

# UNIVERSITY OF LA VERNE

## RESEARCH MISCONDUCT POLICY AND PROCEDURES

### I. Introduction

#### A. General Policy

It is the policy of the University of La Verne (University) to take action when scientific or research misconduct or serious deviation from regulatory and ethical standards in the conduct of research, including human subjects and animal research, undermines the integrity of the scientific process and of the research enterprise. Because of concern about the effect that possible Misconduct, as defined below, may have upon the University and its research activities, this policy was developed to prevent, detect, and address possible Misconduct in the University's research programs. This policy intends to create an environment that balances the need to deal firmly and effectively with allegations of possible Misconduct against the need for openness and creativity in the academic and scientific enterprise.

#### B. Scope and Application

This policy and the associated procedures apply to all research activities conducted under the auspices of the University, whether funded or unfunded. This policy applies to any individual paid by, under the control of, or affiliated with the University, such as faculty members, scientists, post-doctoral fellows, trainees, technicians and other staff members, graduate and undergraduate students, guest researchers, or collaborators at the University. In addition, this policy applies to all individuals utilizing the University's Institutional Review Board and Institutional Animal Care and Use Committee ("Research Boards") for review and monitoring of research projects, regardless of whether the individuals are employed by, under the control of, or formally affiliated with the University.

This policy and the associated procedures will normally be followed when a University official receives an allegation of possible Misconduct in science or research, or noncompliance with legal and ethical standards applicable to human subjects and animal research. Particular circumstances in an individual case may dictate variation from the normal procedures when deemed to be in the best interests of the University and/or any relevant federal agency. Any change from normal procedures also must ensure fair treatment to the subject of the Inquiry or Investigation. Any significant variation from this policy and associated procedures must be approved in advance by the Provost.

### II. Definitions

A. *Allegation* means any written or oral statement or other indication of possible Misconduct made to a University official.

B. *Complainant* means the individual(s) who submits an allegation of Misconduct and/or Retaliation.

C. *Conflict of interest* means the real or apparent interference of one individual's interests with the interests of another individual or of the University, where potential bias may occur due to prior or existing personal or professional relationships.

D. *Deciding Official (DO)* means the University official who makes final determinations on allegations of Misconduct and any responsive University actions. At the University, the DO is the Provost.

E. *Good faith allegation* means an allegation made with the honest belief that Misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for, or willful ignorance of, facts that would disprove the allegation.

F. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of Misconduct warrants an Investigation.

G. *Investigation* means the formal examination and evaluation of all relevant facts to determine if Misconduct has occurred, and if so, to determine the responsible individual and the seriousness of the Misconduct.

H. *Misconduct* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within and/or applicable to the academic and scientific communities for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data, or of regulatory and ethical standards. Misconduct includes significant departure from applicable University policies and Research Board directives on the appropriate and ethical conduct of human subjects and animal research.

I. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services ("DHHS") that is responsible for the Misconduct and research integrity activities of the U.S. Public Health Service.

J. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.

K. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and Investigations into allegations of scientific Misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."

L. *PHS support* means PHS grants, contracts, or cooperative agreements or applications therefor.

M. *Research Integrity Officer (RIO)* means the University official responsible for assessing allegations of Misconduct and determining when such allegations warrant Inquiries and for

overseeing Inquiries and Investigations. At the University, the RIO is the Associate Vice President for Academic Affairs. A detailed listing of the responsibilities of the RIO is set forth in Appendix A

N. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of Misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

O. *Respondent* means the individual against whom an allegation of Misconduct is directed or the individual whose actions are the subject of the Inquiry or Investigation. There can be more than one Respondent in any Inquiry or Investigation.

P. *Retaliation* means any action that adversely affects the employment or other University status of an individual that is taken by the University or an employee of the University, because the individual has made a good faith allegation of Misconduct or of inadequate University response thereto or has cooperated in good faith with an Inquiry or an Investigation of such allegation.

### **III. Procedures for Handling Allegations of Misconduct**

#### **A. General Rights and Responsibilities**

If an individual, in good faith, suspects that an individual subject to this policy is involved in Misconduct, the individual is encouraged to meet privately with the Associate Vice President for Academic Affairs, who is the University's RIO. The purpose of this meeting is to provide a confidential forum in which an initial determination of the need for a formal allegation can be made. The potential Complainant must be informed that if the RIO determines that an allegation of Misconduct is warranted, the RIO must submit an allegation even if the Complainant chooses not to do so. The Complainant must also be informed that an allegation may be submitted by the Complainant and will be accepted by the RIO, regardless of the RIO's opinion of the merits of the allegation. An individual who is not comfortable bringing his or her concerns to the RIO may direct his or her concerns to the University's Chair of the Institutional Review Board (IRB).

Once an allegation of Misconduct has been made, the following procedures will be undertaken, as is described in more detail below: (A) submission of the allegation, assessment and initial Inquiry; (B) when warranted, an Investigation to collect data and thoroughly examine the evidence; and (C) issuance of formal findings and appropriate disposition. If the circumstances described or allegations made by the individual do not meet the definition of Misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

University employees will cooperate with the RIO and other University officials in the review of allegations and the conduct of Inquiries and Investigations. Employees have an obligation to provide relevant evidence to the RIO or other University officials on Misconduct allegations.

The RIO shall, as required by 42 CFR § 93.108: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

If at any time during an Inquiry or an Investigation, information is obtained that reasonably indicates the occurrence of possible criminal violations, the RIO must notify the Provost; the appropriate office of the sponsoring agency; ORI, if applicable; the University's Director of Campus Safety; and other appropriate law enforcement officials within twenty-four (24) hours. If applicable, the RIO will notify ORI at any stage of the Inquiry or Investigation if: (i) there is an immediate health hazard involved; (ii) there is an immediate need to protect the interests of the Complainant(s) or the Respondent(s) or their co-investigators and associates; (iii) there is an immediate need to protect federal funds or equipment; (iv) it is probable that the alleged incident will be reported publicly; or (v) the allegation involves a public health sensitive issue. In addition, ORI must be kept promptly apprised of any developments that disclose facts that may affect current or potential DHHS funding for the individual(s) under Investigation, or that PHS needs to know to ensure appropriate use of federal funds and otherwise protect the public interest. Additional reports shall be made as required under the University's Federalwide Assurance (FWA), Animal Welfare Assurance (AWA), and applicable state law.

The rights and reputations of all parties involved in the allegation of Misconduct, including the individual who reported the alleged incident, must be protected throughout these procedures. The affected individual(s) should be afforded confidential treatment to the maximum extent possible. Individuals accused of Misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice, and may bring the counsel or personal adviser to interviews or meetings on the case. University faculty and staff employees are required to participate in these procedures, including attending meetings and answering questions put to them, upon reasonable notice. If any other individual subject to this policy refuses to cooperate with these procedures, the University reserves the right to take steps to disassociate itself from his or her research, revoke all University support and/or approval, and report to government authorities, as required and applicable.

## B. Submission of an Allegation

After consulting with the RIO, a Complainant may submit an allegation in writing to him or her. If the RIO determines that an allegation of Misconduct is warranted, the RIO must treat it as a submitted allegation even if the Complainant chooses not to submit it. Upon receiving an

allegation of Misconduct, the RIO will immediately assess the allegation to determine whether there is sufficient evidence to warrant an Inquiry. Following the preliminary assessment, if the RIO determines that the allegation provides sufficient information to allow specific follow-up, the RIO will select an *ad hoc* committee to conduct an Inquiry (the “Inquiry Committee”). Members of the committee shall not have real or apparent Conflicts of interest.

The RIO will prepare a charge for the Inquiry Committee that describes the allegation(s) and any related issues identified during the allegation assessment and states that the purpose of the Inquiry is to make a preliminary evaluation of the evidence and testimony of the Respondent, Complainant, and key witnesses to determine whether there is evidence of possible Misconduct that is sufficient to warrant an Investigation. The purpose of the Inquiry is not to determine whether Misconduct definitely occurred or who was responsible. Inquiry by the committee shall begin immediately after the charge is received. The RIO should notify the accused individual(s) of the initiation of the Inquiry, and of the names of the individuals solicited to serve on the Inquiry Committee. The Respondent may at this time raise objections (e.g., Conflict of interest) to the membership of individuals on the Inquiry Committee, and the RIO shall consider these objections.

### C. Inquiry

The Inquiry Committee will normally interview the Complainant, the Respondent, and key witnesses as well as examine relevant research records and materials. In order to avoid any claims of alteration of data, the Inquiry Committee will promptly attempt to locate and secure the originals of all relevant research data and/or documents if it is ascertained that such data and/or documents may be part of the case. Supervised access to the data and/or documents should be available to the Respondent. The Inquiry Committee may employ such outside resources and expertise (e.g., legal or consulting services) as it deems appropriate to assist in the Inquiry. Witness interviews shall be summarized in writing by the Committee or staff to the Committee, and witnesses given the opportunity to review and correct such summary of their own statements.

All Inquiries shall be completed within 60 days of initiation unless circumstances clearly warrant a longer period. If circumstances do so warrant, the record of the Inquiry shall include documentation of the reasons for exceeding the 60-day period. The individuals selected to conduct the Inquiry shall make every effort to be objective, impartial, and fair. The proceedings of the Inquiry will be kept confidential and will not be disclosed except as necessary to facilitate a complete and comprehensive Investigation.

The Inquiry Committee is expected to carry its inquiry through to completion and diligently to pursue all significant issues. If, for any reason, the Inquiry Committee decides that it is appropriate or necessary to terminate the Inquiry, the approval of the DO is required. If the DO approves such termination, a report of the planned termination, including the reasons for the termination, shall be made to ORI, if applicable, which will then decide whether further Investigation should be undertaken.

The Inquiry Committee will evaluate the evidence and testimony obtained during the Inquiry. Upon conclusion of the Inquiry, the Inquiry Committee shall prepare a written report that identifies the evidence reviewed, summarizes relevant interviews, and states the conclusions of the Inquiry. The report must include sufficiently detailed information documenting the Inquiry Committee's recommendation as to whether further Investigation is warranted. The Respondent shall be provided with a copy of the Inquiry Committee's report and shall have ten working days to provide written comments on it. Any comments made by the Respondent may be made a part of the record.

Within 30 days of completion of the Inquiry, and after consultation with the University counsel, the RIO will transmit the final report and any comments to the DO, who will make the determination of whether the findings from the Inquiry provide sufficient evidence of possible Misconduct to justify conducting an Investigation. The DO shall also determine whether any interim administrative actions are appropriate in order to protect federal funds and ensure that the purposes of the federal financial assistance are being carried out. The Inquiry is completed when the DO makes this determination, which will be made within 60 days of the first meeting of the Inquiry Committee. Any extension of this period will be based on good cause and recorded in the Inquiry file. The RIO will notify the Complainant and Respondent in writing of the determination. The RIO will also notify all appropriate University officials of the DO's decision. The sponsoring agency and ORI, if applicable, shall also be notified. Such notification must be done in writing and must contain the name(s) of the Respondent(s), the general nature of the allegation and the PHS application or grant numbers implicated by the Inquiry.

#### D. Investigation

If the DO determines that an Investigation is necessary, the RIO, in consultation with other University officials as appropriate, shall, within 30 days of the DO's written notification that an Investigation is necessary, appoint an *ad hoc* committee (the "Investigation Committee") to hear the formal charges against the Respondent alleged in the previously described Inquiry. The Respondent will be notified within 10 days of the determination that an Investigation is planned, or as soon thereafter as is practicable. The Investigation Committee will include at least three members of the University faculty. Members of the committee shall not have real or apparent conflicts of interest in the case, shall be unbiased, and shall have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the Investigation. Individuals appointed to the Investigation Committee may also have served on the Inquiry Committee. The Respondent will be informed by the RIO of the proposed composition of the Investigation Committee within 5 days of that determination, and will have the opportunity to raise objection to individual appointees. If the Respondent submits a written objection to any appointed member of the Investigation Committee, the RIO shall determine whether to replace the challenged member with a qualified substitute.

If applicable, the University's decision to initiate an Investigation must be reported in writing by the RIO to the Director of ORI on or before the date the Investigation begins. At a minimum, the notification shall include the name of the Respondent(s) against whom the allegations have been

made, the general nature of the allegation as it relates to the PHS definition of Misconduct, and if applicable, the PHS applications or grant number(s) involved.

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 PHS funding is involved, the PHS regulation. The Investigation Committee shall fully investigate the charges set forth and recommend appropriate action. The Investigation shall focus on the allegations of Misconduct, and shall examine the factual matters of the case. The Investigation Committee may employ such outside resources and expertise (e.g., legal or consulting services) as it deems appropriate to assist in the Investigation. Witness interviews shall be summarized in writing by the Committee or staff to the Committee, and witnesses given the opportunity to review and correct such summary of their own statements. The individuals selected to conduct the Investigation shall make every effort to be objective, impartial, and fair.

The Investigation Committee's charge is to generate a report that compiles all of the information considered, the Committee's conclusion as to whether there is sufficient evidence to support the allegation of Misconduct, and any recommended administrative or disciplinary actions to be taken against the Respondent in the event the allegation is substantiated. It is within the discretion of the Investigation Committee to incorporate by reference any report or portions thereof from the Inquiry Committee, to the extent that the Investigation Committee is satisfied with any aspect(s) of the Inquiry Committee report or portions thereof as constituting a comprehensive review and resolution of the issues.

All Investigations should be conducted expeditiously and completed within 120 days of the Investigation Committee's first meeting, if possible. This includes conducting the Investigation, preparing the report of findings to the DO, making the report available for comment by the Respondent and working with the RIO and DO to submit the report to ORI, if applicable. If the 120-day deadline cannot be met, the Investigation Committee shall request an extension from the RIO. If applicable, the RIO shall submit to ORI a written request for an extension and an explanation for the delay. This request to ORI shall include an interim report on the progress to date, an outline of what remains to be done, an estimate for the date of completion of the report, and any other necessary steps. If this request is granted, periodic progress reports may also be requested by ORI. The Investigation Committee shall also recommend to the DO whether any interim administrative actions are appropriate in order to protect federal funds and ensure that the purposes of the federal financial assistance are being carried out.

The Investigation Committee is expected to carry its investigation through to completion and diligently to pursue all significant issues. If, for any reason, the Investigation Committee decides that it is appropriate or necessary to terminate the Investigation, the approval of the DO is required. If the DO approves such termination, a report of the planned termination, including the reasons for the termination, shall be made to ORI, if applicable, which may then decide to undertake its own investigation.

When the Investigation Committee reaches a conclusion regarding the allegation of Misconduct, it shall submit a preliminary report reviewing all information and its conclusion to the Respondent. The preliminary report shall adequately detail the evidence that supports or refutes each allegation included in the Investigation. Respondent will have ten working days to prepare a written response to the preliminary report, which shall be considered by the Investigation Committee before the investigation report is finalized.

After receiving the Respondent's written comments on the preliminary report, if any, the Investigation Committee shall prepare and maintain a final report that lists and adequately substantiates the basis for its findings, describes the policies and procedures under which the Investigation was conducted, and describes how and from whom information was obtained relevant to the Investigation. The final report of the Investigation Committee shall be made available to the Respondent, who will be provided a full and fair opportunity to respond in writing to the Investigation Committee within seven working days of receipt of the final report. Such comments, if any, may be made a part of the record of the Investigation.

The final report, including the Respondent's comments, if any, and the Investigation Committee's recommended administrative or disciplinary actions, if any, shall be provided to the DO. He or she will determine whether to accept the final report, its findings, and any recommended administrative or disciplinary actions. If the DO's determination varies from that of the Investigation Committee's final report, the DO will explain in detail the basis for rendering a decision different from that of the Investigation Committee. The DO's determination, together with the Investigation Committee's final report, constitutes the final investigation report for purposes of ORI review. ORI and/or other government authorities, if applicable, (e.g., the federal Office of Human Research Protections and/or state agencies) shall be provided with the final report, along with the actual text or an accurate summary of the views of any individual(s) found to have engaged in Misconduct, as well as a description of any sanctions taken by the University. The Complainant(s) shall be provided with those portions of the final report that address his, her or their role and opinions in the Investigation.

#### **IV. Consequences of Investigation**

##### **A. Administrative and/or Disciplinary Actions**

If the DO determines that the alleged Misconduct is substantiated by the findings, he or she will decide on the appropriate administrative or disciplinary actions to be taken, if any, after consultation with the RIO and taking into consideration the recommendations of the Investigation Committee. The actions may include one or more of the following:

- i. withdrawal or correction of all pending or published abstracts and papers emanating from the research in which Misconduct was found;
- ii. removal of the responsible individual from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of



steps leading to possible discipline or termination of employment under the applicable University policies;

- iii. notification to other universities, institutions and sponsoring agencies with which the individual has been or is affiliated, if there is reason to believe that previous research may be characterized by Misconduct; and/or
- iv. restitution of funds as appropriate to granting agencies, the University and/or research subjects.

The RIO shall notify the Respondent in writing of any appropriate administrative or disciplinary actions to be taken and shall also meet with the Respondent to discuss the findings and the implementation of any such administrative or disciplinary actions. Any disciplinary action relating to faculty or staff privileges and or Research Boards review shall be coordinated with the applicable academic Dean and/or the Research Boards, as appropriate. If indicated, faculty or staff discipline will be pursued through established University disciplinary policies, but the procedures in this policy are distinct from, and may be taken without recourse to, faculty and staff disciplinary procedures.

#### **B. Restoration of the Respondent's Reputation**

If the finding is that no Misconduct occurred, and if the Inquiry or Investigation has resulted in any damage to the Respondent's reputation, the Respondent shall meet with the RIO to discuss how the Respondent's record shall be cleared and what reasonable efforts will be taken to restore the Respondent's reputation. Any University actions to restore the Respondent's reputation must first be approved by the DO. The implementation of such approved actions will be the responsibility of the RIO. Depending on the particular circumstances, the RIO should consider notifying those individuals aware of or involved in the Inquiry and/or the Investigation of the final outcome, publicizing the final outcome in forums in which the allegation of Misconduct was previously publicized, or expunging all reference to the Misconduct allegation from the Respondent's personnel file.

#### **V. Appeal**

The Respondent and/or other individual(s) affected by the decision of the DO shall be given an opportunity to appeal, but may appeal a decision of Misconduct only on the basis that procedural errors were committed. Within ten working days after the decision is received, the individual(s) shall serve upon the DO a petition, in writing, informing the DO of his, her or their intent to appeal. The DO shall have the power to affirm, reverse, or modify the decision. The DO may base his or her decision on appeal upon the written appeal and the record of the Investigation and the DO's previous decision. Alternatively, the DO in his or her discretion may require the RIO to appoint a new Investigation Committee to reevaluate the record and submit supplemental recommendations to him or her. The DO's decision on appeal will be final. No additional evidence may be introduced into the record on appeal as a matter of course. However, if new evidence is brought to the attention of the DO at any time during the process, he or she will

determine in his or her discretion whether the matter should be referred back to the original Investigating Committee or to a new Investigation Committee appointed to reopen the case. If applicable, ORI will be notified of the appeal and of its disposition.

## **VI. Other Considerations**

### **A. Termination of University Employment or Resignation Prior to Completing Inquiry or Investigation**

The termination of the Respondent's University employment or affiliation, by resignation or otherwise, before or after an allegation of possible Misconduct has been reported, will not preclude or terminate the Misconduct procedures. If the Respondent, without admitting to the Misconduct, elects to resign his or her position or affiliation prior to the initiation of an Inquiry, but after an allegation has been reported, or during an Inquiry or Investigation, the Inquiry or Investigation will proceed. If the Respondent refuses to participate in the process after resignation, the Inquiry Committee and the Investigation Committee, if any, will use their best efforts to reach a conclusion concerning the allegations, noting in their reports the Respondent's failure to cooperate and its effect on the committee's review of all the evidence.

### **C. Protection of the Complainant and Others**

It is the University's policy that no one shall suffer Retaliation for making a good faith allegation of Misconduct, or for providing testimony regarding the facts and circumstances surrounding the alleged Misconduct during an Inquiry or Investigation. Regardless of whether the University or ORI determines that Misconduct occurred, the RIO will undertake reasonable efforts to protect the positions and reputations of Complainants who have made an allegation of Misconduct in good faith and others who cooperate in good faith with Inquiries and Investigations of such allegations. Upon completion of an Investigation, the DO will determine, after consulting with the Complainant, what steps, if any, are needed to restore the position or reputation of the Complainant. 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 Misconduct were made in good faith. If an allegation was not made in good faith, the DO will determine whether any administrative or employment action or discipline should be recommended against the Complainant.

## **VII. Records Retention**

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any Inquiry or Investigation and copies of all documents and other materials furnished to the RIO or the committees. The RIO will keep the file in a secure manner for seven (7) years after completion of the case to permit later assessment of the case. ORI or other authorized government personnel will be given access to the records upon request.

## **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 ORI, as required by 42 CFR Part 93.
- Complies with its written policies and procedures and the requirements of 42 CFR Part 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. Notice and Reporting to ORI and Cooperation with ORI**

The RIO has lead responsibility for ensuring that the institution:

- Files an annual report with ORI containing the information prescribed by ORI.

- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on the institution's research misconduct proceedings and the institution's compliance with 42 CFR Part 93.
- Notifies ORI immediately if, at any time during the research misconduct proceeding, it 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.
- Provides ORI with the written finding by the responsible institutional official that an Investigation is warranted and a copy of the Inquiry report, within 30 days of the date on which the finding is made.
- Notifies ORI of the decision to begin an Investigation on or before the date the Investigation begins.
- Within 120 days of beginning an Investigation, or such additional days as may be granted by ORI, (or upon completion of any appeal made available by the institution) provides ORI with the Investigation report, a statement of whether the institution accepts the Investigation's findings, a statement of whether the institution found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the respondent.
- Seeks advance 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 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.

### **III. Research Misconduct Proceeding**

#### **A. General**

The RIO is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.
- Taking all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to their providing information, research records and evidence.
- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy.
- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.
- Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct.
- In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other institutional members.
- Making all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

- Assisting the DO in implementing his/her decision to take administrative action against any complainant, witness, or committee member determined by the DO not to have acted in good faith.
- Maintaining records of the research misconduct proceeding, as defined in 42 CFR § 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.
- Ensuring that administrative actions taken by the institution and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

### ***Allegation Receipt and Assessment***

The RIO is responsible for:

- Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct.
- Receiving allegations of research misconduct.
- Assessing each allegation of research misconduct to determine if an Inquiry is warranted because the allegation falls within the definition of research misconduct, is within the jurisdictional criteria of 42 CFR § 93.102(b), and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

### ***Inquiry***

The RIO is responsible for:

- Initiating the Inquiry process if it is determined that an Inquiry is warranted.
- At the time of, or before beginning the Inquiry, making a good faith effort to notify the respondent in writing, if the respondent is known.

- On or before the date on which the respondent is notified, or the Inquiry begins, whichever is earlier, taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- Appointing an Inquiry Committee and committee chair as soon after the initiation of the inquiry as is practical.
- Preparing a charge for the Inquiry Committee in accordance with the institution's policies and procedures.
- Convening the first meeting of the Inquiry Committee and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the Inquiry, including the need for confidentiality and for developing a plan for the Inquiry, and assisting the committee with organizational and other issues that may arise.
- Providing the Inquiry Committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.
- Being available or present throughout the Inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in the institution's policies and procedures and 42 CFR § 93.307(d).
- Determining whether circumstances clearly warrant a period longer than 60 days to complete the Inquiry (including preparation of the final Inquiry report and the decision of the DO on whether an Investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 60-day period in the record of the research misconduct proceeding.
- Assisting the Inquiry Committee in preparing a draft Inquiry report, sending the respondent a copy of the draft report for comment (and the complainant if the institution's policies provide that option) within a time period that permits the Inquiry to

be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and the complainant if the institution's policies provide that option), and ensuring that the comments are attached to the final Inquiry report.

- Receiving the final Inquiry report from the Inquiry Committee and forwarding it, together with any comments the RIO may wish to make, to the DO who will determine in writing whether an Investigation is warranted.
- Within 30 days of a DO decision that an Investigation is warranted, providing ORI with the written finding and a copy of the Inquiry report and notifying those institutional officials who need to know of the decision.
- Notifying the respondent (and the complainant if the institution's policies provide that option) whether the Inquiry found an Investigation to be warranted and including in the notice copies of or a reference to 42 CFR Part 93 and the institution's research misconduct policies and procedures.
- Providing to ORI, upon request, the institutional policies and procedures under which the Inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the Investigation.
- If the DO decides that an Investigation is not warranted, securing and maintaining for 7 years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI of the reasons why an Investigation was not conducted.

#### **D. Investigation**

The RIO is responsible for:

- Initiating the Investigation within 30 days after the determination by the DO that an Investigation is warranted.
- On or before the date on which the Investigation begins: (1) notifying ORI of the decision to begin the Investigation and providing ORI a copy of the Inquiry report; and (2) notifying the respondent in writing of the allegations to be investigated.



- Prior to notifying respondent of the allegations, taking all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the Inquiry.
  
- In consultation with other institutional officials as appropriate, appointing an Investigation committee and committee chair as soon after the initiation of the Investigation as is practical.
  
- Preparing a charge for the Investigation committee in accordance with the institution's policies and procedures.
  
- Convening the first meeting of the Investigation committee and at that meeting: (1) briefing the committee on the charge, the Inquiry report and the procedures and standards for the conduct of the Investigation, including the need for confidentiality and developing a specific plan for the Investigation; and (2) providing committee members a copy of the institution's policies and procedures and 42 CFR Part 93.
  
- Providing the Investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews.
  
- Being available or present throughout the Investigation to advise the committee as needed.
  
- On behalf of the institution, the RIO is responsible for each of the following steps and for ensuring that the Investigation committee: (1) uses diligent efforts to conduct an Investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical; (3) interviews each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the respondent, and records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and (4) pursues diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of any additional instances of possible research misconduct, and continues the Investigation to completion.

- Upon determining that the Investigation cannot be completed within 120 days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI), submitting a request to ORI for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with ORI.
  
- Assisting the Investigation committee in preparing a draft Investigation report that meets the requirements of 42 CFR Part 93 and the institution's policies and procedures, sending the respondent (and complainant at the institution's option) a copy of the draft report for his/her comment within 30 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and complainant at the institution's option) and ensuring that the comments are included and considered in the final Investigation report.
  
- Transmitting the draft Investigation report to institutional counsel for a review of its legal sufficiency.
  
- Assisting the Investigation committee in finalizing the draft Investigation report and receiving the final report from the committee.
  
- Transmitting the final Investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting to ORI within the time period for completing the Investigation, a copy of the final Investigation report with all attachments, a statement of whether the institution accepts the findings of the report, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent; or (3) if the institution provides for an appeal by the respondent that could result in a modification or reversal of the DO's finding of research misconduct, ensuring that the appeal is completed within 120 days of its filing, or seeking an extension from ORI in writing (with an explanation of the need for the extension) and, upon completion of the appeal, transmitting to ORI a copy of the Investigation report with all attachments, a copy of the appeal proceedings, a statement of whether the institution accepts the findings of the appeal proceeding, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent.
  
- When a final decision on the case is reached, the RIO will normally notify both the respondent and the complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved

journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.

- Maintaining and providing to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.