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# Research Integrity Assurance- AD.0115



## PURPOSE

The purpose of this policy is to provide guidelines to ensure the integrity of the research process. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

## APPLICABILITY

This policy applies to Lakeland Regional Health Medical Center's **Workforce**.

## POLICY

Lakeland Regional Health (LRH) supports and protect the integrity of the research process, while at the same time encouraging the productivity and creativity of researchers. LRH shall inquire into, investigate, and promptly resolve any instance of alleged misconduct in research, and support those who in **good faith** bring **notice** of such misconduct to the attention of LRH. Research integrity assurance is accomplished according to the following procedure.

## PROCEDURE

I. **Introduction**

Scope

This policy and the associated procedures apply to all individuals at LRH engaged in research, including, but not limited to, that which is supported by or for which support is requested from the United States Public Health Service (**PHS**). The **PHS regulations** at 42 C.F.R. Part 93 apply to any research, research-training, or research-related grant or cooperative agreement with PHS. This policy applies to any person conducting research at LRH, including, but not limited

to, physicians, nurses, members of the Medical Staff, allied health professionals, physician extenders, scientists, trainees, technicians, and other staff members, students, fellows, guest researchers, or collaborators at LRH.

This policy and its associated procedures are followed when an **allegation** of possible **Research Misconduct** is received by an LRH official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interest of LRH and PHS. Any change from normal procedure must ensure fair treatment to the subject of the **inquiry** or **investigation**. Any significant variation is approved in advance by LRH's Executive Leadership Council (Compliance Committee).

II. **Rights and Responsibilities**

A. Research Integrity Officer

LRH's President/Chief Medical Officer appoints a **Research Integrity Officer** who has primary responsibility for implementation of the procedures set forth in this policy. The Research Integrity Officer is an LRH employee who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.



The Research Integrity Officer appoints an investigation committee and ensures that necessary and appropriate expertise is used to carry out a thorough evaluation of the relevant evidence in an investigation. The Research Integrity Officer ensures that confidentiality is maintained.

The Research Integrity Officer assists the investigation committee and all LRH personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The Research Integrity Officer reports to **ORI** as required by regulation and keeps ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential HHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

B. Whistleblower

A **Whistleblower** has an opportunity to testify before the investigation committee, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from **retaliation**. Also, if the Research Integrity Officer has determined that the Whistleblower may be able to provide pertinent information on any portion of the draft report, these portions are given to the Whistleblower for comment.

The Whistleblower is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

C. Respondent

The **Respondent** is provided written notice of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The Respondent also has the opportunity to be interviewed by and present evidence to the investigation committee, to review the inquiry and investigation reports, and to have the advice of his/her own legal counsel.

The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the Respondent is not found guilty of Research Misconduct, the Executive Leadership Council determines, after consulting with the Repondent, what steps, if any, are needed to restore the position or reputation of the Respondent. The Research Integrity Officer is responsible for implementing any steps the Executive Leadership Council approves.

D. Executive Leadership Council (Compliance Committee)

LRH's Executive Leadership Council (Compliance Committee) receives the inquiry and/or investigation report and any written comments made by the Respondent or the Whistleblower on the report. The Executive Leadership Council consults with the Research Integrity Officer or other appropriate officials and determines whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.



## III. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with LRH should report observed, suspected, or apparent Research Misconduct 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 contact the Research Integrity Officer to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of Research Misconduct, the Research Integrity Officer refers the individual or allegation to other offices or officials with responsibility for resolving the concern.

At any time, an employee or other person associated with LRH may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and is counseled about appropriate procedures for reporting allegations.

B. Protecting the Whistleblower

The Research Integrity Officer monitors the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer ensures

that these persons are not retaliated against in the terms and conditions of their employment or other status at LRH and reviews instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

LRH protects the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the Whistleblower requests anonymity, LRH makes an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The Whistleblower is advised that if the matter is referred to an investigation committee and the Whistleblower's testimony is required, anonymity may no longer be possible. LRH shall undertake reasonable efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

C. Protecting the Respondent

Inquiries and investigations are conducted in a manner that ensures fair treatment to the Respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety while carrying out the inquiry or investigation.

Individuals accused of Research Misconduct are encouraged to consult with their own legal counsel to seek advice.

D. Confidentiality

To the extent allowed by law, LRH 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 Research Misconduct proceeding; and
2. ORI as it conducts its review of the Research Misconduct proceeding and any subsequent proceedings.

To the extent allowed by law, any information obtained during the Research Misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the Research Misconduct proceeding.

E. Cooperation with Inquiries and Investigations

LRH employees shall cooperate with the Research Integrity Officer and other LRH officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other LRH officials on misconduct allegations.

F. Preliminary Assessment of Allegations

Promptly after receiving an allegation of Research Misconduct, defined as a disclosure of possible Research Misconduct through any means of communication, LRH shall assess the allegation to determine if:

1. it meets the definition of Research Misconduct in 42 CFR Section 93.103;
2. it involves either the PHS supported research, applications for PHS research support, or research records specified in 42 CFR Section 93.102; and
3. the allegation is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified.

## IV. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up, and meets all the criteria established in Section III - F, he or she immediately initiates the inquiry process. In initiating the inquiry, the Research Integrity Officer identifies clearly the original allegation and any related issues to be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the Respondent, Whistleblower, and key witnesses to determine whether there is sufficient evidence of possible Research Misconduct to warrant an investigation. The purpose of the inquiry is **not** to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.



B. Sequestration of the Research Records

After determining that an allegation falls within the definition of Research Misconduct and involves PHS funding, the Research Integrity Officer must ensure that all original **research records** and materials relevant to the allegation are immediately secured. The Research Integrity Officer may consult with ORI for advice and assistance in this regard.

C. Inquiry Process

The Research Integrity Officer or designee interviews the Whistleblower, the Respondent, and the key witnesses as well as examining relevant research records and materials. The Research Integrity Officer evaluates the evidence and testimony obtained during the inquiry and decides whether there is sufficient evidence of possible Research Misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses. LRH's legal counsel is available throughout the inquiry to advise the Research Integrity Officer as needed.

## V. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name of the Research Integrity Officer, the name and position of the Respondent(s), the allegations of Research Misconduct, the **PHS support,** a list of the research records reviewed, summaries of any relevant interviews, a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not, the Research Integrity Officer's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended, and any comments on the report by the Respondent or Whistleblower. LRH's legal counsel reviews the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent

The Research Integrity Officer provides the Respondent with a draft copy of the inquiry report for comment and rebuttal and provides the Whistleblower, if he or she is identifiable, with portions of the draft inquiry report that address the Whistleblower's role and opinions in the investigation.

1. Confidentiality

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments

Within fourteen (14) calendar days of their receipt of the draft report, the Respondent and Whistleblower provide their comments, if any, to the Research Integrity Officer. Any comments that the Respondent or Whistleblower submit of the draft report become part of the final inquiry report and record. Based on the comments, the Research Integrity Officer may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decision by Executive Leadership Council

The Research Integrity Officer transmits the final report and any comments to LRH's Executive Leadership Council, who makes the determination of whether findings from the inquiry provide sufficient evidence of possible Research Misconduct to justify conducting an investigation. The inquiry is completed when the Executive Leadership Council makes this determination, which is made within sixty (60) days of the initiation of the inquiry. Any extension of this period is based on good cause and recorded in the inquiry file.

2. Notification

The Research Integrity Officer notifies both the respondent and the whistleblower in writing of the Executive Leadership Council's decision of whether to proceed to an investigation and reminds them of their

obligation to cooperate in the event an investigation is opened. The Research Integrity Officer also notifies all appropriate LRH officials of the Executive Leadership Council's decision. Any notice to the respondent shall include a copy of the inquiry report, this policy, and 42 CFR Part 93.

D. Time Limit for Completing the Inquiry Report

The Research Integrity Officer completes the inquiry and report no more than sixty (60) calendar days following the initiation of the inquiry. If the inquiry takes longer than sixty (60) days to complete, the record of the inquiry includes documentation of the reasons for exceeding the sixty (60) day period. The respondent is notified of the extension.

## VI. **Conducting the Investigation**

A. Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegation, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation also determines whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation are set forth in an investigation report.

B. Sequestration of the Research Records

The Research Integrity Officer immediately sequesters any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the Respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including LRH'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.

C. Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other LRH officials as appropriate, appoints an investigation committee and the committee chair within ten (10) days of the notification to the Respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee consists of at least three (3) individuals who do not have real or apparent **conflicts of interest** in the case, are unbiased, and have the necessary expertise to evaluate the evidence and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside LRH.

LRH shall take all reasonable steps to ensure an impartial and unbiased Research Misconduct proceeding. The Research Integrity Officer shall select the investigation committee on the basis of scientific expertise that is pertinent to the matter and prior to selection shall screen them for any unresolved personal, professional, or financial conflicts of interest with the Respondent, Whistleblower, potential witnesses, or others involved in the matter. Any such conflict, which a reasonable person would consider to demonstrate potential bias, shall disqualify the individual from selection.

The Research Integrity Officer notifies the Respondent of the proposed committee membership within five (5) days. If the Respondent submits a written objection to any appointed member of the investigation committee or expert, the Research Integrity Officer determines whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Research Integrity Officer defines the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines the Research Misconduct, and identifies the name of the Respondent. The charge states that the committee is to evaluate the evidence and testimony of the Respondent, Whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, Research Misconduct occurred, and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee notifies the Research Integrity Officer, who determines whether it is necessary to notify the Respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The Research Integrity Officer, with the assistance of LRH's counsel, convenes 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 is provided a copy of these instructions and, where PHS funding is involved, the PHS regulation.

E. Investigation Process

The investigation committee is appointed and the process initiated within thirty (30)

days of the completion of the inquiry if findings from that inquiry provide a sufficient basis for conducting an investigation.

Within a reasonable time after determination is made that investigation is warranted, but not later than thirty (30) calendar days after that determination, the Research Integrity Officer shall notify the Respondent(s) in writing of the allegations to be investigated. Respondent(s) shall be given written notice of any new allegations within a reasonable time after determining to pursue allegations not addressed in the inquiry or in the initial notice of the investigation.

The investigation normally involves examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee interviews the Whistleblower(s), the Respondent(s), and other individuals, who might have information regarding aspects of the allegations. The Respondent shall be notified sufficiently in advance of the scheduling of his/her interview in the investigation so that the respondent may prepare for the interview and arrange for the attendance of the Respondent's own legal counsel, if the Respondent wishes. Summaries or transcripts of the interviews are prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.



In conducting all investigations, the investigation committee shall:

1. 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 the allegations;
2. 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 investigation;
3. Pursue 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 continue the investigation to completion; and
4. Otherwise comply with the requirements for conducting an investigation in 42 CFR Section 93.310.

## VII. **The Investigation Report**

### A. Elements of the Investigation Report

The investigation committee shall prepare the draft and final institutional investigation reports in writing and provide the draft report for comment as provided elsewhere in these policies and procedures and 42 CFR Section 93.312. The final

investigation report shall:

1. Describe the nature of the allegations of Research Misconduct;
2. Describe and document the PHS support, including for example any grant numbers, grant applications, contracts, and publications listing PHS support;
3. Describe the specific allegations of Research Misconduct considered in the investigation;
4. Include the institutional policies and procedures under which the investigation was conducted, if not already provided by the ORI;
5. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody, but not reviewed. The report should also describe any relevant records and evidence not taken into custody and explain why;
6. Provide a finding as to whether Research Misconduct did or did not occur for each separate allegation of Research Misconduct identified during the investigation, and if misconduct was found:
    i. identify it as **falsification**, **fabrication**, or **plagiarism** and whether it was intentional, knowing, or in reckless disregard;
    ii. 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;
    iii. identify the specific PHS support;
    iv. identify any publications that need correction or retraction;
    v. identify the person(s) responsible for the misconduct; and
    vi. list any current support or known applications or proposals for support that the respondent(s) has pending with non-PHS federal agencies.
7. Include and consider any comments made by the Respondent/ Complainant on the draft investigation report.

LRH shall maintain and provide to ORI upon request all relevant research records and records of the Research Misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

B. Comments on the Report

1. Respondent

    The Research Integrity Officer provides the Respondent with a copy of the investigation report for comment and rebuttal and concurrently, a copy of, or supervised access to, the evidence on which the report is based. The Respondent is notified that he/she is allowed thirty (30) days to review and

comment on the report. The Respondent's comments are attached to the final report. The findings of the final report take into account the Respondent's comments in addition to all the other evidence.

2. Whistleblower

   The Research Integrity Officer provides the Whistleblower, if he or she is identifiable, with those portions of the investigation report that address the Whistleblower's role and opinions in the investigation. The report is modified, as appropriate, based on the Whistleblower's comments.

3. LRH Legal Counsel

   The draft investigation report is transmitted to LRH's Legal Counsel for a review of its legal sufficiency. Comments are incorporated into the report as appropriate.

4. Confidentiality

   In distributing the draft report, or portions thereof, to the Respondent and Whistleblower, the Research Integrity Officer informs 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 request the recipient to sign a confidentiality statement or come to his or her office to review the report.

C. Institutional Review and Decision

Based on a preponderance of the evidence, the Executive Leadership Council makes the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the Executive Leadership Council explains in detail the basis for rendering a decision different from that of the investigation committee in LRH's letter transmitting the report to ORI. The Executive Leadership Council's explanation is consistent with the PHS definition of Research Misconduct, LRH's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Executive Leadership Council may also return the report to the investigation committee with a request for further fact-finding or analysis. The Executive Leadership Council determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the Research Integrity Officer notifies both the Respondent and the Whistleblower in writing. In addition, the Executive Leadership Council determines 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 are 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.

D. Transmittal of the Final Investigation Report to ORI

After comments have been received and the necessary changes have been made to the draft report, the investigation committee transmits the final report with attachments, including the Respondent and Whistleblower's comments, to ORI, through the Research Integrity Officer.

E. Time Limit for Completing the Investigation Report

An investigation is ordinarily completed within one hundred and twenty (120) days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Executive Leadership Council for approval, and submitting the report to the ORI.

## VIII. Requirements for Reporting to ORI

A. LRH's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins, and inquiry report and written determination is sent to ORI. Upon a request from ORI, LRH promptly sends them:

1. a copy of this policy;
2. the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
3. the charges for the investigation to consider.



ORI must also be notified of the final outcome of the investigation and must be provided:

1. with a copy of the investigation report, including all attachments;
2. a statement of whether the institution found Research Misconduct and, if so, who committed it;
3. a statement whether the institution accepts the findings in the investigation report; and
4. a description of any pending or completed administrative actions against the respondent.

Any significant variations from the provisions of the institutional policies and procedures are explained in any reports submitted to ORI.

B. If LRH plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer submits a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

C. If LRH determines that it is not able to complete the investigation in one hundred and twenty (120) days, the Research Integrity Officer submits to ORI a written request for

an extension. If the request is granted, the Research Integrity Officer files periodic progress reports as requested by the ORI.

D. When PHS funding or applications for funding are involved and an admission of Research Misconduct is made, the Research Integrity Officer contacts ORI for consultation and advice. Normally, the individual making the admission is asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, LRH cannot accept an admission of Research Misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

E. The Research Integrity Officer notifies ORI at any stage of the inquiry or investigation if:

    1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
    2. HHS resources or interests are threatened.
    3. Research activities should be suspended.
    4. There is a reasonable indication of violations of civil or criminal law.
    5. Federal action is required to protect the interests of those involved in the Research Misconduct proceeding.
    6. There is reasonable belief the Research Misconduct proceeding may be made public prematurely, so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
    7. There is reasonable belief the research community or public should be informed.

F. LRH officials shall cooperate fully and on a continuing basis with ORI during its oversight reviews of this institution and its Research Misconduct proceedings and during the process under which the Respondent may contest ORI findings or Research Misconduct and proposed HHS administrative actions. This includes providing, as necessary to develop a complete record of relevant evidence, all witnesses, research records, and other evidence under their control or custody, or in the possession of, or accessible to, all persons that are subject to their authority.

G. LRH reports to ORI any proposed settlements, admissions, or Research Misconduct, or institutional findings of misconduct that arise at any stage of a misconduct proceeding, including the allegation and inquiry stages.

## IX. Institutional Administrative Actions

LRH takes appropriate administrative actions against individuals when an allegation of Research/Scientific Misconduct has been substantiated.

If the Executive Leadership Council determines that the alleged Research Misconduct is substantiated by the findings, it decides on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The actions may include:

1. withdrawal or correction of all pending or published abstracts and papers emanating

from the research where Research Misconduct was found;

2. 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, revocation of medical staff privileges, or termination of employment;
3. restitution of funds as appropriate; or
4. LRH cooperates with and assists ORI and HHS, as needed, to carry out any administrative actions HHS may impose as a result of a final finding of Research Misconduct by HHS.

X. **Other Considerations**

A. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the Respondent's institutional employment or medical staff privileges, by resignation or otherwise, before or after an allegation of possible Reseach Misconduct has been reported, does not preclude or terminate the misconduct procedures.

If the Respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation proceeds. If the Respondent refuses to participate in the process after resignation, the committee uses its best efforts to reach a conclusion concerning the allegations, noting in its report the Respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

If LRH finds no misconduct and ORI concurs, after consulting with the Respondent, the Research Integrity Officer undertakes all reasonable, practical, and appropriate efforts to restore the Respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer considers notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of Research/Scientific Misconduct was previously publicized, or expunging all reference to the Research Misconduct allegation from the Respondent's personnel file. Any institutional actions to restore the Respondent's reputation must first be approved by the Executive Leadership Council.

C. Protection of the Whistleblower and Others

Regardless of whether LRH or ORI determines that Research Misconduct occurred, the Research Integrity Officer undertakes all reasonable and practical efforts to protect Whistleblowers who made allegations of Research Misconduct in good faith and others (witnesses or committee members) who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an

investigation, the Executive Leadership Council determines, after consulting with the Whistleblower, what steps, if any, are needed to restore the position or reputation of the Whistleblower. The Research Integrity Officer is responsible for implementing any steps the Executive Leadership Council approves. The Research Integrity Officer also takes appropriate steps during the inquiry and investigation to prevent any retaliation against the Whistleblower or others.

D. Allegations Not Made in Good Faith

If relevant, the Executive Leadership Council determines whether the Whistleblower's allegations of Research Misconduct were made in good faith. If an allegation was not made in good faith, the Executive Leadership Council determines whether any administrative action is taken against the Whistleblower.

E. Interim Protective Actions

At any time during a Research Misconduct proceeding LRH officials shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the PHS supported research process. The necessary actions vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of Research Misconduct.

F. The IRB is notified when an allegation of Research Misconduct has been substantiated.



## XI. Maintenance and Custody of Research Records and Evidence

LRH shall take the following specific steps to obtain, secure, and maintain the research records and evidence pertinent to the Research Misconduct proceeding:

A. Either before or when the respondent is notified of the allegation, the Research Integrity Officer shall promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the Research Misconduct proceeding, inventory those materials, and sequester them in a secure manner, except in those cases 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.

B. Where appropriate, give the Respondent copies of, or reasonable, supervised access to the research records.

C. Undertake all reasonable and practical efforts to take custody of additional research records and evidence discovered during the course of the Research Misconduct proceeding, including at the inquiry and investigation stages, or if new allegations arise, subject to the exception for scientific instruments in (A) above.

After completion of a case and all ensuing related actions, the Research Integrity Officer prepares a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer keeps the file for seven (7) years after completion of the case or any ORI or HHS proceeding under Subparts D and E of 42 CFR Part 93, whichever is later, unless LRH has transferred custody of the records and evidence to HHS, or ORI has advised that LRH no longer need retain the records to permit later assessment of the case. ORI or other authorized HHS personnel are given access to the records upon request.

# DEFINITIONS

***Allegation*** means any written or oral statement or other indication of possible Research/Scientific Misconduct made to an LRH official.

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

***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.

***Good faith*** means an allegation made with the honest belief that Research/Scientific Misconduct may have occurred. An allegation is not in good faith if it is made with knowing or reckless disregard for or willful ignorance of facts that would disprove the allegation.

***Inquiry*** means gathering information and initial fact-finding to determine whether an allegation or apparent instance of Research/Scientific Misconduct warrants an investigation.

***Investigation*** means the formal development of a factual record and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

***Notice*** means a written communication served in person, sent by mail or its equivalent to the last known street address, fax number, or e-mail address of the addressee.

***ORI*** means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (HHS) that is responsible for the Research/Scientific Misconduct and research integrity activities of the U.S. Public Health Service.

***PHS*** means the U.S. Public Health Service, an operating component of the HHS.

***PHS regulation*** means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of Research/Scientific Misconduct, which is set forth at 42 C.F.R. Part 93, entitled "Public Health Service Policies on Research Misconduct".

***PHS support*** means PHS grants, contracts, or cooperative agreements or applications.

***Plagiarism*** is the appropriation of another person's ideas, processes, results, or words without giving

appropriate credit.

***Research Integrity Officer*** means the LRH official responsible for assessing allegations of Research/ Scientific Misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

***Research Misconduct/Scientific Misconduct*** means the fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results. ***Research Misconduct/ Scientific Misconduct*** does not include honest error or differences of opinion.

***Research record*** means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of Research/Scientific Misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

***Respondent*** means the person against whom an allegation of Ressearch/Scientific Misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

***Retaliation*** means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of Research/Scientific Misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

***Whistleblower/Complainant*** means a person who makes an allegation of Research/Scientific Misconduct.

**Workforce**: All LRH employees, volunteers, trainees/students, contractors, and medical staff.

# REFERENCES

None.

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|

| | |
|---|---|
| Danielle Drummond: 0001 President & Chief Executive Officer - LRHS | 03/2024 |
| Jonn Hoppe: 1011 Executive VP, Chief Legal Officer-General Cou | 03/2024 |
| Timothy Regan: 0009 President - LRMC/Chief Medical Officer | 03/2024 |
| Renee Reed: 4064 Senior Attorney | 03/2024 |
| Michael Spake: 0057 SVP - External Affairs/Chief Compliance | 10/2023 |
| Deana Nelson: 4080 SVP - Administration and Corporate Initiative | 10/2023 |
| Georgia Ann Keriazes: 0729 QI/ Due Pharmacist | 10/2023 |
| Andrew Bugajski: 4387 AVP - Research and Sponsored Studies | 04/2023 |