POLICY AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT AT UNIVERSIDAD NACIONAL (UNA), COSTA RICA FUNDED BY THE NATIONAL INSTITUTES OF HEALTH (NIH) OF THE UNITED STATES OF AMERICA

1. Policy Statement

As a higher education institution, Universidad Nacional (UNA), Costa Rica is committed to ethical principles and procedures regarding integrity in all forms of research activity for which UNA is responsible. To further such commitment and to comply with University's principles, goals, and ideals described in the UNA Vision Statement, its core values, the Institutional Policy to Promote Ethics in the UNA and the Regulations on Scientific Ethics Committee of UNA, hereby sets forth its Research Misconduct Policy and acknowledges and affirms its adherence to the rules of the Public Health Service (PHS) Policies on Research Misconduct established on Code of Federal Regulations 93 (42 CFR Part 93).

2. Purpose

This policy has been developed to avoid and handle the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, as a requirement of Federal government to entities receiving federal funding and conceived as a prior stage to any action or internal procedure UNA must prosecute, if it is the case. The policy was written to be in conformance with the specific federal agency requirements as defined in the 2005 Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93) and the accomplishment of this regulations by the relationship of funding cooperation between both Institutions.

3. Scope

This policy applies to all research activities proposed and conducted by academic, scientific, and professional staff, employees, students, and independent contractors of the University, in the conduct of their research activities, whether or not they are externally sponsored, during their employment by or term of their contract with the University.

As defined by the Department of Health and Human Services (HHS) Office of Research Integrity (ORI), research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication: making up data or results and recording or reporting them.
- Falsification: 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: the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.

This part applies only to research misconduct occurring within six years of the date UNA or an institution receives an allegation of research misconduct. In those cases, in which misconduct is highly presumable to have occurred and that it is within the time limits established by the institutional regulations, it must be prosecuted according to internal proceedings and regulations.

4. Roles

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

b. Deciding Official (DO): the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Deciding Official shall have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. The DO will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). The DO is the Dean of the correspondent Faculty of the UNA where the RIO and Academic Unit (as a school, institute, others) is leading the inquiry and eventually investigation procedures.

c. Inquiry or Investigation Committee: is the experts panel in charge to carry on the examination of the evidence upon the determination that an inquiry or investigation is warranted, and reporting to the RIO their opinion on the allegation of research misconduct by the respondent(s). The members of the committee must consist of individuals:

- Who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation.

- With the appropriate scientific expertise to:

  - Evaluate the evidence and issues related to the allegation
  - Interview the respondent and complainant
  - Conduct the investigation

d. Research Integrity Officer (RIO): is the institutional official who:

- Receives allegations of research misconduct.
- Assess 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.
- Oversees inquiries and investigations, including the appointment of inquiry and investigation committees.
- Decides whether an investigation is warranted under the criteria in 42 CFR § 93.307(d).
- Informs respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding.
- Makes final determinations on allegations of research misconduct and any institutional administrative actions according to the investigation report.
- Notifies and makes reports to ORI as required by 42 CFR Part 93.

- Ensures that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties.
- Maintains records of the research misconduct proceeding and makes them available to ORI in accordance with this policy.
- Complies with UNA's written policies and procedures and the requirements of 42 CFR Part 93.
- Informing 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.
- Assures that inquiry or investigation committee members complies with the considerations mentioned in this part.

According to the provisions of Articles 3, paragraph h) of the Regulations on impediments, excuses and recusals of the UNA, this role will be executed by the corresponding hierarchical superior, as the authority in charge of the implementation of the institution's policies and procedures on research misconduct.

e. **Respondent:** the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

5. General Policies and Principles

a. Responsibility to Report Misconduct

All UNA personnel will report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO to discuss the suspected research misconduct informally, which might include discussing it anonymously and/or hypothetically. In any case, the RIO reserves for itself the possibility to initiate an assess and even an inquiry procedure about the anonymous and/or hypothetical situation can be identified and sustained. They will make the report, through any means of communication, in case of:

- The respondent is a UNA staff member, to the RIO.
- The respondent is a team member who is not a UNA staff member, to the Office of Research Integrity (ORI) in accordance with 42 CFR Part 93 Subpart D - Responsibilities of the U.S. Department of Health and Human Services General Information.

Research misconduct may also be reported anonymously, however this may limit the extent to which a case may be pursued if the information provided lacks the requisite detail. If the circumstances described by the individual fail to meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

b. Cooperation with Research Misconduct Proceedings

All UNA personnel members will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members,

including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

c. Confidentiality

To maintain confidentiality as required by 42 CFR § 93.108, the RIO shall:

- 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.
- 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.
- Except as otherwise prescribed by law, use written confidentiality agreements or other mechanisms to ensure that the recipient makes no further disclosure of identifying information.

d. Protecting Complainants, Witnesses, and Committee Members

UNA personnel members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report, through any means of communication, all alleged or apparent retaliation against complainants, witnesses, or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

e. Protecting the Respondent

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the institution. Respondents 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, by prior notice to the responsible authority.

f. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and ORI, 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 or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the conditions mentioned at 42 CFR § 93.318 exist.

6. Conducting the Assessment and Inquiry

a. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will assess the allegation to determine whether the allegation:

- Is sufficiently credible and specific so that potential evidence of research misconduct might be identified.
- Falls within the definition of research misconduct.

The RIO will determine if the allegation falls within the jurisdiction of 42 CFR 93.102(b), or other funding source guidelines.

During the assessment, the RIO need not interview the complainant, respondent, or any other witnesses, or gather any data beyond that submitted with the initial allegation, except as necessary to determine the above criteria. In any case, the RIO must elaborate a record of all the evidence and allegation or other relevant documentation concerning the situation since this stage begins.

A written summary of allegations meeting the above criteria and falling under this policy will be provided to the respondent. The full/original concern will not be relayed verbatim due to the Institution's necessity to protect individuals voicing such concerns in good faith.

The assessment period will be brief, preferably conducted within 21 calendar days. Any allegation meeting the bulleted criteria above will necessitate an inquiry. If the allegation is found to lack sufficient merit to warrant an inquiry, the RIO will notify through any means of communication, both the respondent and complainant of this finding within one week of this determination.

If the RIO determines that an inquiry is not warranted, sufficiently detailed documentation of the determination and items considered will be maintained according to record retention procedures outlined in this procedure.

b. 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.

c. Notice to Respondent

At the time of or before beginning an inquiry, the RIO/designee must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing.

d. Inquiry Process

▪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.

▪Notice to Respondent:

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

▪Inputs for the committee:

If needed the RIO may look for support of experts that conforms panels for the academic examination of the facts and their context. Once the committee has been formed, the RIO will:

- Review the charge with the committee.
- Discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry.
- Seek disclosure of any unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry.
- Answer any questions raised by the committee.
- Be present or available throughout the examination of the evidence to advise the committee as needed.

▪Support of the committee:

The inquiry committee will normally:

- Interview the complainant, the respondent, and key witnesses, as well as examine relevant research records and materials.
- Evaluate the evidence, including the testimony obtained during the inquiry.
- Provide technical judgment to the RIO as to whether or not the investigation is warranted based on the criteria in this procedure and 42 CFR 93.307(d).

▪Scope of the inquiry:

Is not required to, and does not normally include:

- Deciding whether misconduct occurred.
- Determining who committed the research misconduct.
- Conducting exhaustive interviews and analyses.

However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct allegation may be. If PHS funded, the institution shall promptly consult with ORI to determine the next steps that should be taken.

e. Time for Completion

The inquiry, including preparation of its final report and the decision of the DO on whether an investigation is warranted, must be completed within 60 calendar days of its initiation, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

7. The Inquiry Report

a. Elements of the Inquiry Report

A written inquiry report must be prepared and provided to the DO. The RIO also will provide the DO with a copy of this statement of policy and procedures and 42 CFR Part 93.

The inquiry report must include the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support; (4) the basis for recommending or not recommending that the allegations warrant an investigation.

b. Notification to Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted. This notification will be made within the time constraints of the Inquiry process (see "Time for Completion of Inquiry" section, above), and ideally within 5 business days. The notification will include a copy of:

- The draft inquiry report or relevant portions of the report.
- The institution's policies/procedures on research misconduct, with reference to applicable federal regulations based on the agency funding the research.

The respondent is offered an opportunity to comment within 10 calendar days. Based on the comments from the respondent, the committee may revise the draft report as appropriate and prepare it in final form. Any comments that are submitted by the respondent will be attached to the final inquiry report.

c. Institutional Decision and Notification

- **Decision by Deciding Official**

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

- **Notification to ORI**

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI with the DO's written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision.

The RIO must provide the following information 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, and copies of all relevant documents; and
- the charges to be considered in the investigation.

- **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 procedure developed to permit a later assessment by ORI of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

8. Conducting the Investigation

a. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on 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. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. Under 42 CFR § 93.313 the findings of the investigation must be set forth in an investigation report.

b. Notifying ORI and Respondent

On or before the date on which the investigation begins, the RIO must notify:

- the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report;
- the respondent in writing of the allegations to be investigated. The RIO must also give the respondent written notice of any new allegations of research misconduct within 10 business days of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The RIO will, prior to notifying respondent of the allegations, take 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.

c. The Investigation Committee

- In case the RIO requires it and during the inquiry process a committee has not been formed, its creation will be managed for this stage. Otherwise, the committee charged with the inquiry will proceed with the investigation upon the determination that an investigation is warranted. The RIO in consultation with the DO will reassess membership to assure that the committee consists of individuals who complies with the considerations mentioned in part 4. Roles of this policy.

- Participating in the inquiry procedure as a committee member will not be considered as a judgement advance situation, as determined in Article 4, paragraphs h) and i) of the Regulations on impediments, excuses, and recusals of the UNA; in case the committee has limited its examination and preparation of the draft report to parts 6.d. and e. and 7.a. of this Policy.

- The RIO may appoint committee members from outside the institution when necessary to secure additional expertise or to avoid conflicts of interest.

d. Inputs for the Committee

- The RIO will define the subject matter of the investigation in a written charge to the committee that:

  - Describes the allegations and related issues identified during the inquiry.
  - Identifies the respondent.
  - Defines research misconduct.
  - 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 in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that:

    ・research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion);

- the research misconduct is a significant departure from accepted practices of the relevant research community; and
- the respondent committed the research misconduct intentionally, knowingly, or recklessly; and
- informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313.

- 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 this statement of policy and procedures and 42 CFR Part 93.

- The RIO will be present or available throughout the investigation to advise the committee as needed.

e. Investigation Process

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented, including examination of all research records and evidence relevant to reaching a decision on the merits of each allegation.
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical.
- Interview each:

  - Respondent.
  - Complainant.
  - 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).

- Record or transcribe each interview.
- Include the recording or transcript in the record of the investigation.
- Pursue 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 continue the investigation to completion.

f. Time for Completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment, and sending the final report to ORI. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress

reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

9. The Investigation Report

a. Elements of the Investigation Report

The RIO is responsible for preparing a written draft report of the investigation that:

- Describes:
  - The nature of the allegation of research misconduct, including identification of the respondent;
  - And documents the PHS, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support; and
  - The specific allegations of research misconduct considered in the investigation.
- Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously.
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed.
- Includes a statement of findings for each allegation of research misconduct identified during the investigation.
- Each statement of findings must:
  - Identify whether
    - the research misconduct was falsification, fabrication, or plagiarism, and
    - it was committed intentionally, knowingly, or recklessly.
  - Summarize the facts and the analysis that supports the conclusion.
  - Consider the merits of any reasonable explanation by the respondent (including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion).
  - Identify:
    - specific PHS support;
    - whether any publications need correction or retraction;
    - the person(s) responsible for the misconduct.
  - List any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.

b. Comments on the Draft Report and Access to Evidence

- **Respondent:**

  The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, supervised access to or the possibility to make a copy, by his / her own costs, of the evidence on which the report is based. The respondent will be allowed 30 calendar days from the date he/she received the draft report to submit comments to the RIO/designee. The respondent's comments must be included and considered in the final report.

- **Complainant:**

  Investigation reports are not routinely provided to the complainant. On a case-by-case basis as determined by the RIO, the institution may provide relevant portions of the draft investigation report to the complainant for comment. If the complainant is asked to comment, responses must be received within 30 days and must be included and considered in the final report.

- **Confidentiality:**

  In distributing the draft report, or portions thereof, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

c. Decision by Deciding Official

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and complainant's comments are included and considered, and transmit the final investigation report to the DO.

The DO will determine in writing:

- whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and
- the appropriate institutional actions in response to the accepted findings of research misconduct.

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

When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. After informing ORI, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent 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.

d. Appeals

An institution's procedures may provide for an appeal by the respondent that could result in a reversal or modification of the institution's findings of research misconduct. If such an appeal is provided for, it must be completed within 120 days of its filing, unless ORI finds good cause for an extension, based upon the institution's written request for an extension that explains the need for the extension. If ORI grants an extension, it may direct the filing of periodic progress reports (42 CFR § 93.314).

If the institution provides for an appeal by the respondent that could result in a modification or reversal of the HS'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.

e. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the allowed period for completing the investigation and subsequent appeal if applies, submit to ORI:

- A copy of the final investigation report with all attachments.
- A statement of whether the institution:
  - Accepts the findings of the investigation report.
  - Found misconduct and, if so, who committed the misconduct.
- A description of any pending or completed administrative actions against the respondent.

f. Maintaining Records for Review by ORI

The RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is 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 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.

10. 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 in advance if there are 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:

- 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, which must be reported to ORI, as prescribed in this policy and 42 CFR 93.315.

11. Other Considerations

a. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, 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.

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 in case the person still linked to the Institution (officials, students, suppliers, etc.), as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. The purpose to continue the academic process seeks to delve deeper into the causes and thus prevent future cases. The requirements will be respected in the preparation of the corresponding reports. 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.

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 expunging all reference to the research misconduct allegation from the respondent's personnel file. 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.

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 the appropriate action is that he/she will inform the hierarchical superior (if the person is related to the UNA) or to inform the employer or group to which the person who failed to act in good faith belongs.

Appendix A
Definitions

1. ***Administrative action:*** action in response to a research misconduct proceeding taken to protect the health and safety of the public, to promote the integrity of PHS supported biomedical or behavioral research, research training, or activities related to that research or research training and to conserve public funds.

2. ***Allegation***: a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or HHS official.

3. ***Charge letter:*** written notice, as well as any amendments to the notice, that are sent to the respondent stating the findings of research misconduct and any HHS administrative actions. If the charge letter includes a debarment or suspension action, it may be issued jointly by the ORI and the debarring official.

4. ***Contract*:** an acquisition instrument awarded under the HHS Federal Acquisition Regulation (FAR), 48 CFR Chapter 1, excluding any small purchases awarded pursuant to FAR Part 13.

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

6. ***Good faith:***

   a. As applied to a complainant or witness: means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time.

   b. As applied to a committee member: means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part.

7. ***Hearing:*** part of the research misconduct proceeding from the time a respondent files a request for an administrative hearing to contest ORI findings of research misconduct and HHS administrative actions until the time the Administrative Law Judge (ALJ) issues a recommended decision.

8. ***Inquiry:*** preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of §§ 93.307-93.309.

9. ***Institution:*** any individual or person that applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, small research institutions, and independent researchers.

10. ***Institutional member* or *members:*** a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

11. ***Investigation:*** the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

12. ***Notice:*** a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number, or e-mail address of the addressee.

13. ***Office of Research Integrity* or *ORI:*** the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.

14. ***Person:*** any individual, corporation, partnership, institution, association, unit of government, or legal entity, however organized.

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

16. ***Public Health Service* or *PHS:*** the unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

17. ***PHS support:*** PHS funding, or applications or proposals therefor, for 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 or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements, or contracts.

18. ***Research*:** a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating, or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

19. ***Research misconduct proceeding*:** any actions related to alleged research misconduct taken under this part, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals.

20. ***Research record:*** the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.

21. ***Retaliation*****:** an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to:

    a. A good faith allegation of research misconduct; or
    b. Good faith cooperation with a research misconduct proceeding.

22. ***Secretary* or *HHS:*** the Secretary of HHS or any other officer or employee of the HHS to whom the Secretary delegates authority.