

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

Research Misconduct Proceedings		SOP #: RSP.021.00
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1. Purpose

Burrell College encourages the pursuit of research and creative scholarly activities as part of its mission, strives to create an environment that supports all academic and scholarly endeavors, and promotes integrity in the conduct and dissemination of research. The College recognizes that incidents of misconduct in research and creative scholarship is rare, but also understands that procedures for fair and thorough investigation of allegations of research misconduct must be defined. The purpose of this document is to set forth the process whereby the College investigates and acts on matters involving allegations of misconduct in research and scholarly activity. The procedures shall conform with 42 CFR Part 93 reporting requirements when applicable.

2. Related Policy/Authority

Burrell College Policies and Procedures

[42 CFR Part 93](#) Public Health Service Policies on Research Misconduct

3. Faculty/Staff Responsibilities

- The Dean and Chief Academic Officer serves as the Deciding Official as defined in this SOP.
- The Assistant Dean for Research/Authorized Institutional Official serves as the Research Integrity Officer as defined in this SOP.

4. Definitions/Abbreviations

- **Allegation** means a disclosure of possible research misconduct through any means of communication. The disclosure may be a written or oral statement to any institutional official.
- **Charge Letter** means the written notice as well as any amendments to the notice, that are sent to the respondent stating the findings of research misconduct and any administrative actions that are resulting. For PHS or HHS supported research, this may include HHS administrative actions.
- **Complainant** means a person who in good-faith makes an allegation of research misconduct.
- **Contract** means an acquisition instrument awarded under the HHS Federal Acquisition Regulation (FAR), 48 CFR Chapter 1.
- **Creative Scholarship** means the development or creation of new work based on a creative vision, reinterpretation of existing work, case report, or any activity in which the definition of research is not met, so long as the activity is viewed as supporting intellectual endeavors of the College.
- **Debarment or Suspension** means the government wide exclusion, whether temporary or for a set term, of a person from eligibility for Federal grants, contracts, and cooperative agreements under HHS regulations 45 CFR 76 and 48 CFR Subparts 9.4 and 309.4.

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

- **Deciding Official** or **DO** means the person within the institution who receives the inquiry and investigation report from the Research Integrity Officer. The Deciding Official determines in writing whether the results of an Inquiry warrants further investigation and also whether that institution accepts the investigation report and its findings.
- **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.
- **Fabrication** means making up data or results and recording or reporting them.
- **Falsification** means manipulating research materials, equipment or process, or charging, or omitting data or results such that the research is not accurately represented in the research record
- **Funding Component** means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training.
- **Good Faith** 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. In other context, it means acting to the best of one's ability to perform a given task in the investigation in a reasonable manner.
- **Hearing** means that part of the research misconduct proceeding from the time a respondent files a request for an administrative hearing to contest ORI findings of research misconduct and HHS administrative actions until the time the ALJ issues a recommended decision.
- **Improprieties of Authorship** means the improper assignment of credit, such as excluding others, misrepresentation of the same material as original in more than one publication, inclusion of individuals as authors who have not made a definite contribution to the work published or submission of multi-authored publications without the knowledge or approval of all authors.
- **Inquiry** means preliminary information gathering and preliminary fact-finding that is relevant to the allegation of research misconduct. The results of the inquiry may or may not result in an investigation.
- **Institution** or **College** or **Burrell College** means any individual or person that represents the Burrell College of Osteopathic Medicine, Las Cruces, NM in an official capacity to discharge the duties of his/her job responsibilities.
- **Institutional Member** or **College Member** or **Member** means any person who is employed by, is an agent of, or is affiliated by contract or agreement with the Burrell College of Osteopathic Medicine. Institutional members may include, but are not limited to faculty, administrators, staff, researchers, research coordinators, technicians, postdoctoral trainees and fellows, medical residents, students, volunteers, contractors, subcontractors, subawardees, and their employees.
- **Investigation** means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.
- **Misappropriation of Intellectual Property** means the unauthorized possession or use of proprietary information, regardless of how it was obtained.
- **Notice** means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number, or email address of the addressee.

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

- **Office of Research Integrity or ORI** means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities
- **Person** means any individual, corporation, partnership, institution, association, unit of government, or legal entity, however organized.
- **Plagiarism** means the appropriation of another person's ideas, processes, results or words without giving appropriate credit.
- **PHS Support** means a grant, contract, or award to the Burrell College for the performance of a specific activity.
- **Preponderance of Evidence** means proof by information that compare with that opposing it leads to the conclusion that the fact at issue is more probably true than not true.
- **Research** means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (i.e., basic research) or specific knowledge (i.e. applied research) relating broadly to public health by establishing, discovering, developing, elucidating, or confirming information about or the underlying mechanism relating to biological causes, functions or effects, diseases, treatments, or related matters to be studied.
- **Research Misconduct Proceeding** 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 by HHS or an institution official by a respondent in the course of the research misconduct proceeding.
- **Respondent** means the person against who an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.
- **Research and Creative Scholarship Misconduct or Research Misconduct or Creative Scholarship Misconduct or Misconduct** means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- **Research Integrity Officer or RIO** means the person within the institution who has lead responsibility for ensuring that the institution: (1) takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities relate to that research or research training, discourages research misconduct and deals promptly with allegations or evidence of possible research misconduct; (2) has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to the Office of Research Integrity as required by 42 CFR Part 93; (3) complies with its written policies and procedures and the requirements of 42 CFR 93; (4) informs its institutional members who are subject to 42 CFR 93 about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures; (5) takes appropriate interim actions during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.
- **Retaliation** means an adverse action taken against a complainant, witness or committee member by an institution or one of its members in response to: (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.
- **Support Person** means a person who is allowed to accompany a complainant or respondent to the interview or hearing. A support person must not be a witness or potential witness in the

inquiry. A support person shall not respond directly to the inquiry panel or investigation committee questions and the inquiry panel or investigation committee shall not direct questions to the support person. The support person may serve as Counsel to the complainant or respondent so long as such Counsel does not disrupt the proceeding.

- **Witness** means a person who has special knowledge relevant to the allegation. A witness may be called during the investigation. A witness must not be a support person.

5. Procedural Steps

5.1 Guiding Principles

The steps described herein define the procedures that the Burrell College of Osteopathic Medicine shall use to investigate allegations of Research and Creative Scholarship Misconduct. The College treats allegations of Misconduct seriously and recognizes that thorough investigation into Misconduct allegations is essential in order to protect the integrity of the Institution and to preserve public confidence in the enterprise of Research and Creative Scholarship. The College also recognizes that findings of Misconduct must be based on evidence that supports the following three criteria: (1) The alleged Misconduct must represent a significant departure from the accepted practices of the relevant research community; (2) The Misconduct must have been committed intentionally, knowingly, or recklessly; and (3) The outcome of the investigation into the allegations shall be supported by a preponderance of evidence. The College also recognizes that 42 CFR Part 93 may be applicable when investigating certain allegations and will follow federal regulations as appropriate.

5.1.1 Confidentiality

To the extent allowed by law, Burrell College shall maintain the identity of respondents and complainants securely and confidentially, and shall not disclose any identifying information except to: 1) those who need to know in order to carry out a thorough, competent, objective, and fair Misconduct proceeding; and 2) the Office of Research Integrity (ORI), when applicable and in accordance with 42 CFR Part 93, as ORI conducts its review of the Burrell misconduct proceeding and any subsequent proceedings.

5.1.2 Institutional Responsibilities

In conducting investigation in Misconduct, the College shall: (1) preserve all records to the extent possible throughout the investigation; (2) avoid conflicts of interest in the investigation proceedings; (3) resolve matters involving allegations as expeditiously as possible; (4) document its actions at all stages of the proceedings; (5) treat all parties fairly and guard the reputations of the complainants and respondents by providing confidentiality to the extent possible under College policies and procedures; (6) comply with 42 CFR Part 93 if the investigation involves PHS support; (7) conclude the investigation to the extent possible, even if the respondent leaves or has left the Institution before the matter is resolved; and (8) pursue the allegations within the scope of Misconduct without regard to whether related civil or criminal proceedings have been initiated.

5.2 Reporting Allegations of Misconduct

Allegations of Research Misconduct may be made by a complainant, or by a faculty, staff, member, or administrator who has been informed of an allegation by a complainant. Allegations made by the complainant may be oral or written. Allegations being conveyed on behalf of a complainant by a faculty, staff, member, or administrator shall be in writing. Allegations may also be reported anonymously through the College grievance and whistleblower policies (B2040 and B2041). All allegations of misconduct must be disclosed to the Research Integrity Officer (RIO) and include the following: (1) name of complainant unless the complainant is submitting information anonymously; (2) name of person disclosing information on behalf of complainant; (3) name of respondent; and (4) essence of misconduct that the respondent is alleged to have committed. Allegations should be sufficiently credible and specific so that potential evidence of research misconduct may be identified. Allegations will be investigated in accordance with 42 CFR 93.102 if the alleged misconduct involves PHS sponsored activities.

Information included in the allegation should include the following:

- A description of what has been falsified, fabricated, or plagiarized.
- The nature of research records and research processes that were affected.
- A brief description of the manipulation of research records.
- Name(s) of the individual(s) responsible for possible falsification, fabrication, or plagiarism, if known.
- Any additional relevant information.

All allegations of Misconduct received by the Office of Compliance will be routed the Research Integrity Officer (RIO) by the Office of Compliance. The RIO will notify the Office of Compliance of all allegations that were received in instances where the allegation did not inform the Office of Compliance. Details of the allegation will remain confidential between the two parties at this stage so that appropriate actions can be taken to protect evidentiary information. This includes allegations against faculty, administrators, staff, members, or students. In allegations solely involving students, the Research Integrity Officer in consultation with other College administrators will make a determination as to whether the complaint should be handled in accordance with the Student Handbook. In such instances, the RIO will forward the allegation to the Executive Director of Student Affairs for disposition.

In conducting investigation in Misconduct, the College shall: (1) preserve all records to the extent possible throughout the investigation; (2) avoid conflicts of interest in the investigation proceedings; (3) resolve matters involving allegations as expeditiously as possible; (4) document its actions at all stages of the proceedings; (5) treat all parties fairly and guard the reputations of the complainants and respondents by providing confidentiality to the extent possible under College policies and procedures; (6) comply with 42 CFR Part 93 if the investigation involves PHS support; (7) conclude the investigation to the extent possible, even if the respondent leaves or has left the Institution before the matter is resolved; and (8) pursue the allegations within the scope of Misconduct without regard to whether related civil or criminal proceedings have been initiated.

5.3 Responding to Allegations of Misconduct

Promptly after receiving an allegation of Misconduct through any means of communication, the College RIO shall assess the allegation and determine if: 1) the allegation meets the definition of research misconduct, and 2) that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. If the RIO determines that the allegation is applicable to the definition of research misconduct, then the RIO shall initiate an Inquiry Proceeding. Should the RIO determine that the allegation does not meet the definition of Misconduct, the RIO may choose to forward the allegation, in consultation with the Office of Compliance, to an appropriate College office for resolution (e.g, student affairs, human resources, finance, etc.)

5.3.1 The Inquiry Proceeding

If it is determined that the allegation meets the definition of research misconduct and is sufficiently credible and specific, the RIO shall appoint a three member inquiry panel with appropriate expertise to review the evidence supporting the allegation. An inquiry is an initial review of the evidence to determine if the criteria for conducting an investigation have been met and if an investigation is warranted. The inquiry stage includes: 1) appointment of an inquiry panel by the RIO, 2) review of the allegation by the inquiry panel, 3) preparation of an inquiry report by the inquiry panel, and 4) giving the respondent a reasonable opportunity to comment on the report. The inquiry panel report shall be submitted to the RIO. The initial inquiry, including comment from the respondent, should be completed within sixty (60) calendar days from the initiation of the inquiry into the allegation of Misconduct. If the inquiry panel takes longer than sixty (60) calendar days to complete its work, the College shall include documentation of the reasons for the delay in the inquiry record.

The RIO will review the findings of the report and forward the report to the Deciding Official along with any additional information that the RIO wishes to disclose. The Deciding Official shall review the allegation of misconduct along with the findings of the inquiry panel and make a determination as to whether a Misconduct Investigation is warranted. The Deciding Official notifies the RIO of the decision and basis for the decision.

The RIO notifies the respondent with a charge letter, and informs the inquiry panel and the complainant of the outcome of the inquiry panel determination and Deciding Official decision. The RIO will also inform the Office of Research Integrity of the DO decision as appropriate. If the decision was to not investigate the allegation further then the RIO will inform ORI of the basis for the DO decision. If the decision is to move forward with an investigation, the RIO will inform ORI on or before the commencement of the investigation.

5.4 Research Misconduct Investigation

Upon receipt of a written notice from the DO that a misconduct investigation is warranted, the RIO shall follow the steps outlined in Section 5.5 that include: (1) notifying the respondent in the form of a charge letter that the institution will be conducting an investigation into the alleged misconduct, (2) appointment of a five member investigating committee, and (3) convening an initial meeting of the committee to review the charge and answer any questions that the committee may have.

5.4.1 Investigation Committee Responsibilities

The Investigation Committee will elect a chair who will lead the committee, develop a plan for investigation and conduct an investigation in a manner that conforms with the guiding principles of: (1) following a process that avoids damage to scholarship and scholarly records; (2) avoiding conflict of interest; (3) properly documenting each step of the investigation; (4) completing the investigation as expeditiously as possible; (5) pursuing the allegations within the scope of the definition of Research Misconduct without regard as to whether separate but related civil or criminal proceedings have been initiated. The investigation should be completed in totality, inclusive of filing a final report with the RIO, and, if applicable, the RIO filing the report with any comments to the ORI within 120 calendar days of initiation of the investigation. Requests for extension of the 120 calendar day completion requirement to the ORI by the RIO must include a statement of reasons for the request. If the extension is granted by ORI, the RIO will file progress reports as required by ORI.

5.4.2 College Responsibilities

In conducting the investigation, the College shall ensure that: (1) 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 the allegations; (2) 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 are interviewed and that the interviews are documented by recording or transcript; (3) each interviewee has been given an opportunity to view the recording or transcript for correction and that the recording or transcript is included in the record of investigation; (4) the investigation pursues diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct and that the investigation has been continued to completion; and (5) otherwise complying with requirements for conducting an investigation an investigation in accordance with 42 CFR Section Part 93.

5.4.3 The Investigation Report

Upon completion of the investigation, the Committee in consultation with the RIO shall prepare a draft of the final committee investigation report. The RIO shall present the draft report to the respondent and complainant for comment.

The final investigation report shall: (1) describe the nature of the allegations of research misconduct; (2) describe and document sources of extramural support including the name of the sponsor or funding agency, any grant numbers, grant applications, contracts, and publications listing the sponsored research support; (3) describe the specific allegation of research misconduct considered in the investigation; (4) include the institutional policies and procedures under which the investigation was conducted and, if applicable, the information that was provided to ORI; (5) identify and summarize the research records and evidence reviewed, and any evidence taken into custody, but not reviewed; the report shall also describe why any relevant records and evidence that were taken into custody were not reviewed; (6) provide a finding as to whether research misconduct identified during the investigation did nor did not occur for each separate allegation of research misconduct identified during the investigation,

and if misconduct was found: (a) identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard; (b) summarize the facts and the analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent and any evidence that rebuts the respondent's explanations; (c) identify the specific extramural support, including PHS support as applicable; (d) identify any publications that need correction or retraction; (e) identify the person(s) responsible for the misconduct, and (f) list any current support or know applications or proposals for support that the respondent has pending with PHS, non-PHS federal agencies, and other extramural research sponsors; and (g) include and consider any comments made by the respondent and complainant on the draft investigation report.

The final report shall be submitted to the RIO for presentation to the Deciding Official. The RIO will review the findings of the investigation report and forward the report to the Deciding Official along with any additional information that the RIO wishes to disclose Deciding Official Responsibilities

5.4.4 Deciding Official Responsibilities

The Deciding Official shall review the investigation report and make a determination as to whether or not to accept the report, its findings, and the recommended institutional actions of the investigation report. Should the DO determine that further fact-finding or analysis is needed, the DO shall return the report to the RIO with written explanation of what is being requested and why. In such instances the RIO shall engage the Investigating Committee with the information provided by the DO. Should the DO review result in determination of acceptance of the report, its findings, and recommended actions in the investigation report, the DO will inform the RIO in writing including the basis for the decision. The RIO will communicate the findings of the DO to the Investigation Committee, the respondent, and the complainant. The decision of the Deciding Official on acceptance of the final investigation report, its findings, and recommended actions is final. The RIO shall communicate the decision to the respondent, the complainant, the investigation committee, and if applicable, the ORI. ORI has the right to investigate the allegation further. In such instances, the RIO will inform the DO and the College will cooperate with the ORI request.

5.5 Roles and Responsibilities of the Research Integrity Officer

The Assistant Dean for Research/Authorized Institutional Official serves as the Research Integrity Officer (RIO) for the College. The RIO has lead responsibility for ensuring that the College: (1) takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research and creative scholarship in the College including research training; (2) discourages Misconduct and deals promptly with allegations or evidence of possible Misconduct; (3) has written policies and procedures for responding to and reporting allegations of Misconduct, including PHS supported research; (4) informs the College research community about research misconduct policies and procedures and the College commitment to compliance with those policies and procedures; (5) takes appropriate interim action during a research misconduct proceeding to protect public health, College resources and in the case of PHS supported activities, federal funds and equipment, and the integrity of the PHS supported research process.

5.5.1 Responsibilities of the RIO in Misconduct Proceedings

The Research Integrity Officer has lead responsibility for ensuring that the Misconduct Proceedings are handled in accordance with College and, where appropriate, Federal requirements. The RIO does not serve on the Inquiry Panel or the Investigation Committee, but may observe the proceedings and shall be available throughout the proceedings in an advisory role to the inquiry panel and investigation committee. The RIO is responsible for ensuring that the inquiry panel and investigation committee receive reasonable institutional support to carry out the inquiry and investigation.

5.5.1.1 Responsibilities of RIO in Responding to an Allegation of Misconduct

The RIO shall:

- (1) be informed of all allegations of research misconduct by the complainant, faculty member or administrator who has become aware of the allegation;
- (2) make a determination regarding next steps in the proceeding as it relates to applicability of institutional policy and 42 CFR Part 93.
 - a. For Misconduct allegations that are subject to 42 CFR 93, the RIO will ensure that requirements of 42 CFR 93 are followed;
 - b. For Research Misconduct allegations that are not subject to 42 CFR 93, the RIO will ensure that the investigation is carried out in accordance with institutional policies and procedures.
- (3) Inform the Deciding Official in writing that an allegation of misconduct has been received within 5 business days of receiving an allegation;
- (4) Appoint a 3-person Inquiry Panel to conduct a preliminary review of the allegation and meet with the panel to charge the inquiry panel with their duties within 30 calendar days of receiving the allegation;
- (5) Inform the respondent in writing that an allegation of Misconduct has been made;
- (6) Promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the Misconduct proceeding, inventory the records and evidence, and sequester the records and evidence in a secure manner;
- (7) Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with the Misconduct proceedings, including but not limited to their providing information, research records, and evidence;
- (8) Take all reasonable and practical steps to provide confidentiality to those involved in the Misconduct proceeding as required by 42 CFR 93 when applicable, other applicable laws, and institutional policy;
- (9) Determine whether each person involved in handling an allegation of Misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action to manage the conflict, including recusal, to ensure that no person with such a conflict is involved in the Misconduct proceeding
- (10) Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of Misconduct;
- (11) In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members, and to counter potential or actual retaliation against them by respondents or other institutional members;

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

- (12) In cooperation with other institutional officials, make all reasonable and practical efforts if requested, and as appropriate, to protect or restore the positions and reputation of persons alleged to have engaged in Misconduct, but against who no finding of Misconduct is made;
- (13) Assist the Deciding Official in implementing his/her decision to take administrative action against any complainant, witness, or committee member determined by the DO not to have acted in good faith;
- (14) Maintain records of the Misconduct proceeding in a secure manner for seven (7) years after completion of the proceeding or in the case of proceedings when 42 CFR 93 is applicable, for seven (7) years after the completion of any ORI proceeding involving the allegation of Misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained;
- (15) Work to ensure that the administrative actions taken by the College and when applicable, ORI, are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of the administrative actions.

5.5.1.2 Role of the RIO in The Inquiry

Upon determining that the allegation meets the definition of Research Misconduct, the RIO shall initiate an inquiry process in accordance with the following steps:

- (1) At the time of, or before beginning the inquiry, the RIO shall make good faith effort to notify the respondent in writing of the inquiry. On or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, the RIO shall take all reasonable and practical steps to obtain custody of all research records and evidence, inventory the records, and sequester the records in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- (2) The RIO will appoint an Inquiry Panel of three (3) persons with expertise relevant to the nature of the allegation to investigate the allegation. In making the panel appointments, the RIO will make good faith effort to screen potential panel members for any conflict of interest that may bias a fair inquiry.
- (3) The RIO shall convene the first meeting of the inquiry panel and at that meeting: (a) brief the panel on the allegations; (b) issue a charge to the inquiry panel; (c) discuss appropriate procedures for conducting the inquiry, including the need for confidentiality, the need for developing an inquiry plan, and documentation of the work of the inquiry panel; and (d) discuss the provision of logistical assistance to the inquiry panel.
- (4) The RIO shall provide logistical assistance to the inquiry panel that may include but is not limited to expert advice, forensic analysis of evidence, and clerical support that is deemed necessary for the inquiry panel to carry out its charge
- (5) The RIO shall be available or present throughout the inquiry to advise the committee as needed and to consult with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in the College policies and procedures and if applicable, 42 CFR 93.307(d).
- (6) The RIO shall be responsible for determining whether circumstances clearly warrant a period of longer than 60 calendar days to complete the inquiry, including preparation of the final inquiry report and the decision of the Deciding Official on whether an

- investigation is warranted. If an extension is warranted, the RIO will document the reasons for the extension in the record of the research misconduct proceeding.
- (7) The RIO shall assist the Inquiry Panel in preparation of a draft inquiry report, sending the respondent and complainant a copy of the draft report for comment within a time period that permits the inquiry to be completed within the allocated time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent and complainant, and ensuring that all comments are attached to the final report.
 - (8) The RIO shall receive the final inquiry report from the inquiry panel and forward the report, together with any additional comments the RIO may wish to make to the Deciding Official who will determine in writing whether a Misconduct Investigation is warranted
 - (9) Within thirty (30) days of a DO determination that an investigation is warranted, the RIO shall notice all institutional officials who need to know of the decision. If the investigation involves PHS supported research, the RIO will provide ORI with the written finding and a copy of the inquiry report.
 - (10) The RIO shall notify the respondent and complainant whether the inquiry found that an investigation of Misconduct is warranted and include the institution's research misconduct policies and procedures and, if applicable, copies of or a reference to 42 CFR Part 93.
 - (11) The RIO shall provide to ORI, upon request, the institutional policies and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts of recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the investigations.
 - (12) If the DO decides that an investigation is not warranted, the RIO is responsible for securing and maintaining for seven (7) years after the determination of the inquiry was made sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted.

5.5.1.3 Role of the RIO in the Investigation

If the DO decides that an investigation is warranted, the RIO shall:

- (1) Initiate the investigation within 30 calendar days of the DO determination. For PHS Supported research, the RIO shall notify the ORI of the decision to begin the investigation and provide a copy of the inquiry report on or before the date of beginning the investigation.
- (2) Notice the respondent that the institution is beginning an investigation of Misconduct.
- (3) 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 investigation that were not previously obtained and sequestered during the inquiry.
- (4) In consultation with other institutional officials, as appropriate, appoint an Investigation Committee and Committee Chair as soon after the decision to initiate an investigation as is practical. The Investigation Committee shall be five (5) members. The Investigation Committee shall be different in composition from the Inquiry Panel and include some members who are knowledgeable of the type of research in which the allegation was levied (e.g., clinical research, basic research, etc.)
- (5) Prepare a charge for the Investigation Committee and convene the first meeting of the Investigation Committee that includes the following items on the agenda: (a) briefing the committee on their charge; (b) distributing the Inquiry Report; (c) reviewing the procedures and standards for conduct of the investigation, including the need for

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

- confidentiality and the development of a specific plan for the investigation; (d) providing the committee members with a copy of or reference to the institution's policies and procedures, and 42 CFR Part 93, if applicable; and (e) discussing logistical support.
- (6) Provide the Investigation Committee with needed logistical support including expert advice, forensic analysis of evidence, clerical support, arranging interviews with witnesses, and recording or transcribing those interviews
 - (7) Be available or present throughout the investigation to advise the committee as needed.
 - (8) Act on behalf of the institution to ensure that the investigation committee: (a) uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (b) takes reasonable steps to ensure an impartial and unbiased investigation to the maximal extent practical; (c) interviews each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording transcript in the record of the Research Misconduct Proceeding; (d) pursues diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continues the investigation to completion.
 - (9) Upon determination that the investigation cannot be completed within 120 calendar days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI, if applicable), submitting a request for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with ORI.
 - (10) Assist the investigation committee in preparation of a draft investigation report that meets the requirements of the institution and 42 CFR Part 93, if applicable, sending the respondent and complainant a copy of the draft report for comment within 30 days of their receipt of the draft report, and taking appropriate action to protect the confidentiality of the draft report, receive any comments from the respondent and complainant, and ensuring that the comments are included and considered in the final investigation report.
 - (11) Transmit the draft report to the institutional Counsel for a review of its legal sufficiency;
 - (12) Assist the investigation committee in finalizing the draft investigation report and receive the final report from the committee;
 - (13) Transmit the final investigation report to the DO and (a) if the DO determines that further fact-finding or analysis is needed, receive the report back from the DO for that purpose, or (b) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting the decision to ORI within the time period for completing the investigation, a copy of the final investigation report with all attachments, a statement of whether the institution accepts the findings of the report, a statement of whether the institution found Misconduct, and if so who committed it, and a description of any pending or completed administrative actions

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

against the respondent; or (c) if an appeal by the respondent could result in a modification or reversal of the DO's finding of research misconduct, ensuring that the appeal will be completed within 120 days of the filing or whether the institution is seeking an extension from ORI with an explanation of the need for the extension, and upon completion of the appeal transmitting to ORI a copy of the investigation report with all attachments including a statement of whether the institution accepts the findings of the appeal proceedings, a statement of whether the institution found misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent;

- (14) Notify both the respondent and complainant when a final decision is reached, and determine in consultation with other institutional officials whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be noticed of the outcome of the case;
- (15) Maintain and provide ORI, upon request, all relevant research records and records of the institution research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.

6. Reports/Charts/Forms/Attachments/Cross References

Attachments:

[42 CFR Part 93 - Public Health Service Policies On Research Misconduct](#)

7. Maintenance

Identify if the organizational unit/staff who developed the procedure; when it will be reviewed and updated.

This SOP will be reviewed annually or upon completion of a misconduct proceeding by the Assistant Dean for Research and Research Advisory Council. The SOP cannot be reviewed if a Misconduct Proceeding is ongoing.

8. Signature

Signature on File

Assistant Dean for Research

4.13.2021

Date

9. Distribution List

Internal/External

10. Revision History

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

Revision Date	Subsection #	Summary of Changes	New/Cancellation/Replacement Procedure? (if applicable)	Approval Date
1	[e.g., 3.1]			