San Francisco Department of Public Health

*Policy & Procedure Detail**

Policy & Procedure Title: Research Misconduct: Definitions and Procedures	
Category: Compliance	
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DPH Unit of Origin: Office of Compliance & Privacy Affairs	
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All sections in table required. Updated 12/28/2022

1. **Purpose of Policy**

The purpose of this policy is to:

a. Define research misconduct, and clarify roles and responsibility of San Francisco Department of Public Health (DPH) staff
b. Establish a process to ensure compliance with all Federal, State and local regulations and research conducted at DPH adhere to the highest standards of moral and ethical values.
c. Specify the procedures and appropriate safeguards for responding to allegations of research misconduct.

2. Policy

It is the policy of DPH to ensure the integrity of research conducted under its auspices and condemn any form of dishonesty or misconduct in research. DPH Office of Compliance and Privacy Affairs (OCPA) is responsible for evaluating and investigating all allegations of misconduct related to research at DPH. If it is alleged that research misconduct has occurred, OPCA will respond by adhering to the procedures detailed in this policy.

The procedures conform to the US Public Health Service (PHS) regulations, which is set forth by 42 CFR Part 93 entitled "Public Health Service Policies on Research Misconduct". While 42 CFR Part 93 applies to individuals who may be involved with a project supported by, or who have submitted a grant application to, PHS, this policy applies to all individuals engaged in DPH research regardless of the funding source.

3. Definitions

a. DPH staff refers to DPH workforce members including employees, contracted staff, medical personnel, interns, volunteers and other individuals representing or working at DPH who, on behalf of DPH, furnish or authorize the furnishing of Medicare or Medi-Cal services, perform billing or coding functions, monitor the healthcare, or conduct research. DPH staff

does not include UCSF researchers. All allegations of misconduct by UCSF researchers will be referred to the UCSF Office of Ethics and Compliance.

b. **Fabrication** is making up data or results and recording or reporting them.

c. **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.

d. **Inquiry** means preliminary information gathering and fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

e. **Investigation** means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions including administrative actions.

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

g. **PHS** means the U.S. Public Health Services, an operating component of the U.S. Department of Human and Health Services (HHS)

h. **Research misconduct** means fabrication, falsification, or plagiarism, in proposing, performing, or reviewing research, or in reporting research results. Under DPH policy, it also includes failure to comply with requirements for the protection of human or animal research subjects. Research misconduct is distinguished from honest error or differences of opinion.' (§ 93.103, 42 CFR Part 93).

i. **Respondent** means the person against whom an allegation of research 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.

4. Procedures

a. Responsibility of OCPA**:** DPH Office of Compliance and Privacy Affairs (OCPA) has primary responsibility for implementation of the procedures set forth in this document and may appoint a designee to carry out all or any portion of the investigative procedures, as needed. OCPA will:

i. Coordinate all procedures related to allegations of research misconduct under the DPH aegis.

ii. Appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is represented to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation.

iii. Take reasonable steps to ensure no real or apparent conflicts of interest arise in those appointed to pursue this process, they have the appropriate disciplinary expertise, and due regard is given to the prevailing standards of the field.

iv. confidentiality or anonymity, fairness and objectivity of proceedings.

v. Ensure a full and complete inquiry, investigation, and resolution process.

vi. Assume responsibility for securing and maintaining the confidentiality of records, in accordance with established DPH policy, relating to the investigation and resolution of incidents of misconduct in research.

vii. Notify concerned parties such as sponsors, co-authors, collaborators, editors, licensing boards, professional societies, and criminal authorities of the outcome of investigations as required by regulation.

viii. Make efforts to protect and/or restore the positions and reputations of those persons who, in good faith, make allegations of research misconduct, and those against whom allegations of misconduct are made and later determined to be unfounded or not confirmed.

ix. Assist inquiry and investigation committees and all DPH staff with complying with these procedures and with applicable standards imposed by regulations or external funding sources.

b. **Requirements for Findings of Research Misconduct**: a finding of research misconduct requires that the following conditions be met:

i. There be a significant departure from accepted practices of the relevant research community;

ii. The misconduct be committed intentionally, knowingly, or recklessly; and

iii. The allegation be proven by a preponderance of the evidence

c. **Reporting Misconducts**: Existing DPH policy and procedures assert the responsibility of Principal Investigators in maintaining ethical standards, and direct reporting of allegations to OCPA. All individuals associated with DPH should report observed, suspected or apparent research misconduct to OCPA.

i. An allegation should, in addition to stating the nature of the suspected misconduct, present the evidence that leads the reporting individual to believe that an incident of research misconduct has occurred.

ii. OCPA will immediately respond, as outlined below, to each allegation or other evidence of possible misconduct.

iii. If an individual is unsure whether a suspected incident falls within the definition of research misconduct they should contact OCPA and ask to discuss the suspected misconduct informally. If the circumstances described do not meet the definition or research misconduct, OCPA will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

iv. The informal discussion of possible research misconduct, as well as all subsequent stages in this procedure will be, as far as is feasible, treated as strictly confidential.

d. **Preliminary Assessment of Allegations:** Upon receiving an allegation of research misconduct, OCPA will assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified and whether the allegation falls under the definition of research misconduct. If it is concluded

that a bona fide allegation of research misconduct has been made, the misconduct procedure enters its inquiry phase.

e. **Conducting the Inquiry**: Following the preliminary assessment, OCPA will conduct an inquiry. The purpose of the inquiry is not to reach a final conclusion as to whether misconduct occurred or who was responsible but is a process for gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation. This phase should take no more than sixty calendar days from the receipt of the allegation unless circumstances clearly warrant a longer period. If the inquiry phase must be extended beyond sixty days, the reasons for doing so should be documented.

   i. OCPA will appoint an inquiry committee. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses and conduct the inquiry.

   ii. OCPA will notify the respondent (the individual about whom misconduct allegations have been made) that an inquiry is being undertaken and of the procedure that will be followed; indicate who have been appointed to conduct the inquiry; and, describe the nature of the misconduct allegation(s).

      1. The respondent has five days to challenge, in writing, the appointments based on bias or conflict of interest. OCPA determines whether to replace the challenged member with a qualified substitute.

   iii. At the time of notification, and in the course of the inquiry, or of any subsequent investigation, OCPA will sequester such information as is necessary to protect the integrity of the investigation.

      1. Where appropriate, the respondent will be provided copies of, or reasonably supervised access to, the research records.

      2. All records of the DPH research misconduct proceeding will be retained for seven years after the proceeding's conclusion.

   iv. If the research at issue receives or has received Federal funding, and, at any point during an inquiry or subsequent investigation, it is ascertained that any of following conditions pertain, DPH will notify the sponsoring Federal agency (such as Office of Research Integrity (ORI)) .

      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 reasonable indication of possible violations of civil or criminal law.

      5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.

6. 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.

7. The research community or public should be informed.

8. In the case of Federally funded research, DPH will take appropriate interim administrative actions to protect Federal funds and ensure that the purpose of the Federal financial assistance is carried out.

v. Matters pertaining to the inquiry will be treated confidentially to the maximum extent possible consistent with fact finding and required reporting to funding agencies.

vi. The inquiry committee will evaluate the evidence and testimony obtained during the inquiry. Based on the evidence reviewed the committee will decide whether there is sufficient evidence of possible research misconduct to recommend that an investigation be conducted

vii. The inquiry committee will prepare a written report of the inquiry and submit it to OPCA. It should describe the evidence that was reviewed, summarize any interviews that were conducted, and include the conclusion of the inquiry.

viii. The respondent will be given a copy of the report of inquiry and is invited to comment in writing. Comments provided are included in the record.

ix. Upon receipt of the inquiry report, OCPA will make, in writing, the determination of whether an investigation is warranted. Records of the inquiry, including all documentary evidence, interview notes, the inquiry report, and OCPA's written determination are to be maintained in a secure manner for at least seven years.

1. If an inquiry is terminated before its completion, a report of the planned termination, including the reasons for such an action, should be made to those Federal funding agencies that require it.

2. The inquiry report and supporting documentation will be provided to relevant authorized federal agencies upon request.

x. If it is determined that there is sufficient evidence to warrant a formal investigation, OCPA shall initiate investigation with 30 calendar days.

f. **Conducting the Investigation**: The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom and to what extent. The investigation will also determine whether there are individual instances of possible misconduct that would justify broadening the scope beyond the initial allegations.

i. An Investigative Committee will be appointed to conduct the investigation. The investigation phase should be completed within 120 days from the appointment of the investigative committee, unless circumstances warrant a longer period. If the investigation stage is extended beyond 120 days the reasons for doing so should be documented.

ii. When Federal funding is involved; the pertinent agency shall be informed that an investigation will be initiated within 30 days after determining that an investigation is warranted.

    1. When it is required by Federal funding agencies, an extension of the investigation beyond 120 days must be requested from the relevant agency. The extension request should include an explanation for the delay, an interim report on the progress to date, an outline of what remains to be done, and an estimated date of completion.

iii. OPCA will notify the respondent in writing that an investigation is being undertaken, will inform them of the allegations that are under investigation, as well as of the composition of the investigative committee and the procedures that will be followed in the course of the investigation. If new allegations arise during the investigation, OCPA will notify the respondent in writing.

    1. The respondent has five days to challenge, in writing, the committee's membership based on bias or conflict of interest. OCPA will determine whether to replace the challenged committee member with a qualified substitute.

iv. The investigation will normally involve examination of pertinent documents, including but not limited to research records, computer files, proposals, manuscripts, publications, correspondence, and memoranda. Typically, the investigative committee will conduct interviews as part of its fact-finding process, including interviews with the complainant and the respondent. Whenever it is feasible, investigators shall create and maintain recorded records of their interviews and be included as part of the investigatory file.

    1. All individuals involved in the investigation will be accorded confidential treatment to the maximum extent possible during the investigation.

    2. If an investigation is terminated before its completion, a report of the planned termination, including the reasons for such an action, should be made to those Federal funding agencies that require it.

    3. DPH will notify relevant Federal funding agencies if, during the course of the investigation, facts are disclosed that may affect current or potential Federal funding for individual(s) under investigation or that the Federal agency needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

v. Once the investigation is completed, the investigative committee shall prepare a draft report. The report should describe:

    1. the allegations,

    2. sources of external funding, if any,

    3. specific allegations of research misconduct,

    4. policies and procedures under which the investigation was conducted,

5. how and from whom information relevant to the investigation was obtained,

6. the findings, and the basis for the findings.

vi. OCPA shall make the draft report available to the respondent for comment or rebuttal and may be shared with City Attorney's Office for legal sufficiency review.

1. The respondent has twenty-one calendar days to submit to OCPA comments on the investigative report. The respondent's comments will be attached to the final report.

vii. Based on a reading of the Investigative Report and any comments provided, OCPA will make the final determination whether to accept the investigation report, its findings and any recommended corrective action plan. If this determination varies from that of the committee, OCPA will explain in detail the basis for rendering a decision different from that of the committee. OCPA may also return the report to the investigation committee with a request for further fact-finding or analysis. OCPA's determination together with the investigation committee's report, constitutes the final investigation report for the purposes of external sponsor review.

viii. OCPA will issue a Final Report to Director of Health and to the ORI or any external funding agency that requires it. The final report should also include a description of any sanctions taken by DPH. Documentation to substantiate an investigation's findings will also be made available to ORI.

1. After the investigation is complete, if there is a confirmation of research misconduct, OCPA should also notify the sponsoring Institutional Review Board.

2. OCPA decides whether to recommend the imposition of disciplinary actions to the Director of Health.

g. Disciplinary Procedure

i. If, **in the case of a DPH employee**, OCPA may recommend disciplinary actions based on the severity and nature of the misconduct.

ii. If, **in the case of an external researcher,** the investigative committee makes a finding of research misconduct, its report, the postdoctoral scholar's response, and the recommendations made by OCPA as to appropriate disciplinary actions, if any, are forwarded to the Chair of the academic researcher or postdoctoral scholars department, who decides with respect to the matter of discipline.

iii. If, **in the case of students**, the investigative committee makes a finding of research misconduct, its report, the student's response, and the recommendation of OCPA as to appropriate disciplinary sanctions, if any, are forwarded to the appropriate academic institution, which following its procedures, decides with respect to the matter of discipline.

iv. OCPA shall report any disciplinary actions taken by DPH to ORI and to any other external funding agency that requires it.

5. References/Attachments

a. 42 Code of Federal Regulations, Part 93