Penn Medicine
Lancaster General Health

POLICY TITLE: RESEARCH MISCONDUCT

Former Policy Title:

POLICY PURPOSE:

The purpose of this Policy is to set forth the guidelines for reporting and investigating potential Research Misconduct, as defined below, occurring within research activity at Lancaster General Health ("LG Health") as required by federal law and regulations. The general guidelines should be read in conjunction with the applicable specific guidelines for either inquiry or investigation.

POLICY STATEMENT:

LG Health will promptly inquire into and, if warranted by the circumstances, investigate and correct all suspected incidents of Research Misconduct in connection with any research activity conducted at LG Health. LG Health will report any confirmed Research Misconduct to the appropriate funding and/or governing agency, and it will take appropriate disciplinary measures against offenders as required under 42 CFR Sections 93.101-93.319 ("the Regulations").

APPLICABILITY/SCOPE/EXCLUSION:

This Policy applies to any LG Health entity or individual conducting research pursuant to a federally funded research grant or cooperative agreement.

DEFINITIONS:

Research Misconduct: fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results.

a) Fabrication is making up data or results and recording or reporting them.
b) 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.
c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
d) Research Misconduct does not include honest error or differences of opinion.

Inquiry: a preliminary information-gathering and preliminary fact-finding that meets the legal criteria set forth in the Regulations.

Investigation: 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 that may include a recommendation for other appropriate actions, including administrative actions.

PROCEDURE:

A. GENERAL REQUIREMENTS

1. All allegations of Research Misconduct shall be made, in writing, to the LG Health Corporate Compliance Officer.

2. The Compliance Officer is responsible for the following:

   a. Appointing an impartial investigator who shall be responsible for initiating an immediate inquiry into each allegation. The investigator must agree to abide by this policy and all applicable procedures in accordance with the Regulations. If necessary, the investigator shall be authorized to select impartial experts to assist in the conduct of inquiries and investigations.

   b. Immediately notifying the Department of Health and Human Services' (HHS) Office of Research Integrity (ORI) in writing during an inquiry or investigation if any of the following conditions exist:

      i. Health or safety of the public is at risk, including an immediate need to protect human subjects.
      ii. HHS resources or interests are threatened.
      iii. Research activities should be suspended.
      iv. There is a reasonable indication of possible violations of civil or criminal law.
      v. Federal action is required to protect the interests of those involved in the research misconduct proceeding.
      vi. The research institution believes 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.
      vii. The research community or public should be informed.

   c. Implementing appropriate precautions against real or apparent conflicts of interest in an inquiry or an investigation.

   d. Reporting findings to management and any other appropriate party within LG Health.

3. The Compliance Department is responsible for the following:

   a. Notifying the persons who are the subject of an allegation of Research Misconduct ("Respondents") and afford confidential treatment to the maximum extent possible, a prompt and thorough investigation, and a copy of the inquiry and/or the investigation report in accordance with the procedures outlined below.

   b. Taking appropriate interim administrative actions to protect federal funds and ensure that the purposes of the federal financial assistance are being carried out.

c. Protecting, to the maximum extent possible, the positions, confidentiality, and reputations of those persons who, in good faith, make allegations of scientific misconduct ("Complainants"), and those against whom allegations of Research Misconduct are not confirmed.

d. Informing its scientific and administrative staff of this policy and the procedures set forth herein and the importance of compliance with this policy and these procedures.

e. Providing full and continuing cooperation with ORI during its oversight review and any subsequent administrative hearings, as applicable.

4. In the event that LG Health plans to terminate an inquiry or investigation for any reason without completing all relevant requirements under 42 CFR Sections 93.307-93.316 (regarding inquiries, investigations, and reporting-specific requirements), a report of such planned termination, including a description of the reasons for such termination, shall be made to ORI. For at least seven (7) years after termination of the inquiry or investigation, LG Health shall maintain sufficiently detailed documentation of the inquiry or investigation and the reasons why LG Health decided not to conduct an investigation or inquiry.

B. REQUIREMENTS SPECIFIC TO INQUIRIES

1. At the time of, or before beginning, an inquiry, the Compliance Department shall make a good faith effort to notify, in writing, the presumed Respondents, if any have been identified. If the Respondents are subsequently identified during the inquiry process, the Compliance Department shall provide notice at that time.

2. The investigator shall complete each inquiry within sixty (60) calendar days from receipt of an allegation, including preparation of a written report to the Compliance Department. The content of the inquiry report shall include evidence reviewed, interview summaries, and conclusions of the inquiry.

3. If the inquiry takes longer than sixty (60) days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

4. The Compliance Department shall notify the Respondent(s) and the Complainant(s) if the inquiry found that an investigation is warranted.

5. The Respondent(s) shall have the opportunity to provide written comments on the inquiry report.

6. LG Health shall maintain detailed documentation of each inquiry for at least seven (7) years, which must, upon request, be provided to authorized personnel of the Department of Health and Human Services.

C. REQUIREMENTS SPECIFIC TO INVESTIGATIONS

1. Within thirty (30) calendar days of the completion of an inquiry, the Compliance Officer shall authorize the investigator to initiate an investigation, if findings from that inquiry provide sufficient basis to conduct an investigation.

2. Within thirty (30) days after finding that an investigation is warranted, the Compliance Department shall provide ORI with the written finding and a copy of the inquiry report and notice that an investigation will be conducted.

3. The Compliance Department also shall notify the Respondent(s) in writing within a reasonable amount of time that an investigation is warranted.

4. The investigator shall complete the investigation and submit the final report of the investigation to ORI within 120 calendar days after initiation of the investigation.

5. The investigator shall submit to ORI a request for an extension if the investigation cannot be completed in 120 days. The extension request shall include an explanation for the delay, an interim report on progress to date, an outline of what remains to be done, and an estimated date of completion of the investigation and inquiry report.

6. The Respondent(s) shall have the opportunity to provide written comments to the draft investigation report. Concurrently, the Compliance Department shall provide Respondent(s) with a copy of, or supervised access to, the evidence on which the report is based. The Respondent(s) shall have thirty (30) days from the date on which they received the report to provide any comments. The Compliance Department may, but is not required to, provide the Complainant(s) with a draft copy of the report for comment.

7. The investigator shall prepare, and LG Health shall maintain, the documentation to substantiate an investigation's findings, and a copy of the final report, for at least seven (7) years after ORI's acceptance of the final report.

8. The Compliance Department shall be responsible for promptly advising ORI of any developments during the course of the investigation that disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the Public Health Service needs to know in order to ensure appropriate use of federal funds and otherwise protect the public interest.

9. The Compliance Officer shall be responsible for the following:

    a. Imposing appropriate sanctions on individuals when the allegation of Research is conduct has been substantiated.

    b. Notifying the ORI of the final outcome of the investigation with a written report that thoroughly documents the investigative process and findings. This final written report to ORI shall describe the policies and procedures under which the investigation was conducted; how and from whom information was obtained relevant to the investigation; the findings; the basis for such findings, including the actual test or an accurate summary of the views of any individual(s) found to

have engaged in misconduct; and a description of any sanctions implemented by LG Health.

ROLES/REPONSIBILITIES: As described above.

APPENDICES: N/A

FORMS: N/A

REFERENCE DOCUMENTS: N/A

REGULATORY/ACCREDITATION/INDUSTRY STANDARD CITATIONS:

Public Health Service Act, 42 U.S.C. § 201 *et. seq.*

42 CFR §§ 93.100-93.319