



# San Francisco Department of Public Health

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## SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

### RESEARCH MISCONDUCT: DEFINITIONS AND PROCEDURES

The following procedures conform to the Public Health Service (Department of Health and Human Services) Final Rule 42 Code of Federal Regulations (CFR) Part 93.

While 42 CFR Part 93 applies to all individuals who may be involved with a project supported by, or who have submitted a grant application to, the Public Health Service (PHS), San Francisco Department of Public Health (SF-DPH) policy applies to all individuals engaged in DPH research whatever the funding source.

### INVESTIGATION OF ALLEGED RESEARCH MISCONDUCT

#### I.A DEFINITION OF RESEARCH MISCONDUCT

*Research misconduct* means 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. ' (§ 93.103, 42 CFR Part 93).

Research misconduct under SF-DPH policy also includes failure to comply with requirements for the protection of human or animal research subjects.

#### I.A.1 REQUIREMENTS FOR FINDINGS OF RESEARCH MISCONDUCT

A finding of research misconduct requires that --

- a. There be a significant departure from accepted practices of the relevant research community; and
- b. The misconduct be committed intentionally, knowingly, or recklessly; and
- c. The allegation be proven by a preponderance of the evidence.

#### I.B. DELEGATION OF AUTHORITY AND RESPONSIBILITY



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The Director of Public Health for the City and County of San Francisco delegates to the DPH Compliance Officer responsibility for investigation of the matter. The DPH Compliance Officer may appoint a designee to carry out all or any portion of the investigative procedures as follows below:

- Coordination of all procedures related to allegations of research misconduct by anyone performing research under the SF-DPH aegis.
- Assurance of appropriate confidentiality or anonymity, fairness and objectivity of proceedings.
- Assurance of a full and complete inquiry, investigation, and resolution process. Assurance that no real or apparent conflicts of interest arise in those appointed to pursue this process that they have the appropriate disciplinary expertise and that due regard is given to the prevailing standards of the field.
- Maintenance of confidentiality of records, in accord with established SF-DPH policy, relating to the investigation and resolution of incidents of misconduct in research.
- If appropriate or required, the Compliance Officer and/or Designee shall notify concerned parties such as sponsors, co-authors, collaborators, editors, licensing boards, professional societies, and criminal authorities of the outcome of investigations, taking care to clear the name of anyone falsely charged.
- Protecting, to the maximum extent possible, the positions and reputations of those persons who, in good faith, make allegations of research misconduct, and those against whom allegations of misconduct are not confirmed.
- Efforts to restore the reputation of persons alleged to have engaged in misconduct when allegations are not confirmed.

## I.C INQUIRIES AND INVESTIGATIONS INTO ALLEGATIONS OF MISCONDUCT IN RESEARCH

Existing SF-DPH policy and procedures assert the responsibility of Principal Investigators in maintaining ethical standards, and direct reporting of allegations to DPH Compliance Officer.

All individuals associated with SF-DPH should report observed or suspected research misconduct to the DPH Compliance Officer.

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.



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The Compliance Officer and/or Designee will immediately respond, as outlined below, to each allegation or other evidence of possible misconduct.

If an individual is unsure whether a suspected incident falls within the definition of research misconduct he or she should contact the Compliance Officer (415-255-3706) and ask to discuss the suspected misconduct informally. If the circumstances described do not meet the definition of research misconduct, the Compliance Officer and/or Designee will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

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.

The following describes procedures to be followed once an allegation or other evidence of misconduct is received.

## (1) PRELIMINARY ASSESSMENT

A. The Compliance Officer and/or Designee assesses the reported incident to determine if it constitutes a bona fide allegation of research misconduct—i.e., does the alleged incident fit the definition of research misconduct and is the evidence sufficiently credible and specific so that potential evidence of research misconduct may be identified? If it is concluded that a bona fide allegation of research misconduct has been made, the misconduct procedure enters its inquiry phase.

## (2) INQUIRY:

A. Upon receiving an allegation of research misconduct, the Compliance Officer and/or Designee appoint one or more persons to conduct an inquiry to determine whether there is sufficient substance to the allegation to warrant a formal investigation. The purpose of the inquiry is not to reach a final conclusion as to whether misconduct occurred or who was responsible. This preliminary phase of information gathering and fact-finding 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.

B. The Compliance Officer and/or Designee notifies 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; indicates the membership of the inquiry committee; and, describes the nature of the misconduct allegation(s).



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B.1. The Respondent has five days to challenge, in writing, the committee's membership based on bias or conflict of interest. The Compliance Officer and/or Designee will determine whether to replace the challenged member with a qualified substitute.

C. At the time of notification, and in the course of the inquiry, or of any subsequent investigation, the Compliance Officer and/or Designee will sequester such information as is necessary to protect the integrity of the investigation.

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

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

D. 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 five conditions pertain, the campus will notify the sponsoring Federal agency (For example, the Office of Research Integrity (ORI) of the Department of Health and Human Service (DHHS)).

a. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

b. HHS resources or interests are threatened.

c. Research activities should be suspended.

d. There is reasonable indication of possible violations of civil or criminal law.

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

f. 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.

g. The research community or public should be informed.

D. 1. In the case of federally funded research, the campus will take appropriate interim administrative actions to protect Federal funds and insure that the purpose of the Federal financial assistance is carried out.

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

F. A written report of the inquiry shall be prepared that describes the evidence that was reviewed, summarizes any interviews that were conducted, and includes the conclusion of the inquiry.



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G. The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry, and shall be invited to comment in writing. When comments are provided they will be included in the record.

H . Upon receipt of the inquiry report, the Compliance Officer and/or Designee 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 the Compliance Officer's written determination shall be maintained in a secure manner for at least seven years.

H.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 (the Office of Research Integrity of DHHS, for example).

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

I. If it is determined that there is sufficient evidence to warrant a formal investigation, the Compliance Officer and/or Designee shall (within 30 calendar days) initiate the process as follows:

### (3) INVESTIGATION:

A. An Investigative Committee is appointed to determine whether research misconduct has occurred, and, if so, to make recommendations with respect to the imposition of disciplinary sanctions. 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.

B. When Federal funding is involved; the pertinent agency shall be informed that an investigation will be initiated within 30 days of the DPH Compliance Officer and or Designee's determination that there exists sufficient evidence to warrant an investigation of research misconduct.

B.1. When it is required by Federal funding agencies, such as ORI of DHHS, 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.

C . The Compliance Officer and/or Designee will notify the Respondent(s) in writing that an investigation is being undertaken, will inform him/her of the allegations that are under investigation, as well as of the composition of the investigative committee and the procedures



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that will be followed in the course of the investigation. In the event that new allegations arise in the course of the investigation, the respondent will be so notified in writing.

C.1. The Respondent has five days to challenge, in writing, the committee's membership based on bias or conflict of interest. The Compliance Officer and/or Designee will determine whether to replace the challenged member with a qualified substitute.

D. The investigation will normally include examination of pertinent documents, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda. Typically, the investigative committee will conduct interviews as part of its fact-finding process, including interviews with those making allegations of research misconduct and with the individual(s) against whom the allegations are made. Whenever it is feasible, investigators shall create and maintain recorded records of their interviews.

D.1. All individuals affected by the investigation will be accorded confidential treatment to the maximum extent possible in an investigation.

D.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 (the Office of Research Integrity of DHHS, for example). D.3. SF-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.

E. When the investigation is completed, the DPH Compliance Officer and/or Designee shall prepare, and submit to the Director of Public Health, a written report of the results, reviewing the facts, and stating the investigative committee's findings. The DPH Compliance Officer and/or Designee shall make the report available to the Respondent(s) for comment. In a separate communication to the Director of Public Health, the investigative committee shall offer its recommendations with respect to disciplinary sanctions, if any.

E.1. The respondent (s) shall have twenty-one calendar days to submit to the DPH Compliance Officer and/or Designee comments on the investigative report.

F.2 Based upon a reading of the Investigative Report and any comments thereon, the DPH Compliance Officer and/or Designee will make a determination of whether or not research misconduct has been committed. The DPH Compliance Officer and/or Designee will issue a Final Report to the ORI or any external funding agency that requires it. The final report to ORI, for example, must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained, the findings, and the basis for the findings, and include an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by SF-DPH.



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Documentation to substantiate an investigation's findings will also be made available to the Director of ORI.

After the investigation is complete, if there is a confirmation of research misconduct, the sponsoring Institutional Review Board should be notified by the DPH Compliance Office and/or Designee.

F.3. The DPH Compliance Officer and/or Designee decides whether or not to recommend the imposition of disciplinary sanctions to the Director of Public Health.

#### (4) DISCIPLINARY PROCEDURE:

A. If, **in the case of a DPH employee**, the DPH Compliance Officer and/or Designee intends to file charges pursuant to the imposition of disciplinary sanctions, the processing of those charges will proceed in accordance with the provisions of the Employee Code of Conduct for SF-DPH.

B. If, **in the case of an academic researcher or postdoctoral scholar**, the investigative committee makes a finding of research misconduct, its report, the postdoctoral scholar's response, and the recommendation of the DPH Compliance Officer and/or Designee as to appropriate disciplinary sanctions, if any, are forwarded to the Chair of the academic researcher or postdoctoral scholars department, who decides with respect to the matter of discipline.

C. 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 the DPH Compliance Officer and/or Designee as to appropriate disciplinary sanctions, if any, are forwarded to the appropriate academic institution's Office of Student Conduct, which following its procedures, decides with respect to the matter of discipline.

D. The DPH Compliance Officer and/or Designee shall report any disciplinary actions taken by the campus to ORI and to any other external funding agency that requires it.