

# CLARK ATLANTA UNIVERSITY

## Policy 11.1 Responding to Misconduct in Research

POLICY/PROCEDURE	Subject: Policy 11.1 Responding to Misconduct in Research

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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





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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 responsibilities 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;



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- 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;



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- Provide the inquiry and investigation committees with advisory services; and
  - Report to the Pertinent Federal Office as required by regulation and keep the Pertinent



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At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the CO, RIO, or the VPRSP 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



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During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities 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 assessments performed by the RIO are subject to the provisions of 42 CFR §93.103, and the RIO will



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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, except 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



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**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 assc[nirre.69(a)4(n)-12st9(is3)-27(a)4(4(sc)(a)4(1 90.089(sc)(a





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- 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





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### 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



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The RIO will notify the respondent of the proposed committee membership within 5 business days of composition of the proposed committee



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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



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### 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



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