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## RESEARCH MISCONDUCT POLICY

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### **POLICY STATEMENT**

This policy codifies the responsibilities of Lipscomb University (“Lipscomb”) under the PHS Policies on Research Misconduct, set forth in 42 CFR Part 93. This policy applies to Allegations of Research Misconduct involving:

- An Institutional Member; and
- (a) PHS support for biomedical or behavioral Research, Research training or activities related to that Research or Research training, such as the operation of tissue and data banks and the dissemination of Research information, (b) applications or proposals for PHS support for biomedical or behavioral Research, Research training or activities related to that Research or Research training, or (c) plagiarism of Research records produced in the course of PHS-supported Research, Research training or activities related to that Research or Research training. This includes any Research proposed, performed, reviewed, or reported, or any Research record generated from that Research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support. (See 42 § CFR 03.102.)

This policy does not apply to authorship or collaboration disputes and applies only to Allegations of Research Misconduct that occurred within six years of the date Lipscomb or HHS received any Allegation of Research Misconduct, subject to the exceptions set forth in 42 CFR § 93.105(b).

### **PURPOSE**

The purpose of this policy is to:

- Establish the responsibilities and administrative actions of Lipscomb in reporting and responding to Research Misconduct, including Allegations and Research Misconduct Proceedings, pursuant to the requirements of 42 CFR Part 93;
- Establish consistent procedures for reporting any and all occurrences of Research Misconduct to HHS, PHS, and the Office of Research Integrity;
- Define Research Misconduct at Lipscomb; and
- Protect the health and safety of the public and promote the integrity of Research and the Research process (including PHS Research).

### **APPLICABILITY**

This policy requires all Institutional Members to report observed, suspected, or apparent Research Misconduct to Lipscomb’s Research Integrity Officer, whose contact information shall be made available to the public and Lipscomb community on the website of Lipscomb’s Office of Research and Grants.

### **DEFINITIONS**

Capitalized terms that are used but not otherwise defined in this policy have the following meanings:

*Allegation*, as defined in 42 CFR § 93.201, means a disclosure of possible Research Misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to a Lipscomb or HHS official.

*CFR* means the Code of Federal Regulations.

*Complainant*, as defined in 42 CFR § 93.203, means a person who in Good Faith makes an Allegation of Research Misconduct.

*Deciding Official*, as defined in 42 CFR § 93.221, means the Lipscomb official who makes final determinations on Allegations of Research Misconduct and any institutional administrative actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in Lipscomb's Inquiry, Investigation, or assessment of Allegations. A Deciding Official's appointment of an individual to assess Allegations of Research Misconduct, or to serve on an Inquiry or Investigation committee, is not considered to be direct prior involvement.

*Evidence*, as defined in 42 CFR § 93.208, 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.

*Good Faith*, as defined in 42 CFR 93.210, means, as applied to a Complainant or witness, 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 made with knowing or reckless disregard for information that would negate the Allegation or testimony. Good Faith as applied to a committee member means cooperating with the Research Misconduct Proceeding by carrying out the duties assigned impartially for the purpose of helping Lipscomb meet its responsibilities under this policy and applicable law. A committee member does not act in Good Faith if his or her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the Research Misconduct Proceeding.

*HHS*, as defined in 42 CFR § 50.603, means the United States Department of Health and Human Services, and any components of such department to which the authority involved may be delegated.

*Inquiry*, as defined in 42 CFR § 93.212, means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR §§ 93.907-.309.

*Institutional Member*, as identified in 42 CFR § 93.214, means a person who is employed by, is an agent of, or is affiliated by contract or agreement with Lipscomb. 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.

*Investigation*, as defined in 42 CFR § 93.215, 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 or to a recommendation for a finding of Research Misconduct which may include a recommendation for other appropriate actions, including administrative actions.

*Office of Research Integrity*, as defined in 42 CFR § 93.217, means the office to which the HHS Secretary has delegated responsibility for addressing Research integrity and misconduct issues related to PHS supported activities.

*Preponderance of the Evidence*, as defined in 42 CFR § 93.219, 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.

*PHS*, as defined in 42 CFR § 50.603, means the Public Health Service of the HHS and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

*Records of Research Misconduct Proceedings*, as defined in 42 CFR § 93.317, includes:

- The records that Lipscomb secures for the proceeding pursuant to 42 CFR §§ 93.305, 93.307(b) and 93.310(d), except to the extent Lipscomb subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;
- The documentation of the determination of irrelevant or duplicate records;
- The Inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate as required by 42 CFR § 93.309(d); and
- The Investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted pursuant to 42 CFR § 93.310(g).

*Research*, as defined in 42 CFR § 93.222, means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

*Research Integrity Officer* means the Lipscomb official appointed by the Associate Provost for Research and Graduate Studies/Chief Research Officer who is primarily responsible for:

- assessing Allegations of Research Misconduct to determine if they fall within the definition of Research Misconduct, are covered by this policy and/or 42 CFR Part 93, and warrant an Inquiry on the basis that the Allegation is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified;
- overseeing Inquiries and Investigations; and
- the other responsibilities described in this policy.

The same individual cannot serve as the Deciding Official and the Research Integrity Officer.

*Research Misconduct*, as defined in 42 CFR § 93.103, means fabrication, falsification, or plagiarism in proposing, performing, or reviewing Research, or in reporting Research results. For purposes of this definition:

- Fabrication is making up data or results and recording or reporting them;
- 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; and

- Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

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

*Research Misconduct Proceeding*, as defined in 42 CFR § 93.223, means any actions related to alleged Research Misconduct taken under this policy and/or 42 CFR Part 93, including but not limited to, Allegation assessments, Inquiries, Investigations, Office of Research Integrity oversight reviews, and hearings.

*Respondent*, as defined in 42 CFR § 93.225, means the person against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct Proceeding.

*Retaliation*, as defined in 42 CFR § 93.226, means an adverse action taken against a Complainant, witness, or committee member by Lipscomb or an Institutional Member in response to:

- A Good Faith Allegation of Research Misconduct; or
- Good Faith cooperation with a Research Misconduct Proceeding.

*U.S.C.* means the United States Code.

## **PROCEDURES**

### GENERAL POLICIES AND PRINCIPLES

*Responsibility to Report Research Misconduct.* All Institutional Members will report observed, suspected, or apparent Research Misconduct to the Research Integrity Officer or to the Associate Provost of Research and Graduate Studies/Chief Research Officer, who will then refer the matter to the Research Integrity Officer. If an individual is unsure whether a suspected incident falls within the definition of Research Misconduct, he or she may meet with or contact either individual, whose contact information is available on the website of Lipscomb’s Office of Research and Grants, to discuss the suspected Research Misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of Research Misconduct, the Research Integrity Officer will refer the individual or Allegation to other offices or officials with responsibility for resolving the problem, if applicable. At any time, an Institutional Member may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer or the Associate Provost of Research and Graduate Studies/Chief Research Officer and will be counseled about appropriate procedures for reporting Allegations.

*Cooperation with Research Misconduct Proceedings.* Institutional Members will cooperate with the Research Integrity Officer and other Lipscomb officials in the review of Allegations and the conduct of Inquiries and Investigations. Institutional Members, including Respondents, have an obligation to provide Evidence relevant to Research Misconduct Allegations to the Research Integrity Officer or other Lipscomb officials.

*Confidentiality.* The Research Integrity Officer 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 as allowed by law; provided, however, that Lipscomb must disclose the identity of Respondents and Complainants to the Office of Research Integrity pursuant to an

Office of Research Integrity review of Research Misconduct Proceedings pursuant to 42 CFR § 93.403; and

- Except as otherwise prescribed by law, limit the disclosure of any records or Evidence from which Research subjects and reporting witnesses might be identified to those who need to know in order to carry out a Research Misconduct Proceeding.

*Protecting Complainants, Witnesses, and Committee Members.* Institutional Members may not Retaliate in any way against Complainants, witnesses, or committee members. Institutional Members should immediately report any alleged or apparent Retaliation against Complainants, witnesses or committee members to the Research Integrity Officer, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual Retaliation and protect and restore the position and reputation of the person against whom the Retaliation is directed.

*Protecting the Respondent.* As requested and as appropriate, the Research Integrity Officer and other Lipscomb 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. (See 42 CFR § 93.304(k).)

During the Research Misconduct Proceeding, the Research Integrity Officer is responsible for ensuring that Respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and this policy. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice, but such counsel and advisers may not be present at or accompany Respondents to interviews or meetings.

*Interim Administrative Actions and Notifying the Office of Research Integrity of Special Circumstances.* Throughout the Research Misconduct Proceeding, the Research Integrity Officer will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS-supported Research process. In the event of such a threat, the Research Integrity Officer will, in consultation with other Lipscomb officials and the Office of Research Integrity, take appropriate interim action to protect against any such threat.<sup>4</sup> (See 42 CFR § 93.304(h).) Interim action might include additional monitoring of the Research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of Research data and results, or delaying publication. The Research Integrity Officer shall, at any time during a Research Misconduct Proceeding, notify the Office of Research Integrity immediately if he or she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the Research Misconduct Proceeding;
- The Research Misconduct Proceeding may be made public prematurely and HHS action may be necessary to safeguard Evidence and protect the rights of those involved; or
- The Research community or public should be informed. (See 42 CFR § 93.318.)

## CONDUCTING THE ASSESSMENT AND INQUIRY

*Assessment of Allegations.* Upon receiving an Allegation of Research Misconduct, the Research Integrity Officer will promptly assess the Allegation to determine if it is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified, if it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the Allegation falls within the definition of Research Misconduct in this policy. (See 42 CFR § 93.307(a).) An Inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within a week (subject to extenuating circumstances). In conducting the assessment, the Research Integrity Officer need not interview the Complainant, Respondent, or other witnesses, or gather data beyond any that may have been submitted with the Allegation, except as necessary to determine whether the Allegation is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified. The Research Integrity Officer 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 set forth in the subsection below entitled “Notice to Respondent; Sequestration of Research Records.”

*Initiation and Purpose of the Inquiry.* If the Research Integrity Officer determines that the criteria for an Inquiry are met, he or she will promptly initiate the Inquiry process. The purpose of the Inquiry is to conduct an initial review of the available Evidence to determine whether to conduct an Investigation. An Inquiry does not require a full review of all the Evidence related to the Allegation. (See 42 CFR § 93.307(c).)

*Notice to Respondent; Sequestration of Research Records.* At the time of or before beginning an Inquiry, the Research Integrity Officer must make a Good Faith effort to notify the Respondent in writing, if the Respondent is known. If the Inquiry subsequently identifies additional Respondents, they must be notified in writing. On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is earlier, the Research Integrity Officer must take all reasonable and practical steps to obtain custody of all the Research records and Evidence needed to conduct the Research Misconduct Proceeding, inventory the records and Evidence and sequester them in a secure manner, except that where the Research records or Evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or Evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. (See 42 CFR §§ 93.305, 93.307(b).) The Research Integrity Officer may consult with the Office of Research Integrity for advice and assistance in this regard.

*Appointment of the Inquiry Committee.* The Research Integrity Officer, in consultation with the Chief Research Officer and other appropriate Lipscomb officials, will appoint an Inquiry committee and committee chair as soon after the initiation of the Inquiry as is practical. The Inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Inquiry and should include 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. (See 42 CFR § 93.304(b).) The Research Integrity Officer will notify the Respondent of the identity of the appointed Inquiry committee members and committee chair and provide the Respondent with ten (10) calendar days to provide a written objection to any member of the Inquiry committee based upon a personal, professional, or financial conflict of interest. In the event of any proper objection by the Respondent, the Research Integrity Officer (in consultation with the Chief Research Officer) will make the final determination

as to whether any conflict of interest exists. If the Research Integrity Officer determines that any member of the Inquiry committee has a conflict of interest, the Research Integrity Officer will remove such individual from the Inquiry committee and, in consultation with the Chief Research Officer and other appropriate Lipscomb officials, appoint a new member. The Research Integrity Officer will notify the Respondent of the identity of such appointed new member of the Inquiry committee and provide the Respondent with an additional ten (10) calendar days to provide a written objection to any member of the Inquiry committee.

Charge to the Inquiry Committee and First Meeting. The Research Integrity Officer will prepare a charge for the Inquiry committee that:

- Sets forth the time for completion of the Inquiry;
- Describes the Allegations and any related issues identified during the Allegation assessment;
- States that the purpose of the Inquiry is to conduct an initial review of the Evidence, including the testimony of the Respondent, Complainant and key witnesses, to determine whether an Investigation is warranted, not to determine whether Research Misconduct definitely occurred or who was responsible;
- States that an Investigation is warranted if the committee determines:
  - There is a reasonable basis for concluding that the Allegation falls within the definition of Research Misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and,
  - The Allegation may have substance, based on the committee's review during the Inquiry.
- Informs 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).

At the Inquiry committee's first meeting, the Research Integrity Officer will review the charge with the committee, discuss the Allegations, any related issues, and the appropriate procedures for conducting the Inquiry, assist the committee with organizing plans for the Inquiry, and answer any questions raised by the committee. The Research Integrity Officer will be present or available throughout the Inquiry to advise the committee as needed.

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, including the testimony obtained during the Inquiry. After consultation with the Research Integrity Officer, the committee members will decide whether an Investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d). The scope of the Inquiry is not required to, and does not normally include, deciding whether Research Misconduct definitely occurred, determining definitely who committed the Research Misconduct, or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of Research Misconduct is made by the Respondent, misconduct may be determined at the Inquiry stage if all relevant issues are resolved. In that case, Lipscomb shall promptly consult with the Office of Research Integrity to determine the next steps that should be taken.

Time for Completion. The Inquiry, including preparation of the final Inquiry report and the decision of the Deciding Official on whether an Investigation is warranted, must be completed within 60 calendar days of initiation of the Inquiry, unless the Research Integrity Officer determines that circumstances clearly warrant a longer period. If the Research Integrity Officer approves an extension, the Inquiry record must include documentation of the reasons for exceeding the 60-day period. (See 42 CFR § 93.307(g).) The Research Integrity Officer will notify the Respondent of any such extension.

## THE INQUIRY REPORT

*Elements of the Inquiry Report.* A written Inquiry report must be prepared by the Inquiry committee that includes the following information:

- The name and position of the Respondent;
- A description of the Allegations of Research Misconduct;
- The PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support;
- The basis for recommending or not recommending that the Allegations warrant an Investigation;
- Any comments on the draft report by the Respondent or Complainant. (See 42 CFR § 93.309(a).)

Lipscomb's General Counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the Research Integrity Officer and the Inquiry committee.

*Notification to the Respondent and Opportunity to Comment.* The Research Integrity Officer shall notify the Respondent whether the Inquiry found an Investigation to be warranted, include a copy of the draft Inquiry report for the Respondent's comment within ten (10) calendar days, and include a copy of or refer to 42 CFR Part 93 and this policy. (See 42 CFR § 93.308(a).)

The Research Integrity Officer may, in his or her discretion, notify the Complainant whether the Inquiry found an Investigation to be warranted and include a copy of the draft Inquiry report for the Complainant's comment within ten (10) calendar days. In such circumstances, the Research Integrity Officer may require that the Complainant sign a confidentiality agreement.

Any comments that are submitted by the Respondent or Complainant will be attached to the final Inquiry report. Based on the comments, the Inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the Research Integrity Officer.

*Determination of Whether Investigation is Warranted and Notification.* The Research Integrity Officer will transmit the final Inquiry report and any comments to the Deciding Official, who will determine in writing whether an Investigation is warranted. The Inquiry is completed when the Deciding Official makes this determination.

Within 30 calendar days of the Deciding Official's decision that an Investigation is warranted, the Research Integrity Officer will provide the Office of Research Integrity with the Deciding Official's written decision and a copy of the Inquiry report. The Research Integrity Officer will also notify those Lipscomb officials who need to know of the Deciding Official's decision. The Research Integrity Officer must provide the following information to the Office of Research Integrity upon request:

- The Lipscomb policies and procedures under which the Inquiry was conducted;
- The Research records and Evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
- The charges to be considered in the Investigation. (See 42 CFR §§ 93.309(a) and (b).)

*Documentation of Decision Not to Investigate.* If the Deciding Official decides that an Investigation is not warranted, the Research Integrity Officer shall maintain in a secure manner for seven (7) years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a



later assessment by the Office of Research Integrity of the reasons why an Investigation was not conducted. These documents must be provided to the Office of Research Integrity or other authorized HHS personnel upon request. (See 42 CFR § 93.309(c).)

## CONDUCTING THE INVESTIGATION

*Initiation and Purpose.* An Investigation must begin within 30 calendar days after the determination by the Deciding Official that an Investigation is warranted. (See 42 CFR § 93.310(a).) The purpose of the Investigation is to develop a factual record by exploring the Allegations in detail and examining the Evidence in depth, leading to recommended findings on whether Research Misconduct has been committed, by whom, and to what extent. The Investigation will also determine whether there are additional instances of possible Research Misconduct that would justify broadening the scope beyond the initial Allegations. Broadening the scope of an Investigation is particularly important where the alleged Research Misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects Research that forms the basis for public policy, clinical practice, or public health practice. Pursuant to 42 CFR § 93.313, the findings of the Investigation must be set forth in an Investigation report.

*Notifying the Office of Research Integrity and Respondent; Sequestration of Research Records.* The Research Integrity Officer must:

- Notify the Director of the Office of Research Integrity of the decision to begin the Investigation on or before the date the Investigation begins, and provide the Office of Research Integrity a copy of the Inquiry report; and
- Notify the Respondent in writing of the Allegations to be investigated within a reasonable amount of time after determining that an Investigation is warranted, but before the Investigation begins. The Research Integrity Officer 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. (See 42 CFR §§ 93.310(b) and (c).)

The Research Integrity Officer 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 for the Investigation may occur for any number of reasons, including, without limitation, Lipscomb'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. (See 42 CFR § 93.310(d).)

*Appointment of the Investigation Committee.* The Research Integrity Officer, in consultation with the Chief Research Officer, will appoint an Investigation committee and committee chair as soon as practical after the beginning of the Investigation. The Investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Investigation and should include individuals with the appropriate scientific expertise to evaluate the Evidence and issues related to the Allegation, interview the Respondent and Complainant and conduct the Investigation. Individuals who previously served on the Inquiry committee may also be appointed to the Investigation committee. When necessary to secure the requisite expertise or to avoid conflicts of interest, the Research Integrity Officer may select committee members from outside Lipscomb or utilize consultants to evaluate specific Allegations.

The Research Integrity Officer will notify the Respondent of the identity of the appointed Investigation committee members and committee chair and provide the Respondent with ten (10) calendar days to provide a written objection to any member based upon a personal, professional, or financial conflict of interest. In the event of any proper objection by the Respondent, the Research Integrity Officer (in consultation with the Chief Research Officer) will make the final determination as to whether any conflict of interest exists. If the Research Integrity Officer determines that any member of the Investigation committee has a conflict of interest, the Research Integrity Officer will remove such individual from the Investigation committee and, in consultation with the Chief Research Officer, appoint a new member. The Research Integrity Officer will notify the Respondent of the identity of such appointed new member of the Investigation committee and provide the Respondent with an additional ten (10) calendar days to provide a written objection to any member of the Inquiry committee.

*Charge to the Investigation Committee and First Meeting.* The Research Integrity Officer will define the subject matter of the Investigation in a written charge to the Investigation 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 set forth in the subsection below entitled “Investigation Process”;
- Defines the Research Misconduct that allegedly occurred;
- 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 if the Respondent committed Research Misconduct it must find that a Preponderance of the Evidence establishes that:
  - Research Misconduct, as defined in this policy, occurred (Respondent has the burden of proving by a Preponderance of the Evidence any affirmative defenses raised, including honest error or a difference of opinion);
  - The Research Misconduct is a significant departure from accepted practices of the relevant Research community; and
  - The Respondent committed the Research Misconduct intentionally, knowingly, or recklessly; and
- Informs the committee that it must prepare or direct the preparation of a written Investigation report that meets the requirements of this policy and 42 CFR § 93.313.

The Research Integrity Officer will convene the first meeting of the Investigation committee to review the charge, the Inquiry report, and the prescribed procedures and standards for the conduct of the Investigation, including the necessity for confidentiality and for developing a specific Investigation plan. The Investigation committee will be provided with a copy of this policy and 42 CFR Part 93. The Research Integrity Officer will be present or available throughout the Investigation to advise the committee as needed.

*Investigation Process.* The Investigation committee and the Research Integrity Officer 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; (See 42 CFR § 93.310(e).)
- Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical; (See 42 CFR § 93.310(f).)

- 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; (See 42 CFR § 93.310(g).) 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. (See 42 CFR § 93.310(h).)

*Time for Completion.* The Investigation is to be completed within 120 days of beginning it, including conducting the Investigation, preparing the report of findings, providing the draft report for comment and sending the final report to the Office of Research Integrity. However, if the Research Integrity Officer determines that the Investigation will not be completed within this 120-day period, he or she will submit to the Office of Research Integrity a written request for an extension, setting forth the reasons for the delay. The Research Integrity Officer will ensure that periodic progress reports are filed with the Office of Research Integrity, if the Office of Research Integrity grants the request for an extension and directs the filing of such reports. (See 42 CFR § 93.311.)

## THE INVESTIGATION REPORT

*Elements of the Investigation Report.* The Investigation committee and the Research Integrity Officer 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 PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
- Describes the specific Allegations of Research Misconduct considered in the Investigation;
- Includes the Lipscomb policies and procedures under which the Investigation was conducted, unless those policies and procedures were previously provided to the Office of Research Integrity;
- 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. (See 42 CFR § 93.313.) Each statement of findings must:
  - Identify whether the Research Misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;
  - 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;
  - Identify the specific PHS support;
  - Identify whether any publications need correction or retraction;
  - Identify the person(s) responsible for the misconduct; and
  - List any current support or known applications or proposals for support that the Respondent has pending with non-PHS federal agencies. (See 42 CFR § 93.313(f).)

*Comments on the Draft Report and Access to Evidence.* The Research Integrity Officer must give the Respondent a copy of the draft Investigation report for comment and, concurrently, a copy of, or

supervised access to, the Evidence on which the report is based. The Respondent will be allowed 30 days from the date he or she received the draft report to submit comments to the Research Integrity Officer. The Respondent's comments must be included and considered in the final report. (See 42 CFR §§ 93.312(a), 93.313(g).)

The Research Integrity Officer may, in his or her discretion, provide the Complainant a copy of the draft Investigation report, or relevant portions of it, for comment. In such circumstances, the Complainant's comments must be submitted within 30 days of the date on which he or she received the draft report and the comments shall be included and considered in the final report. (See 42 CFR §§ 93.312(b) and 93.313(g).)

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

*Decision by Deciding Official.* The Research Integrity Officer will assist the Investigation committee in finalizing the draft Investigation report, including ensuring that the Respondent's and Complainant's comments are included and considered, and transmit the final Investigation report to the Deciding Official, who will determine in writing:

- Whether Lipscomb accepts the Investigation report, its findings, and the recommended institutional actions; and
- The appropriate institutional actions in response to any accepted findings of Research Misconduct.

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

When a final decision on the Investigation has been reached, the Research Integrity Officer will normally notify both the Respondent and the Complainant in writing. After informing the Office of Research Integrity, the Deciding Official 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 Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

*Notice to the Office of Research Integrity of Institutional Findings and Actions.* Unless an extension for the Investigation has been granted, the Research Integrity Officer must, within the 120-day period for completing the Investigation, submit the following to the Office of Research Integrity:

- A copy of the final Investigation report with all attachments;
- A statement of whether Lipscomb accepts the findings of the Investigation report;
- A statement of whether Lipscomb found Research Misconduct and, if so, who committed the misconduct; and
- A description of any pending or completed administrative actions against the Respondent. (See 42 CFR § 93.315.)

Maintaining Records for Review by the Office of Research Integrity. The Research Integrity Officer must maintain and provide to the Office of Research Integrity upon request Records of Research Misconduct Proceedings. Unless custody has been transferred to HHS or the Office of Research Integrity has advised in writing that the records no longer need to be retained, Records of Research Misconduct Proceedings must be maintained in a secure manner for seven (7) years after the later of the completion of the proceedings or the completion of any PHS proceeding involving the Research Misconduct Allegation. (See 42 CFR § 93.317(b).) The Research Integrity Officer is also responsible for providing any information, documentation, Research records, Evidence or clarification requested by the Office of Research Integrity to carry out its review of an Allegation of Research Misconduct or of Lipscomb's handling of such an Allegation. (See 42 CFR §§ 93.300(g), 93.403(b) and (d).)

#### COMPLETION OF CASES; REPORTING PREMATURE CLOSURES TO THE OFFICE OF RESEARCH INTEGRITY

Generally, all Inquiries and Investigations will be carried through to completion and all significant issues will be pursued diligently. The Research Integrity Officer must notify the Office of Research Integrity 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:

- Closing of a case at the Inquiry stage on the basis that an Investigation is not warranted; or
- A finding of no misconduct at the Investigation stage, which must be reported to the Office of Research Integrity, as prescribed in this policy and 42 CFR § 93.315. (See 42 CFR § 93.316(a).)

#### INSTITUTIONAL ADMINISTRATIVE ACTIONS

If the Deciding Official determines that Research Misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The administrative actions may include, without limitation:

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

#### OTHER CONSIDERATIONS

Termination or Resignation Prior to Completing Inquiry or Investigation. The termination of the Respondent's employment with Lipscomb, by resignation or otherwise, before or after an Allegation of possible Research Misconduct has been reported, will not preclude or terminate the Research Misconduct Proceeding or otherwise limit any of Lipscomb's responsibilities under 42 CFR Part 93.

If the Respondent, without admitting to Research Misconduct, elects to resign his or her position after Lipscomb 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 Research Integrity Officer and any Inquiry or Investigation committee will use their best efforts to

reach a conclusion concerning the Allegations, noting in the report the Respondent's failure to cooperate and its effect on the Evidence.

Restoration of the Respondent's Reputation. Following a final finding of no Research Misconduct, including the Office of Research Integrity concurrence where required by 42 CFR Part 93, the Research Integrity Officer must, at the request of the Respondent, undertake all reasonable and practical efforts to restore the Respondent's reputation. (See 42 CFR § 93.304(k).) Depending on the particular circumstances and the views of the Respondent, the Research Integrity Officer should consider notifying those individuals aware of or involved in the Investigation of the final outcome, publicizing the final outcome in any forum in which the Allegation of Research Misconduct was previously publicized, and expunging all reference to the Research Misconduct Allegation from the Respondent's personnel file. Any institutional actions to restore the Respondent's reputation should first be approved by the Deciding Official.

Protection of the Complainant, Witnesses and Committee Members. During the Research Misconduct Proceeding and upon its completion, regardless of whether Lipscomb or the Office of Research Integrity determines that Research Misconduct occurred, the Research Integrity Officer must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual Retaliation against, any Complainant who made Allegations of Research Misconduct in Good Faith and of any witnesses and committee members who cooperated in Good Faith with the Research Misconduct Proceeding. (See 42 CFR § 93.304(l).) The Deciding Official will determine, after consulting with the Research Integrity Officer, and with the Complainant, witnesses, or committee members, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual Retaliation against them. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves.

Allegations Not Made in Good Faith. If relevant, the Deciding Official will determine whether the Complainant's Allegations of Research Misconduct were made in Good Faith, or whether a witness or committee member acted in Good Faith. If the Deciding Official determines that there was an absence of Good Faith, the Deciding Official will determine whether any administrative action should be taken against the person who failed to act in Good Faith.

## RESPONSIBILITIES

Complainant. The Complainant is responsible for making Allegations in Good Faith, maintaining confidentiality, and cooperating with the Inquiry and Investigation. As a matter of good practice, the Complainant should be interviewed at the Inquiry stage and given the transcript or recording of the interview for correction. The Complainant must be interviewed during an Investigation, and be given the transcript or recording of the interview for correction.<sup>31</sup>

The Research Integrity Officer may, in his or her discretion, provide to the Complainant for comment relevant portions of the draft Inquiry report (for response within ten (10) calendar days), and/or the draft Investigation report or relevant portions of it (for response within 30 days). The Investigation committee will consider any comments made by the Complainant on the draft Investigation report and include those comments in the final Investigation report.

Respondent. The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an Inquiry and Investigation. The Respondent is entitled to:

- A Good Faith effort from the Research Integrity Officer to notify the Respondent in writing at the time of or before beginning an Inquiry (See 42 CFR §§ 93.304(c), 93.307(b));

- An opportunity to comment on the Inquiry report and have his or her comments attached to the report (See 42 CFR §§ 93.304(e), 93.307(f));
- Be notified of the outcome of the Inquiry, and receive a copy of the Inquiry report that includes a copy of, or refers to 42 CFR Part 93 and this policy (See 42 CFR § 308(a));
- Be notified in writing of the Allegations to be investigated within a reasonable amount of time after the determination that an Investigation is warranted but before the Investigation begins, and be notified in writing of any new Allegations within a reasonable amount of time after the determination to pursue Allegations not addressed in the Inquiry or in the initial notice of Investigation (See 42 CFR § 310(c));
- Be interviewed during the Investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the Investigation (See 42 CFR § 310(g));
- Have interviewed during the Investigation any witness who has been reasonably identified by the Respondent as having information regarding any relevant aspects of the Investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of Investigation (See 42 CFR § 310(g)); and
- Receive a copy of the draft Investigation report and, concurrently, a copy of, or supervised access to, the Evidence on which the report is based, and provide any comments on the draft Investigation report within 30 days of the date on which the copy was received, and have any such comments considered and addressed by the Investigation committee before issuing the final report (See 42 CFR §§ 93.304(f), 93.312(a)).

The Respondent should be given the opportunity to admit that Research Misconduct occurred and that he or she committed the Research Misconduct. With the advice of the Research Integrity Officer and/or other Lipscomb officials, the Deciding Official may terminate Lipscomb's review of an Allegation that has been admitted, if Lipscomb's acceptance of the admission and any proposed settlement is approved by the Office of Research Integrity. (See 42 CFR § 93.316.)

*Deciding Official.* The Deciding Official will receive the Inquiry report and after consulting with the Research Integrity Officer and/or other Lipscomb officials, decide whether an Investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an Investigation is warranted must be made in writing by the Deciding Official and must be provided to the Office of Research Integrity, together with a copy of the Inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an Investigation is not warranted, the Deciding Official and the Research Integrity Officer will ensure that detailed documentation of the Inquiry is retained in a secure manner for at least seven (7) years after termination of the Inquiry, and upon request, provide them to the Office of Research Integrity or other authorized HHS personnel. (See 42 CFR § 93.309(c).)

The Deciding Official will receive the Investigation report and, after consulting with the Research Integrity Officer and/or other Lipscomb officials, decide the extent to which Lipscomb accepts the findings of the Investigation and, if Research Misconduct is found, decide what, if any, institutional administrative actions are appropriate. The Deciding Official shall ensure that the final Investigation report, the findings of the Deciding Official, and a description of any pending or completed administrative actions are provided to the Office of Research Integrity, as required by 42 CFR § 93.315.

*Research Integrity Officer.* The Associate Provost for Research and Graduate Studies/Chief Research Officer will appoint the Research Integrity Officer, who will have primary responsibility for implementation of Lipscomb's policies and procedures on Research Misconduct. These responsibilities include the following duties related to Research Misconduct Proceedings:

- Consult confidentially with persons uncertain about whether to submit an Allegation of Research Misconduct;
- Receive Allegations of Research Misconduct;
- Assess each Allegation of Research Misconduct in accordance with the section of this policy entitled "Conducting the Assessment and Inquiry – Assessment of Allegations" to determine whether it falls within the definition of Research Misconduct and warrants an Inquiry;
- As necessary, take interim action and notify the Office of Research Integrity of special circumstances, in accordance with the section of this policy entitled "General Policies and Principles – Interim Administrative Actions and Notifying the Office of Research Integrity of Special Circumstances";
- Sequester Research data and Evidence pertinent to the Allegation of Research Misconduct in accordance with the section of this policy entitled "Conducting the Assessment and Inquiry – Notice to Respondent; Sequestration of Research Records" and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the Research Misconduct Proceeding as required by 42 CFR § 93.108, other applicable law, and Lipscomb policy;
- Notify the Respondent and provide opportunities for him or her to review, comment, and respond to Allegations, Evidence, and committee reports in accordance with the section of this policy entitled "Rights and Responsibilities – Respondent";
- Inform Respondents, Complainants, and witnesses of the procedural steps in the Research Misconduct Proceeding;
- Appoint the chair and members of the Inquiry and Investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the Evidence;
- Determine whether each person involved in handling an Allegation of Research Misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the Research Misconduct Proceeding;
- In cooperation with other Lipscomb 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 Institutional Members;
- Keep the Deciding Official and others who need to know apprised of the progress of the review of the Allegation of Research Misconduct;
- Notify and make reports to the Office of Research Integrity as required by 42 CFR Part 93;
- Ensure that administrative actions taken by Lipscomb and the Office of Research Integrity are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
- Maintain Records of Research Misconduct Proceeding and make them available to the Office of Research Integrity in accordance with the section of this policy entitled "The Investigation Report – Maintaining Records for Review by the Office of Research Integrity."

In addition to the foregoing, the Research Integrity Officer has lead responsibility for ensuring that Lipscomb:



- Takes all reasonable and practical steps to foster a Research environment that promotes the responsible conduct of Research, Research training, and activities related to that Research or Research training, discourages Research Misconduct, and deals promptly with Allegations or Evidence of possible Research Misconduct;
- 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;
- Complies with its written policies and procedures and the requirements of 42 CFR Part 93;
- Informs its Institutional Members about its Research Misconduct policies and procedures and its commitment to compliance with those policies and procedures; and
- Takes appropriate interim action during a Research Misconduct Proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported Research process.

### **CONFLICT**

This policy is subject to applicable law. In the event of a conflict between the provisions of this policy and applicable law, including, without limitation, 42 CFR § 93, the provisions of applicable law shall control.

### **CONTACT**

For additional information or questions regarding this policy, contact the Office of Research and Grants by email at [researchandgrants@lipscomb.edu](mailto:researchandgrants@lipscomb.edu) or by phone at 615-966-5907.

### **EFFECTIVE DATE**

This policy was approved by the Office of the Provost on July 15, 2024.