determination of research misconduct findings, the RIO will add the DO's written decision to the investigation report and organize the institutional record in a logical manner. The institutional record consists of the records that were compiled or generated during the research misconduct proceeding, except records the institution did not rely on. These records include documentation of the assessment, a single index listing all research records and evidence, the inquiry report and investigation report, and all records considered or relied on during the investigation. The institutional record also includes the DO's final decision and any information the respondent provided to the institution. The institutional record must also include a general description of the records that were sequestered but not considered or relied on.

XI. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the Respondent's Institutional employment or status as a student or

trainee, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the Institution's responsibilities under 42 CFR Part 93, other applicable regulations or these guidelines and procedures.

If the Respondent, without admitting to the misconduct, elects to resign his or her position after the Institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the Inquiry and Investigation, as appropriate based on the outcome of the preceding steps. If the Respondent refuses to participate in the process after resignation, the RIO and any Inquiry or Investigation Committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence or proceedings.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the RIO must, at the request of the Respondent, undertake all reasonable and practical efforts to restore the Respondent's reputation. Depending on the particular circumstances and the views of the Respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and ensuring any reference to the research misconduct allegation from the respondent's personnel file is accurate. Any institutional actions to restore the Respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the RIO, and with the Complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.

D. Allegations Not Made in Good Faith

If relevant, the DO will determine whether the Complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith, he/she will determine and recommend whether any administrative action should be taken against the person who failed to act in good faith.

E. Responsibility for maintaining all records

The RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for seven (7) years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.

Appendix A: Research Integrity Officer Responsibilities

I. General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that the institution:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.
- Has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to PHS/ORI, as required by 42 CFR Part 93.
- Complies with its written policies and procedures and the requirements of 42 CFR 93.
- Informs its institutional members who are subject to 42 CFR Part 93 about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures.
- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.

II. Notification, Reporting and Cooperation with PHS (including NIH)/ORI (if applicable)

The RIO has lead responsibility for ensuring that the institution:

- Files an annual report with PHS/ORI containing the information prescribed by PHS/ORI.
- Sends to PHS/ORI with the annual report such other aggregated information as PHS/ORI may prescribe on the institution's research misconduct proceedings and the institution's compliance with 42 CFR Part 93.
- Notifies PHS/ORI and NIH, if applicable, immediately if, at any time during the research misconduct proceeding,s/he has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is reasonable indication of possible violations of civil or criminal law, federal action is required to protect the interests of those involved in the research misconduct proceeding, the Institution believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.

• Notifies NIH, if the project that is the subject of the research misconduct proceedings is NIH funded, when the University finds, learns of, or suspects research misconduct that impacts or might impact the conduct or performance of NIH-supported projects, whether at the University or at a University sub-contractor, in order to work with NIH to assess the effect on the ability to continue the project as originally approved by the NIH. Notifies NIH, if the project that is the subject of the research misconduct proceedings is NIH funded, when University finds, learns, or suspects that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research, including but not limited to, applications for funding and progress reports, or published research or research products supported by NIH funds, where NIH has a need to know this information, and the University must immediately provide information on the affected research to the NIH Office of Extramural Research – Research Integrity (OER-RI), in a manner consistent with the ORI confidentiality regulations set forth in 42 CFR § 93.108.

Provides PHS/ORI with the written finding by the responsible institutional official that an investigation is warranted and a copy of the inquiry report, within thirty (30) days of the date on which the finding is made.

• Notifies PHS/ORI of the decision to begin an investigation on or before the date the investigation begins.

When appropriate, conducts a materiality analysis in consultation with the Office of University Counsel to determine whether the inclusion of inauthentic data was material to the sponsor's decision to fund the project.

• Seeks advance PHS/ORI approval if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage.

• Cooperates fully with PHS/ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.