CLARK ATLANTA UNIVERSITY

Policy 11.1 – Responding to Misconduct in Research

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1.0 Policy Statement

The cornerstones of Clark Atlanta University's research quest for knowledge is based on trust, honesty, integrity, and ethics. When events related to research misconduct occur that threaten these basic tenents of belief, Clark Atlanta University (University) will repond quickly to correct, mitigate and eliminate the threats. Research misconduct is the fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposition, conducting, or reporting research. However, honest error or honest differences in interpretations or judgments of data are not considered research misconduct.

This policy provides ways through which the University will respond to allegations relative to research misconduct. Specifically, the policy provides procedures for the investigation of allegations of misconduct of research with attention to the protection of the rights of those making the allegations, those accused, and the University. In developing the policy, Clark Atlanta University is mindful that faculty, administrators, researchers and scholars are highly principled. Nevertheless, this policy is designed to address those occurrences of research misconduct. The intention is not to stifle creativity or freedom of speech, but to resolve issues of dishonest behaviors whenever they occur.

The University acknowledges that research misconduct cannot be prevented by University policy or federal law alone, but by each individual's firm commitment to academic ethics, honesty, trust, and integrity. University administrators, project director, deans, chairs, and unit heads must stress the importance of such commitment by faculty, students, staff, and research associates and assistants.

1.01 Scope

This policy and the associated procedures apply to all individuals at Clark Atlanta University engaged in research that is supported by or for which support is requested from a federal department or agency and other external entities. It applies to any research, research-training or research-related grant, contract or cooperative agreement. This policy applies to any person paid by, under the control of, or affiliated with the institution, such as scientists, researchers, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at the University. The University will comply with those Federal regulations to which it is subject relative to allegations of research misconduct, in particular, those of the National Science Foundation (45 CFR, §689) and the Public Health Service (42 CFR, §93).

The policy and associated procedures will normally be followed when an allegation of possible misconduct in research is received by a University official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of CAU or the pertinent federal department or agency. When an allegation under this policy involves work supported by federal funding, the research misconduct regulations, policies and procedures of the cognizant agency shall supercede this policy in the event of a conflict. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Provost.

1.02 Definitions

a) *Allegation* means any written or oral statement or other indication of possible research misconduct made to a University official.

b) *Complainant* means a person who makes an allegation of research misconduct in good faith.

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

d) *Deciding Official* (DO), the Provost shall be the DO. The DO is the University official who makes final determinations on allegations of research misconduct and any responsive University actions. The DO will have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment proceedings.

e) *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.

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

g) *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 [i.e., the record of data or results that embody the facts emerging from the research, and includes but is not limited to, research proposals, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, books, background information, including biographical data, citation of publications or status or transcripts].

h) *Federal support* means federal department or agency grants, contracts, or cooperative agreements or applications therefor.

i) *Goodfaith allegation,* 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. An allegation or cooperation with a research misconduct proceeding 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 committee members means cooperating with the purpose of helping an institution meet its responsibilities under 42 CFR § 92. A committee member does not act in good faith if his/her actions or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in research misconduct proceedings.

j) *HHS* means the United States Department of Health and Human Services.

k) *Inquiry* means gathering preliminary information and fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation, as prescribed under 42 CFR §§ 93.307-93.309. [1]

l) *University member* means a person who is employed by, is an agent of, or is affiliated by contract or agreement with the University. 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. [2]

m) *Investigation* means the formal examination and evaluation of all relevant facts to determine whether misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct. [3]

n) *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.

o) *Public Health Service (PHS)* means the unit within HHS that includes the Office of Public Health and Sciences.

p) *Pertinent Federal Office* means the office within a federal department or agency that is responsible for research misconduct and research integrity activities. For PHS this is the Office of Research Integrity (ORI), within the US Department of Health and Human Services.

q) *Pertinent federal department or agency* means the federal department or agency providing support for research or to which an application for support is made.

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

s) *Preponderance of the 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. It means that a review of the evidence leads to a finding that is more likely than not, or more than 50% likely.[4]

t) *Public Health Services (PHS) regulation* means the Public Health Service regulation establishing standards for University inquiries and investigations into allegations of research misconduct, which is set forth at 42 CFR §50 Subpart A, titled "Responsibility of PHS

Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science."

u) *Research Integrity Officer* is the institutional official responsible for assessing allegations of research misconduct and determining whether such allegations warrant inquiry. The RIO is appointed by the VPRSP in consultation with the Provost, serves as the chair of the Responsible Conduct of Research Committee, and oversees the inquiry and investigations.

v) *Responsible Official* (RO) will be the Dean of the School or, for units not administratively under a dean, the director or vice president of the unit in which the accused is working. If the accused is a dean/director of the unit the Responsible Official will be the Associate Vice President for Academic Affairs.

w) *Research misconduct:*

1. Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposition, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. [5]

2. The commitment of fraud in research. This includes the intentional fabrication of falsification of research data; the omission in publications of conflicting or non-confirming observations or data; the theft of research methods or data from others, the plagiarizing of research ideas, research results or research publications; or other serious deviations "from accepted practices in carrying out or reporting results from research." [5]

3. The condoning of fraud in research or violations of University research policies. This includes failure on the part of a member of the University to comply with University policies and procedures to notify the University authorities whenever it becomes obvious to him/her that misconduct in research probably has occurred, and the failure to cooperate in an investigation under these procedures.

4. Material failure to comply with Federal and University requirements pertaining to the conduct of research. Examples: the failure to obtain proper review and approval by the responsible University committee for research that involves human subjects, animals, radioactive materials or other hazardous materials; the failure to follow recommendations made by the responsible University committees concerning research subjects, materials, or procedures, etc.

x) *Research record* means 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 a University official by a respondent in the course of the research misconduct proceeding. Other

examples of research records include but are not limited to grant or contract applications, whether funded or unfunded; grant or contract progress reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment-use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files. "Data or results" shall be interpreted broadly to encompass all forms of scholarly information about the research at issue without regard to the type of recording or storage media, including, but not limited to, raw numbers, field notes, interviews, notebooks and folders, laboratory observations, computers and other research equipment, CD-ROMs, hard drives, floppy disks, Zip disks, back-up tapes, machine counter tapes, research interpretations and analysis, tables, slides, photographs, charts, gels, individual facts, statistics, tissue samples, reagents, and documented oral representations of research results, as well as any documents and material provided to Department of Health and Human Services (HHS) or a University official by a respondent in the course of the research misconduct proceeding.

y) *Research Sponsor* means the agency, institution, or organization, if any, that sponsored the research that is the subject of an inquiry or investigation. The research sponsor can be governmental, private, or nonprofit in nature, It also includes the Office of Research Integrity of the U.S. Department of Health and Human Services for research that is sponsored by any part of HHS. Other research sponsors may include the National Science Foundation (NSF), National Institutes of Science (NIS), Department of Defense (DOD, National Aeronautical and Space Administration (NASA), National Institutes of Health (NIH), etc.

z) *Respondent* means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

aa) *Retaliation* means any action that adversely affects the employment or other University status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of research misconduct or of inadequate institution response thereto or has cooperated in good faith with an investigation of such allegation.

2.0 Procedures

Whenever a Clark Atlanta University faculty member, graduate student, undergraduate student, or any other person involved in research is accused of misconduct in research, the University will conduct an assessment, an inquiry, and when necessary, an investigation to make a determination concerning the truth or falsity of the allegation(s), and take appropriate disciplinary action. The processes of inquiry and investigation will be expeditious, fair, confidential, and protect the rights of all persons concerned, including the complainant, the accused, witnesses, and committee members. In addition, Federal regulations require the University to have explicit procedures for

addressing incidences in which there are allegations of misconduct in research. In keeping with these requirements, Clark Atlanta University has created specific procedures.

2.01 Roles and Responsibilities of Parties Responding to Allegations of Misconduct in Research

2.01A Research Integrity Officer (RIO)

The Research Integrity Officer is appointed by the VPRSP and serves as the chair of the University's Responsible Conduct of Research committee. The RIO is responsible for assessing allegations of research misconduct to determine if it falls within the definition of research misconduct and if an investigation is warranted. The Division of Research and Sponsored Programs and the Office of the General Counsel will assist the RIO by providing current pertinent federal requirements and documents relating to allegations of research misconduct and in reviewing the requirements of the University's policies and procedures. Any finding that an investigation is warranted must be made in writing to the VPRSP and Provost so that said information can be communicated to the Officer of Research Integrity.

The RIO, in consultation with RO and VPRSP, will ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. All parties involved will attempt to ensure that confidentiality is maintained.

The RIO will assist the inquiry committee and all University personnel in complying with the procedures and with applicable standards imposed by government or external funding sources. The RIO will also be responsible for maintaining files of all documents and evidence, and for the confidentiality and the security of the files of the inquiry committee.

The RIO's responsibility will include discussing the allegations confidentially with the complainant and prepare a report to the appropriate committee or body, if the allegation seems serious enough to warrant reporting. In addition, the RIO's responsiblities will include the following:

- Receive allegations of research misconduct;
- Assess each allegation of research misconduct to determine whether it falls within the definition of research misconduct and warrants an inquiry, and provide written response if an investigation is warranted to VPRSP and Provost;
- Initiate the inquiry process, with consultation with the RO, Provost, and VPRSP;
- Provide confidentially to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and University policy;

- Chair the inquiry committee which is composed of the members of the Responsible Conduct of Research committee and recommend additional members with domain expertise, if necessary;
- Ensure that the committee is properly staffed and that the expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Recommend additional committee members, in consultation with RO and VPRSP, with domain expertise, if necessary;
- Determine whether each person involved in handling an allegation of research misconduct has no unresolved personal, professional, or financial conflict of interest;
- Take appropriate action to recuse anyone to ensure that no person with such conflict is involved in the research misconduct proceeding;
- Cooperate with other University officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other University members;
- Assist the investigation committee with the draft report; and
- Ensure the investigative committee members secure all related documents obtained and used while in performance of the investigation.

2.01B Provost/Vice President of Academic Affairs (Provost)

The Provost/Vice President for Academic Affairs will serve as the Deciding Official for the University and receive the recommendations of the inquiry committee.

2.01C Vice President for Research and Sponsored Programs (VPRSP)

The Vice President for Research and Sponsored Programs is the Chief Research Officer of the University. The VPRSP will assist the RIO in assessing whether the allegation of research misconduct is warranted because the allegation falls within the definition of research misconduct, and is within the jurisdictional criteria of 42 CFR § 93.102 (b). The allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

Also, the VPRSP will be responsible for the following:

- Communicate with ORI and other affected sponsoring agencies on the status of inquiry and investigation proceedings;
- Provide ORI, upon request, the University policies and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts, recordings of any interviews, copies of all relevant documents, and the charges to be considered in the investigation;

- Provide the inquiry and investigation committees with advisory services; and
- Report to the Pertinent Federal Office as required by regulation and keep the Pertinent Federal Office apprised of any developments during the course of the inquiry or investigation that may affect current r potential federal funding for the individual(s) under investigation or that the federal department or agency needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.[6]

2.01D Complainant

The complainant will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation and to be protected from retaliation. Also, if the RO has determined that the complainant may be able to provide pertinent information on any portions of the draft report, these portions will be given to the complainant for comment. At any time during the proceeding, the complainant can consult with the CO or VPRSP.

The complainant is responsible for making allegations in good faith, maintaining confidentiality and cooperating with an inquiry or investigation. At any time during the proceeding, the complainant can consult with the CO or VPRSP.

2.01E Compliance Officer

The Compliance Officer (CO) will be the University official who is qualified to provide oversight to inquiries and investigations and ensure that the procedural requirements are carried out and who is sensitive to the varied demands made on those who conduct the research, those who are accused of misconduct and those who report misconduct in good faith.

The CO will have responsibility for consulting with the RO, Provost, and VPRSP with regards to the inquiry and the investigation; assisting the respondent, the complainant and witness with any questions regarding the procedural steps in the research misconduct proceedings. The CO will serve as an ex officio member of the investigation committee without vote.

2.01F Respondent

The respondent will be informed in writing of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigations. If the respondent is not found guilty of research misconduct, he or she has the right to receive University assistance (nonmonetary) in restoring his or her reputation. [7] The respondent is entitled to:

- A good faith effort from the RO to notify the respondent in writing at the time of or before beginning an inquiry;

- An opportunity to comment on the inquiry report and have his/her comments attached to the report;
- Be notified of the outcome of the inquiry report and have his/her comments attached to the report;
- 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 calendar days after the University 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;
- Be interviewed during the investigation, have the opportunity to clarify recording and transcripts, and have the clarified recording or transcripts included in the record of investigation;
- Received a copy of the draft investigation report and review any evidence on which the report is based, and be notified that any comments must be submitted within thirty (30) calendar days of the date on which the copy was received and that the comments will be considered by the University and addressed in the final report to the DO.

The respondent shall be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the VPRSP, CO, and the RO, the Provost may terminate the University's review or investigation of an allegation that has been admitted if, in consultation with University Counsel, the University's acceptance of that admission and any proposed settlement is approved by ORI or the appropriate oversight entity.

2.01G Deciding Official

The Deciding Official (DO) will be the Provost/Vice President for Academic Affairs. The DO will receive the investigation report and any written comments made by the respondent or the complainant on the draft report. The DO will make the final determination and impose administrative action(s), if applicable.

2.02 General Guidelines

2.02A Responsibility to Report Misconduct

All employees or individuals associated with CAU will report observed, suspected, or apparent misconduct in research to the respondent's Dean or unit head, who will serve as the RO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he/she may call the RIO or VPRSP to discuss the suspected research misconduct informally. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO or VPRSP will refer the individual or allegation to the CO or other offices or officials with responsibility for resolving the problem.

At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the CO, RIO, or theVPRSP and will be counseled about appropriate procedures for reporting allegations.

2.02B Cooperation with Research Misconduct Proceedings

University employees will cooperate with the RIO and other University officials in the review of allegations and the conduct of inquiries and investigations. Employees, including respondents, have an obligation to provide relevant evidence to the RIO or other University officials on research misconduct allegations.

2.02C Confidentiality

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

2.02D Protecting Complainants, Witnesses, and Committee Members

The RO will monitor the treatment of individuals who bring allegations of research misconduct or of inadequate University response thereto, and those who cooperate in inquiries or investigations. The RO will ensure that all persons (complainants, witnesses and committee members) will not be retaliated against in the terms and conditions of their employment or other status at the University and will review instances of alleged retaliation for appropriate action. Employees should immediately report any alleged or apparent retaliation to the RO, CO, or RIO. The RIO 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. As appropriate, the RIO will refer the individual to the CO.

2.02E Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation. [8] As requested and as appropriate, the RIO and other University 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. [7]

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunitites provided for in 42 CFR §93 and the policies and procedures of CAU. University employees accused of research misconduct may consult with the VPRSP or the CO at any time during the proceedings.

2.02F Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the RIO, in collaboration with the RO and the VPRSP, will review the situation to determine whether there is any threat of harm to public health, federal funds and equipment, or the integrity of the funded supported research process. In the event of such a threat, the RO will, in consultation with other University officials and ORI, take appropriate interim action to protect against any such threat. [9] Interim action might include additional monitoring of the research process. The RO, VPRSP, and Vice President for Finance and Business Services will be responsible for the handling of federal funds and equipment, and reassignment of personnel. The RO will determine whether there is a need for additional review of research data and results, or for delaying publication. The VPRSP shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has cause. [See section 2.01C]

2.03 Conducting the Inquiry

2.03A Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO, in collaboration with the RO and VPRSP, will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether Federal department or agency support or Federal department or agency applications for funding are involved, and whether the allegation falls within the jurisdictional criteria cited in 42 CFR §93.102(b) and whether the allegation falls within the definition of research misconduct in this policy and as cited in 42 CFR §93.103. An inquiry must be conducted if the cited criteria are met.

The assessment period should be brief, perferably concluded within seven working days. During this timeframe, the RIO need not interview the complainant, respondent, or other witnessess, 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. The RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph C, of this section.

2.03B Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the RIO, in collaboration with the RO and VPRSP determines that the allegation provides sufficient information to allow specific follow-up, involves Federal department or agency support, and falls under the Federal department or agency definition of research misconduct, he or she will immediately initiate the inquiry process. In

initiating the inquiry, the RIO should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The finding of the inquiry must be set forth in an inquiry report.

2.03C Notice to Respondent; Sequestration of the Research Records

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 inquiry subsequently identified additional respondents, they must be notified in writing, as well. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, 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 inquiry proceeding, inventory the records and evidence and sequester them in a secure manner, execpt that where the research records or evidence encompasses scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments. During the inquiry all appropriate files should be secured under lock and key and available only to the investigation committee members. The files should not be comingled with other records. After the inquiry proceeding is closed, the files will be secured and maintained by the RIO. If need be, the VPRSP may consult with ORI or the pertinent federal government or external entity for advice and assistance in this regard.

2.03D Appointment of the Inquiry Committee

The inquiry committee will usually consist of members of the Responsible Conduct of Research Committee to include the RIO who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matters experts, administrators, or other qualified persons, and they may be from inside or outside the University. The committee may also include other individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. [10] If the Respondent is a student, the Dean of Undergraduate Studies or the Dean of Graduate Studies or a designee may also serve as a member.

The RIO will notify the respondent of the proposed committee membership within 10 days of the initiation of the inquiry. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 business days, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

2.03E Charge to the Committee and the First Meeting

The RIO will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and state that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation as required by the federal department or agency regulation. The purpose is not to determine whether research misconduct definitely occurred or who was responsible. The inquiry is to determine whether there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and that the allegation may have substance, based on the committee's review during the inquiry proceeding. The charge shall inform the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR §93.309(a). The charge shall set forth the time for completion of the inquiry.

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

2.03F Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examine relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

2.03G Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the RIO 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-calendar-day period. [11] The respondent will be notified of the extension.

2.04 The Inquiry Report

2.04A Elements of the Inquiry Report

A written inquiry report must be prepared within 15 business days of finding that an investigation is warranted that states the following:

- the name and position of the respondent,

- the name and title of the committee members and experts, if any;
- the allegations,
- the Federal department or agency support;
- a summary of the inquiry process used;
- a list of the research records reviewed;
- summaries of any interviews;
- a description of the evidence in sufficient detail to demonstrate whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended;
- the basis for recommending or not recommending that the allegations warrant an investigation must be included.

University counsel will review the report for legal sufficiency and modifications made as appropriate.

2.04B Notification to Respondent and Complainant and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted. The RIO will provide the respondent with a copy of the draft inquiry report for comment and rebuttal. At the time of receipt of the draft inquiry report, a confidentiality agreement must be signed by both the respondent and the complainant. The respondent must submit their comments in writing within ten (10) calendar days to the RIO. The RIO will notify the complainant in writing regarding whether the inquiry found an investigation to be warranted and provide relevant portions of the draft inquiry report for comments within ten (10) calendar days. Both the respondent and complainant will be provided a copy of or referred to 42 CFR §93 and the University's policies and procedures on research misconduct. [12]

1. Confidentiality

   The RIO shall establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments

   Any comments that the complainant or respondent submits on the draft report will become part of the final inquiry report and record. [6] Based on the comments, the inquiry committee may revise the report as appropriate.

2.04C University Decisions and Notification

1. Decision by Provost to Investigate

   The RIO will transmit the final inquiry report with recommendations and any comments to the VPRSP and the Provost who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Provost makes this determination, which will be made within 60 calendar days of the first meeting of the inquiry committee unless an extension has been granted. The final inquiry report will have the date of the first meeting of the inquiry committee recorded in it. Any extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification to Complainants and to the Respondent

   The Provost will notify the VPRSP, RIO and both the respondent and the complainant in writing of the decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Provost will also notify all other appropriate University officials of the decision.

3. Notification to ORI

   The VPRSP will provide to ORI with the written decision and copy of the inquiry report within 30 calendar days of the decision that an investigation is warranted. Upon request the RIO will provide, via the VPRSP, to ORI the following: 1) the University policies and procedures under which the inquiry was conducted, 2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents, and 3) the charges to be considered in the investigation. [13]

4. Documentation of Decision Not to Investigate

   If the Provost decides that an investigation is not warranted, the RIO will inform all parties in writing. The RIO will be instructed to secure and maintain for seven (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 personnel from external funding agencies upon request.

2.05 Conducting the Investigation

2.05A Purpose of the Investigation

The investigation must begin within 30 calendar days after the determination by the Provost that an investigation is warranted. [14] The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged 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.

2.05B Notifying ORI and Respondent; Sequestration of the Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify ORI, via the VPRSP, of the decision to begin the investigation and provide 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. [15]

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. The need for additional sequestration of records may occur for any number of reasons, including the University'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. [16]

2.05C Appointment of the Investigation Committee

The investigation committee will be composed of members of the Responsible Conduct of Research Committee as well as the RIO. The RIO may select additional committee members either internal to the University or from outside the University with expertise in the research or content areas under investigation. The CO will serve in an advisory capacity to the committee. The chair of the committee will usually be the RIO, unless otherwise selected by the committee in consultation with the RIO and VPRSP within 5 business days of the notification to the respondent that an investigation is planned or as soon thereafter as practical. The members of the investigation committee should not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigations. [10]

The RIO will notify the respondent of the proposed committee membership within 5 business days of composition of the proposed committee. The respondent may object to a proposed member based upon a personal, professional, or financial conflict of interest. The respondent must submit a written objection to any appointed member of the investigation committee or expert within 10 days. The RIO, in consultation with the RO and VPRSP, will determine whether a conflict exists and replace the challenged member or expert with a qualified substitute.

2.05D Charge to the Investigation Committee and the First Meeting

(1) Charge to the Committee

The RIO, with the assistance of the RO and VPRSP, 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;
- Informs the committee that it must conduct the investigation as prescribed in paragraph 2.05E;
- 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: (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 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.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the RIO will notify the Provost and VPRSP, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

(2) The First Meeting

The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, along with supporting documentation, 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 §93. The RIO will be present or available throughout the investigation to advise the committee, as needed.

2.05E Investigation Process

The investigation committee 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; [17]

- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical; [10]

- 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 include the recording or transcript in the record of the investigation; [18] 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. [19]

2.05F Time for Completion

The investigation is to be completed within 120 days of initiating it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI or the relevant external entities. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI or the relevant external entities, via the VPRSP, a written request for an extension at least five days before the scheduled completion of the report, 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. [20]

2.06 The Investigation Report

2.06A Elements of the Investigation Report

The investigation committee and the RIO are 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;
- Describes and documents the federal support or other entitites, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing the external support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the University policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI or the cognizant agency 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 findings for each allegation of research misconduct identified during the investigation. [21] Each statement of findings must: (1) report whether allegation is substantiated or not, and the possible impact of the violation on the University; (2) identify whether the research misconduct was falsification, fabrication, plagiarism, or combination thereof, and whether it was committed intentionally, knowingly, or recklessly; (3) 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 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; (4) identify the specifc external support; (5) identify whether any publications need correction or retraction; (6) identify the person(s) responsible for the misconduct; and (7) list any current support or known applications or proposals for support that the respondent has pending with all federal agencies or other entities. [21]

- The final report must include any comments made by the respondent or complainant on the draft report. [22]

2.06B Comments on the Draft Report and Access to Evidence

1. Respondent

   The RIO must provide the respondent with 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 30 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. [23]

2. Complainant

   The University may provide, via the RIO, the complainant with 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 complainant will be allowed 30 calendar days from the date he/she received the draft report, if provided, to submit comments to the RIO. The complainant's comments must be included and considered in the final report. [23]

3. 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. Prior to release of the draft report by the RIO, the respondent and complainant will be required to sign a confidentiality statement prepared by University counsel.

2.06C Decision by the Deciding Official (Provost)

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's comments are included and considered. Comments by the complainant will be reviewed for consideration of inclusion. The RIO will transmit the final investigation report, including recommendations, to the VPRSP and Deciding Official.

The DO will make the final determination in writing: (1) whether the University accepts the investigation report, its findings, and the recommended University actions; and (2) the appropriate University actions in response to the accepted findings and conclusions of research misconduct. If this determination varies from the findings of the investigation committee, the DO will, as part of the written determination, explain in detail the basis for rendering a decision different from the findings and conclusions 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 DO will notify both the respondent and the complainant in writing. In addition, after the VPRSP informs ORI or the appropriate cognizant agency, the Deciding Official, in consultation with the University's counsel and VPRSP, 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 VPRSP is responsible for ensuring compliance with all notification requirements to funding or sponsoring entitites. University counsel or other appropriate University officals will advise the DO on appropriate actions.

The DO's written report together with the investigation committee's report constitutes the final investigation report.

2.06D Transmittal of the Final Investigation Report to the Pertinent Federal Department or Agency

Unless an extension has been granted, the VPRSP must, within the 120-day period for completing the investigation and or any appeal, submit the following to ORI or the appropriate entities: (1) a copy of the final report with all attachments; (2) a statement of whether the University accepts the findings of the investigation report; (3) a statement of whether the University found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent. [24]

2.06E Maintaining Records for Review by ORI or Other Entities

The RIO must maintain and provide to ORI or other entitites upon request "records of research misconduct proceedings" as defined by 42 CFR §93.317. Unless custody has been transferred to HHS, or ORI or the appropriate cognizant oversight entity has advised in writing that the records no longer need to be retained, the 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 or proceeding of a cognizant entity involving the research misconduct allegation. [25] The RIO is also responsible for providing, via the VPRSP, any information, documentation, research records, evidence or clarification requested by ORI or appropriate entities to carry out its review of an allegation of research misconduct or of the University's handling of such an allegation. [26]

2.07 Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues have been pursued diligently. The VPRSP must notify ORI in advance if there are plans to close a case at the inquiry or investigation 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 or other entities, as prescribed in this policy and 42 CFR §93.315. [24]

2.08 University Administrative Actions

The DO, after consultation with the Office of Human Resources. the RO, CO and the VPRSP, will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated by the findings and supporting evidence. The administrative actions may include but are not limited to:

- 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 or other projects, letter of reprimand, special monitoring of future work, demotion, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;

- Restitution of funds to the sponsor as appropriate; assurance requirement to ensure compliance with applicable regulations, or terms of award, written warning, or

- Applying a combination of actions listed above, commensurate to offense(s) committed.

With respect to administrative actions or discipline imposed upon employees, the University shall comply with all relevant personnel policies and laws. With respect to administrative actions or discipline imposed upon students, the University shall comply with all relevant student policies and codes.

2.09 Other Considerations

2.09A Termination of University Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's University employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct inquiry or investigative proceedings or otherwise limit any of the University's responsibilities under 42 CRF Part 93.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the University 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 Provost, VPRSP, and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the the evidence.

2.09B Restoration of the Respondent's Reputation

If the University finds no misconduct and ORI or the cognizant federal office concurs, after consulting with the respondent, the Provost must undertake all reasonable and practical efforts to restore the respondent's reputation. [7] Depending on the particular circumstances and the views of the respondent, the Provost in consultation with theVPRSP will consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any University actions to restore the respondent's reputation should first be approved by the Provost.

2.09C Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the University or ORI or the appropriate entities determine that research misconduct occurred, the RIO, RO, Provost, and VPRSP will 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 any witnesses and committee members who cooperated in good faith with inquiries and investigations of such allegations. [27] The Provost will determine, after consulting with the RIO, RO,and the VPRSP, the complainant, witnesses, or committee members, respectively, what steps, if any are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The Provost is responsible for implementing these steps.

2.09D Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine from the evidence presented whether the complainant's allegations of research misconduct were made in good faith or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith, he/she, in consultation with the RO, VPRSP and the Office of Human Resources, will determine what, if any, administrative action should be taken against the persons who failed to act in good faith.

End Notes

1 42 CFR §93.212.
2 42 CFR §93.214
3 42 CFR §93.215.
4 42 CFR §93.219
5 42 CFR §93.103(d).
6 42 CFR §93.309(a).
7 42 CFR §93.304(k).
8 42 CFR §93.108.
9 42 CFR §93.304(h).
10 42 CFR §93.310(f).
11 42 CFR §93.307(g).
12 42 CFR §93.308(a).
13 42 CFR §93.309(a) and (b).
14 42 CFR §93.310(a).
15 42 CFR §93.310(b) and (c).
16 42 CFR §93.310(d).
17 42 CFR §93.310(e).
18 42 CFR §93.310(g).
19 42 CFR §93.310(h).
20 42 CFR §93.311.
21 42 CFR §93.313(f).
22 42 CFR §93.313(g).
23 42 CFR §93.312(a), 93.313(g). .
24 42 CFR §93.315.
25 42 CFR §93.317(b).
26 42 CFR §93.300(g), 93.403(b) and (d).
27 42 CFR§93.304(l).