

UNIVERSITY OF HAWAI'I

E5.211 POLICY FOR RESPONDING TO ALLEGATIONS OF RESEARCH AND SCHOLARLY MISCONDUCT

I. INTRODUCTION

The University of Hawai'i (UH) policies, definitions, and procedures regarding research and scholarly misconduct are stated here in the Executive Policy E5.211, "Policy for responding to allegations of research and scholarly misconduct." This policy was originally distributed in 1989, revised in 1992 and again in 1998 to attain compliance with Public Health Service Policies on Research Misconduct expressed in 42 CFR Part 50. In 2005 the Policies were revised and promulgated in 42 CFR Part 93. This update of Executive Policy E5.211 has been written to comply with Public Health Service (PHS) expectations expressed in Part 93 for research funded by the PHS; however, it also applies to all other research and scholarly activities conducted by UH employees, regardless of the source of funding. In addition, what is considered in E5.211 to be research and scholarly misconduct includes more than falsification, fabrication, and plagiarism as found in the 42 CFR Part 93 definitions.

Reporting suspected academic, scientific and research misconduct is a shared and serious responsibility of all members of the academic community. Allegations should not be made capriciously, but indications or evidence of fraud or misconduct must not be ignored. Allegations of unethical conduct are serious and can ruin professional careers. The policies and procedures herein provide mechanisms to screen unfounded complaints while minimizing damage to the wrongly accused. When a formal allegation is rendered, the procedures also provide due process rights, as specified in the prevailing UH faculty and staff bargaining unit agreements, to ensure that any decisions rest on evidence fully and fairly assessed.

Principle Investigators have a central role and responsibility in the strategy, operation, and management of their research group. They must make every effort to maintain the standards of professional and ethical conduct, and to foster an environment that discourages misconduct in all areas of their work. Retaining such outstanding integrity conveys respect and credibility among students, colleagues, and the community which the University serves.

1.1 GENERAL POLICY

In addition to protection for the accused, the procedures in this document take into account the concerns of those who suspect misconduct. These procedures work to encourage the reporting of misconduct by limiting the burdens and risks on those who

bring forward information. The Research Integrity Officer (RIO), in consultation with the Ethics Committee, has the responsibility of investigating allegations of misconduct. To the greatest extent possible, the complainant's and/or informant's assistance in the procedures will remain confidential. In cases where an investigation is not warranted, the RIO will retain a record of efforts to call attention to misconduct, should it later develop that unethical violations were indeed occurring. The respondent is thus spared later accusations of complicity or cover-up.

Furthermore, in cases where the complainant or informant is uncertain whether violations are taking place, the initial stage provides the opportunity for **confidential** consultation with knowledgeable individuals. These guidelines specifically distinguish between informants whose testimony will not be required at a hearing and who retain a right to confidentiality, and complainants and witnesses who agree to testify in a hearing and, as a result, waive confidentiality.

1.2 SCOPE

This policy and these procedures apply to all faculty, researchers, and staff members including, without limitation, students, both graduate and undergraduate, postdoctoral fellows and postdoctoral research associates, visiting faculty or staff, faculty or staff on sabbatical leave, adjunct faculty when performing University work and faculty or staff on leave without pay. If research or scholarly misconduct is suspected to have been committed by a former employee of the UH while employed by the UH, this policy also applies. **Hereafter, the term "research misconduct" will be used to refer to any unethical conduct involved in academic, research-related, or scholarly activity (see Definitions Part II, O and P). Misconduct on the part of UH students may be governed by the Student Conduct Code (Office of Student Affairs; July 1992).**

1.3 COVERAGE

1.3.1

This policy is written to carry out the University of Hawaii's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. As such, the policy applies to allegations of research misconduct (e.g., fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results). However, research activities supported by sources of funding other than the PHS are also governed by this policy. Covered by the policy are persons who, at the time of the alleged research misconduct, were employed by, were agents of, or were affiliated by contract or agreement with the University of Hawai'i. The policy applies only to allegations of research misconduct that occurred within six years of the date the institution or HHS received the allegation, excluding those subject to the grandfather exceptions noted in 42 CFR § 93.105(b).

Activities included are non-PHS and PHS-supported biomedical or behavioral research, research training or activities related to that research or research training, such as the

operation of tissue and data banks and the dissemination of research information, (2) applications or proposals for funding to support biomedical or behavioral research, research training or activities related to that research or research training, or (3) plagiarism of research records produced in the course of funded research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for funds resulted in a grant, contract, cooperative agreement, or other form of support.

1.3.2

This policy also applies to a broader range of research and scholarly misconduct that includes, but is not limited to, fraud and/or misappropriation of funds, and violations of Federal and/or State of Hawai'i regulations with respect to the protection of human and animal subjects, conflict of interest, use of recombinant DNA, use of radioactive material, biosafety, and use of hazardous chemicals. See also, Section II. Definitions, Part P - Misconduct Definition (UH).

II. DEFINITIONS

- A. ***Allegation*** means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to the RIO or other institutional official such as an Ethics Committee member, or Departmental Chairs or Deans.
- B. ***Assessment*** means the initial evaluation of an allegation of research misconduct by the Research Integrity Officer and Ethic Committee Chairperson. During this time it will be determined whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.
- C. ***Complainant*** means a person who makes an allegation of research misconduct.
- D. ***Conflict of Interest*** means the real or apparent interference of one person's interests with the interests of another person where the disinterestedness of an adjudicator may reasonably be called into question and potential bias may occur due to prior or existing personal or professional relationships. As expressed in Executive Policy E5.214, a potential or actual conflict of interest exists when commitments and obligations to the University or to widely recognized professional norms are likely to be compromised by a person's other interests or commitments, especially financial, particularly if those interests or commitments are not disclosed.
- E. ***Deciding Official (DO)*** means a Senior Academic or Research Institutional Official appointed by the University President. This individual makes final determinations on allegations of research misconduct and any institutional administrative action. The DO will not be the same individual as the Research Integrity Officer and should have

- no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. A Deciding Official's appointment of individuals to evaluate allegations of research misconduct is not considered to be direct prior involvement on the part of the DO.
- F. *Ethics Committee (EC)*** means the standing committee appointed by the DO and established to assist the RIO in evaluating alleged violations of research misconduct. The Ethics Committee shall have 16 members consisting of a Chairperson and 15 members selected from faculty and staff within the UH system.
- G. *Evidence*** means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.
- a) *Burden of Proof*. The University has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of misconduct where the University has established by a *preponderance of evidence* that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.
- b) *Preponderance of evidence* means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.
- c) *Standard of Proof*. An UH finding of research misconduct must be proved by a preponderance of the evidence.
- H. *General Counsel*** means the legal counsel who represents the University and is responsible for advising the DO, RIO, and Ethics Committee whenever such counsel is sought. The UH General counsel does not represent the respondent, the complainant/informant, or any other person participating during the Inquiry or Investigation stages, or any follow-up action, except the Institutional officials, EC members, and others responsible for managing or conducting the University of Hawaii's evaluations of research misconduct allegations as part of their official duties.
- I. *Good Faith***, as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony such that a reasonable person would call attention to the perceived irregularities known at the time. An allegation, testimony, or cooperation on the part of a complainant, informant, witness, or respondent is not in good faith if it is made with knowing or reckless disregard for information that would

negate the allegation or testimony. Good faith as applied to members of a committee or review panel means cooperation for the purpose of helping an institution meet its responsibilities to investigate potential research misconduct.

- J. *HHS*** means the United States Department of Health and Human Services.
- K. *Informant*** means a person who wishes to remain anonymous and who informs the University (e.g., through the Ethics Committee, the RIO, an institutional official) of the possibility of research misconduct.
- L. *Inquiry*** means preliminary information-gathering and fact-finding to determine whether an allegation of research or scholarly misconduct warrants an investigation.
- M. *Institutional Member*** means 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 sub-awardees, and their employees.
- N. *Investigation*** means the formal development of a factual record and the examination of that record by an EC Review Panel, leading to a decision not to make a recommendation of a charge of research misconduct or to recommend such a charge. Decisions are reported in writing to the DO.
- Institutional Investigation*** means the Institution's (e.g., DO and Administrators) evaluation of the EC investigation, for the purpose of either concurring with the EC's findings or initiating ancillary procedures, such as additional interviews and/or further investigation.
- O. *Misconduct Definition (PHS)***. For the purposes of PHS regulations and reporting to the Office of Research Integrity, "Misconduct" or "Research Misconduct" means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

a) Fabrication is making up data or results and recording or reporting them.

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

c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research Misconduct does not include honest error or differences of opinion.

P. *Misconduct Definition (UH)*. Under this policy (E5.211), the UH definition of misconduct includes the PHS definition and the following elements:

- a) Abuse of confidentiality. Taking or appropriating confidential or private information without proper authority or releasing or disclosing to others, without proper authority, ideas, data, or other information given with the expectation of confidentiality. This includes any unauthorized disclosure of personal health information as defined by HIPAA in the context of research misconduct.
- b) Property Violation. Misappropriation, maliciously destroying, or altering without proper authority the research-related papers, data, supplies, equipment, or other products of research or scholarship. “Property” in this context can be regarded as either physical or intellectual property.
- c) Improprieties of Authorship: Improper assignment of credit, such as excluding others, misrepresentation of the same material as original in more than one publication; listing as an author any persons who (i) did not contribute significantly to the published research, (ii) do not or cannot stand behind the research results or (iii) have not carefully examined the manuscript. Improprieties also include allowing oneself to be listed as an author when significant contributions have not been made and submission of multi-authored publications without the concurrence of all authors.
- d) Misappropriation of Funds. Using research, or scholarship-related, funds for purposes that are in clear and substantial violation of the terms of a grant or regulations and policies
- e) Violation of generally accepted research practices. Serious deviation from accepted practices in proposing or carrying out research, improper manipulation of experiments to obtain biased results, deceptive statistical or analytical manipulations, or improper reporting of results.
- f) Material failure to comply with federal, state, or university regulations pertaining to care and protection of animal subjects; protection of human subjects; use of recombinant DNA, radioactive, biological, or chemical materials; or the conduct of classified research. This includes but is not limited to serious or substantial willful violations that involve inappropriate use of funds.
- g) Inappropriate behavior including accusations of misconduct made in bad faith, withholding or destruction of information relevant to a claim of misconduct, reckless or false testimony to an Ethics Committee or Review Panel member, and retaliation against persons involved in an investigation.

h) Deliberate material misrepresentation of qualifications, experience, or research accomplishments to advance a research program, to obtain external funding, or for other professional advancement.

i) Conduct that violates research and scholarly-related ethical standards as expressed in relevant codes of conduct promulgated by professional associations and learned societies within the various disciplines.

j) Violations of provisions of Executive Policy E5.214 regarding conflict of interest.

- Q. *Office of Research Integrity (ORI)*** means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.¹ (website: <http://ori.dhhs.gov/>)
- R. *PHS support*** means PHS funding for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research, or training that may be provided through: 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.
- S. *Public Health Service or PHS*** means the unit within HHS 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.
- T. *Records of Research Misconduct Proceedings*** means: (1) the research records and evidence secured for the research misconduct proceeding pursuant to this policy and 42 CFR §§ 93.305, 93.307(b), and 93.310(d), except to the extent the RIO determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that have been retained; (2) the documentation of the determination of irrelevant or duplicate records; (3) the inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate, as required by 42 CFR § 93.309(c); (4) the investigation report and all records (other than drafts of the report) in support of the report, including the recordings or transcripts of each interview conducted; and (5) the complete record of any appeal within the institution from the finding of research misconduct.
- U. *Research Integrity Officer (RIO)*** is appointed by the DO or his/her designee. The RIO, in consultation with the Chairperson of the Ethics Committee, is responsible for: (1) assessing allegations of research misconduct to determine if they fall within the

definition of research misconduct, as covered by this policy (E5.211) and whether they warrant an inquiry on the basis of the allegation being sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquiries and investigations; and 3) providing staff support to Review Panels.

- V. *Research Misconduct Proceeding*** means any actions related to alleged research misconduct that is within 42 CFR Part 93 and E5.211, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings and administrative appeals.
- W. *Research Record*** means the record of data (both written and electronic) or results that embody the facts resulting from academic research or scholarly work, including but not limited to, research proposals, laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to the RIO, an EC member, or an institutional official during the course of a research misconduct proceeding.ⁱⁱ
- X. *Respondent*** means the person against whom an allegation of research misconduct is directed and who is the subject of a research misconduct proceeding.
- Y. *Retaliation*** means an adverse action taken against a complainant, informant, witness, or EC Committee or Panel member of this institution or one of its institutional members in response to (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.
- Z. *Review Panel*** means the group of faculty and staff that conducts an inquiry or investigation dealing with allegations of research misconduct. The Review Panel shall be composed of five (5) individuals. The RIO, in consultation with the EC Chairperson, will appoint the Review Panel members who may include non-EC members who have relevant expertise.

III. RIGHTS AND RESPONSIBILITIES

- A. *Research Integrity Officer (RIO)***
The Deciding Official (DO) will appoint the RIO who will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. The RIO will be an institutional official who is well qualified to administer the procedures and is sensitive to the varied demands made on those who conduct research, those who are accused of research misconduct, those who make good faith allegations of research misconduct, and those who may serve on inquiry and investigation panels.

A detailed listing of the responsibilities of the RIO are as follows:

- Consult **confidentially** with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- In consultation with the Chairperson of the Ethics Committee, assess each allegation of research misconduct in accordance with Section V.,A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify ORI of special circumstances, in accordance with Section IV.,F. of this policy;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.,C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in a research or scholarly misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and panel reports in accordance with Section III.,C. of this policy;
- Inform respondents, complainants, and witnesses of the procedural steps in a research misconduct proceeding;
- Appoint in consultation with the Chairperson of the Ethics Committee, members of the inquiry and investigation review panels, ensure that those panels are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, informants, witnesses, and panel members and counter potential or actual retaliation against them by respondents or other institutional members;

- In cases where a respondent is found not culpable at any stage in the proceedings, all reasonable and practical steps will be taken to protect or restore his/her position and reputation;
- Consult with institutional legal counsel;
- Keep the Deciding Official and others who need to know apprised of the progress of review of allegations of research misconduct;
- Notify and make reports to ORI as required by 42 CFR Part 93;
- Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, editors of journals, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section VIII., F. of this policy.

B. Complainant/Informant

Complainants are responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the assessment, inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the interview for correction.

The informant is also responsible for making allegations in good faith, maintaining confidentiality, and, to the extent possible, cooperating with the research misconduct process. The informant is under no obligation to be interviewed and retains the right to remain anonymous. However, it must be noted that whereas the University may be able to control its own investigative process, in a court of law or in arbitration of a grievance anonymity cannot be guaranteed.

As a matter of policy or on the basis of case-by-case determinations, the institution may provide to the complainant for comment: (1) relevant portions of the inquiry report (within a timeframe that permits the inquiry to be completed within 60 days of its initiation); and (2) the draft investigation report or relevant portions of it. Comments on the report(s) must be submitted within 14 days of the date on which the complainant received the report(s). Comments made by the complainant on the draft investigation report will be included in the final investigation report.

C. **Respondent**

The respondent is responsible for maintaining confidentiality, cooperating with the conduct of an assessment, inquiry and investigation, providing good-faith testimony, and refraining from retaliatory actions. The respondent is entitled to:

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;ⁱⁱⁱ
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;^{iv}
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to, 42 CFR Part 93 and the institution's policies and procedures on research misconduct;^v
- Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;^{vi}
- Be interviewed during the inquiry and investigation, correct and certify the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;^{vii}
- Have the Review Panel interview during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 14 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and institutional legal counsel, the Deciding Official may terminate the institution's review of an allegation that has been admitted if the institution's acceptance of the admission is approved by ORI when PHS funds are involved.

As provided in 42 CFR § 93.314(a), the respondent will have the opportunity to appeal an institutional decision. Procedures contained in relevant collective bargaining agreements will apply. For interviews with the Review Panel, the respondent has the right to request union assistance and may request that a union agent be present at the interview.

D. Deciding Official (DO)

The DO will receive the inquiry report and after consulting with the RIO and the EC Chairperson, decide whether an investigation is warranted. Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI in cases where PHS funds are involved, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.^{viii}

The DO will receive the investigation report and, after consulting with the RIO and other appropriate officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. If PHS funds are involved, the DO shall ensure that the final investigation report, the findings of the DO and a description of the any pending or completed administrative action are provided to ORI, as required by 42 CFR § 93.315.

IV. GENERAL PRINCIPLES AND POLICIES

A. Responsibility to Report Misconduct.

All institutional members should immediately report observed, suspected, or apparent research misconduct directly to the RIO, to members of the University of Hawaii administration, or to members of the Ethics Committee. Any official or member of the Ethics Committee who receives an allegation of research misconduct must report it immediately 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 may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not 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 Misconduct Proceedings.

Institutional members should cooperate with the RIO and other institutional officials in the review of allegations and the conduct of assessment, inquiries, and investigations. Institutional members, including respondents, have an obligation

to provide evidence relevant to research misconduct allegations to the RIO, EC Chairperson, or to other institutional officials.

C. Confidentiality.

The RIO shall, as required by 42 CFR § 93.108, (1) limit disclosure of the identity of respondents, complainants, informants, and witnesses 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.

D. Protecting Complainants, Informants, Witnesses and Committee Members.

Institutional members may not retaliate in any way against complainants, informants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, informants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, take 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.

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts 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.^{ix}

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.

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 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.^x 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, immediately notify ORI, if PHS funds are involved and if he/she has reason to believe that any of the following conditions exist or following actions are advisable:

- HHS resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding; or
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved.

If at any time during an assessment, inquiry, or investigation, it appears that there has been a violation of criminal law, the proceedings will be suspended, the Deciding Official will be notified, and he or she will consult with the University General Counsel Office to determine the next action to be taken.

V. CONDUCTING THE ASSESSMENT AND INQUIRY

A. Assessment of Allegations.

Upon receiving an allegation of research misconduct, the RIO, in consultation with the Ethics Committee Chairperson will immediately assess the allegation to determine whether 1) it is sufficiently credible, 2) it is sufficiently specific so that potential evidence of research misconduct may be identified, 3) it is within the jurisdictional criteria of 42 CFR § 93.102, and 4) it falls within the definition of research misconduct in this policy or 42 CFR § 93.103. An inquiry must be conducted if these criteria are met. Allegations deemed to be without substance will not be moved to the Inquiry stage.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, informant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

B. Initiation and Purpose of the Inquiry.

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

- C. Notice to Respondent, Sequestration of Research Records.
Before beginning or during 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. On or before the time at which the respondent is notified, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments (42CFR §93.307(b)). The RIO may consult with ORI for advice and assistance in this regard.
- D. Appointment of the Inquiry Panel.
The RIO, in consultation with the Chairperson of the Ethics Committee and other institutional officials as appropriate, will appoint an inquiry panel and panel chair within 10 days of the decision to conduct an inquiry or as soon thereafter as practical. The inquiry panel must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved and should include individuals with the appropriate subject expertise to evaluate the evidence and issues related to the allegation, interview the principal and key witnesses, and conduct the inquiry.
- E. Instructions to the Panel and First Meeting.
The RIO, in consultation with the Chairperson of the Ethics Committee, will prepare instructions for the inquiry panel that:
- Sets forth the time for completion of the inquiry;
 - Describes the allegations and any related issues identified during the allegation assessment;
 - States that the purpose of the inquiry is preliminary information gathering and fact-finding to determine whether an allegation of research or scientific misconduct warrants an investigation;
 - States that an investigation is warranted if the panel determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(a), or E5.211; and (2) the allegation has substance, based on the panel's review during the inquiry;

- Informs the inquiry panel that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

At the panel's first meeting, the RIO will review the instructions to the panel, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the panel with organizing plans for the inquiry, and answer any questions raised by the panel. The RIO will be present or available throughout the inquiry to advise the panel as needed and to provide staff support to the panel.

F. Inquiry Process.

The inquiry panel will interview the complainant, the respondent, and key witnesses as well as examine relevant research records and materials. The inquiry panel will evaluate the evidence, including the testimony obtained during the inquiry, and will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d). When an investigation is warranted the panel will notify the RIO, and get consultation on the subsequent course of action following the inquiry. The scope of the inquiry is not required to decide, and does not normally include deciding, whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved (See Section III., C.). If an admission is affirmed in a case involving PHS funds the institution shall promptly consult with ORI to determine the next steps that should be taken.

G. Time for Completion.

The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, 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. The respondent will be notified of the extension.

VI. THE INQUIRY REPORT

A. Elements of the Inquiry Report.

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the funding support, including for example, grant numbers, grant applications, contracts and publications listing funding support; (4) the basis for recommending or not recommending that the allegations warrant

an investigation; (5) any comments on the draft report by the respondent or complainant.^{xi}

The inquiry report should also include: the names and titles of the panel members who conducted the inquiry; their signatures; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; and whether any other actions should be taken if an investigation is not recommended.

B. Notification to the Respondent and Opportunity to Comment.

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted. The respondent shall receive a copy of the draft inquiry report for comment within 14 days. Any comments that are submitted within 14 days will be attached to the final inquiry report. Based on the comments, the inquiry panel may revise the draft report as appropriate and prepare it in final form.

The institution may notify the complainant whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment within 14 days.

C. Institutional Decision and Notification.

1. Decision by Deciding Official.

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

2. 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 if PHS funds were involved. 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: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the allegations to be considered in the investigation.^{xii}

3. Documentation of Decision Not to Investigate.

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

VII. CONDUCTING THE INVESTIGATION

A. Initiation and Purpose.

The investigation must begin within 60 calendar days after the determination by the DO that an investigation is warranted.^{xiii} 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 charges if warranted. 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 general public, or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Notifying ORI and Respondent, Sequestration of Research Records.

On or before the date on which the investigation begins, the RIO must: (1) for cases involving PHS funding, notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify 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 a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.^{xiv}

The RIO will, prior to notifying the 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. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.^{xv}

C. Appointment of the Investigation Panel.

The RIO, in consultation with the Chairperson of the Ethics Committee and with other institutional officials, as appropriate, will appoint an investigation panel and the panel chair within 10 days of the beginning of the investigation or as soon thereafter as practical. The investigation panel must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the

appropriate expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation panel may also have served on the inquiry panel.

When necessary to secure the needed expertise or to avoid conflicts of interest, the RIO may select panel members from outside the institution. The RIO will notify the respondent of the proposed panel membership to give the respondent an opportunity to object to a proposed member or members based upon a personal, professional, or financial conflict of interest. If so, the university will limit the period for submitting objections to no more than 10 calendar days. The RIO will make the final determination of whether a conflict exists.

D. Instructions to the Panel and the First Meeting.

The RIO will define the subject matter of the investigation in a written set of instructions to the panel that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the respondent;
- Informs the panel that it must conduct the investigation as prescribed in paragraph E of this section;
- Defines research misconduct;
- Informs the panel that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, recommended charges of research misconduct will be forwarded to the Deciding Official. If so, the type and extent of the charges and who is being held responsible will be stated;
- Informs the panel that in order to determine that the respondent should be charged with research misconduct, it must find that a preponderance of the evidence establishes that: (1) 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); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; and

- Informs the panel 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 panel to review the allegation(s), 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 panel will be provided with a copy of this policy and 42 CFR Part 93. The RIO will be present or available throughout the investigation to advise the panel as needed and to provide staff support.

E. Investigation Process.

The investigation panel and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;^{xvi}
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;^{xvii}
- Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction and certification, and include the recording or transcript in the record of the investigation;^{xviii} and
- 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 of 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 when necessary. However, if an investigation will not be completed within this 120-day period, the RIO will be officially notified and he/she will inform the respondent of the need for an extension. Additionally, when involving PHS funds, the RIO 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.

VIII. THE INVESTIGATION REPORT

Elements of the Investigation Report.

- A. The investigation panel 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. The respondent's C.V. or resume is to be included as a part of the identification.
 - Describes and documents the funding agencies, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing funding support;
 - Describes 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; and
 - Includes a statement of charges, if warranted, for each allegation of research misconduct identified during the investigation.^{xix} Each statement of charges must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; or whether the charges fall under the University of Hawai'i's (this policy's) definition of misconduct; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by the 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; (3) identify the specific funding support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with both non-PHS and PHS federal agencies.^{xx}
- B. Comments on the Draft Report and Access to Evidence

1. Respondent
The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 14 calendar days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.
2. Complainant
On a case by case basis the University may provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. If the institution chooses this option, the complainant's comments must be submitted within 14 calendar days of the date on which he/she received the draft report and the comments must be included and considered in the final report.
3. Investigation Report
The draft investigation report will be transmitted to the UH Counsel for a review of its legal sufficiency. Modifications will be made as appropriate, in consultation among the RIO, the Chairperson of the Ethics Committee, the investigation panel and the Institutional Counsel.
4. Confidentiality
In distributing the draft report, or portions thereof, to the respondent, and complainant 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.

- C. Decision by Deciding Official
The RIO will assist the investigation panel 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, who will determine: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the investigation panel, 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 panel. Alternatively, the DO may return the report to the investigation panel 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 (when necessary), the DO will also 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
These procedures provide for an appeal by the respondent, as specified in the prevailing UH faculty and staff bargaining unit agreements, that could result in a reversal or modification of the institution's findings of research misconduct. Regardless of the funding source, the appeal must be completed within 120 days of its filing, unless the DO or RIO (or ORI, when PHS-funding is involved) finds good cause for an extension, based upon a written request 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).
- E. Notice to ORI of Institutional Findings and Actions (cases involving PHS funds). Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation submit the following to ORI: (1) a copy of the final investigation report with all attachments and any appeal; (2) a statement of whether the institution accepts the findings of the investigation report or the outcome of the appeal; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent (42 CFR §93.315).
- 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 (if PHS funds are involved). 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.^{xxi} 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.

IX. COMPLETION OF CASES; REPORTING PREMATURE CLOSURE 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 (when necessary) in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the

basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.^{xxii}

X. INSTITUTIONAL ADMINISTRATIVE ACTIONS

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

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the misconduct.

XI. 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, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation panel 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 if PHS funds are involved, the RIO will, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.^{xxiii} 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, Informant, 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 will undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant or informant 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.^{xxiv} The DO will determine, after consulting with the RIO, and with the complainant, informant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.
- D. Allegation(s) or Testimony Not Made in Good Faith.
If relevant, the DO will determine whether the complainant's or informant's allegations of research misconduct were made in good faith, or whether a witness, respondent, or committee member acted in good faith. If the DO determines that there was an absence of good faith he/she will determine whether any administrative action should be taken.

NOTES:

ⁱ 42 CFR § 93.217

ⁱⁱ 42 CFR § 93.224

ⁱⁱⁱ 42 CFR §§ 93.304(c), 93.307(b)

^{iv} 42 CFR §§ 93.304(e), 93.307(f)

^v 42 CFR § 308(a)

^{vi} 42 CFR § 310(c)

^{vii} 42 CFR § 310(g)

^{viii} 42 CFR § 93.309(c)

^{ix} 42 CFR § 93.304(k)

^x 42 CFR § 93.304(h)

^{xi} 42 CFR § 93.309(a)

^{xii} 42 CFR § 93.309(a) and (b)

^{xiii} 42 CFR § 93.310(a)

^{xiv} 42 CFR § 93.310(b) and (c)

^{xv} 42 CFR § 93.310(d)

^{xvi} 42 CFR § 93.310(e)

^{xvii} 42 CFR § 93.310(f)

- xviii 42 CFR § 93.310(g)
- xix 42 CFR § 93.313
- xx 42 CFR § 93.313(f)
- xxi 42 CFR § 93.317(b)
- xxii 42 CFR § 93.316(a)
- xxiii 42 CFR § 93.304(k)
- xxiv 42 CFR § 93.304(l)