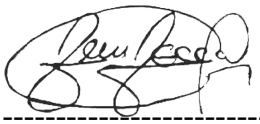
RESEARCH MISCONDUCT POLICY – versión 1.0

Scope: This Policy applies to all individuals who are engaged in research at SES, or who are otherwise, in their SES capacity, involved in or perceived to be involved in research.

Responsible Office: Program Management Department

Responsible Executive: Director of Program Management



Leonid Lecca
Executive Director
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I. PURPOSE

Socios En Salud Sucursal Peru ("SES") is committed to the preservation of the integrity of research, to fostering a research environment that encourages appropriate behavior, to ensuring compliance with regulatory requirements, and to maintaining the confidence of our employees, patients, research subjects and peers. The SES Research Misconduct Policy (the "Policy") reflects SES's interest in the accuracy and reliability of the research record and the processes involved in its development.

II. DEFINITIONS

Allegation means a disclosure of possible research misconduct through any means of communication.

Complainant means an individual or group of individuals who in good faith makes an allegation of research misconduct.

Deciding Official means the Director of Program Management of SES, or his or her designee, and shall not be the same individual as the Research Integrity Officer.

Fabrication means making up data or results and recording or reporting them.

Falsification means 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.

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

Research Integrity Officer means the Director of Program Management of SES, or other official designated by the Directory board of SES to be responsible for assessing allegations of research misconduct, determining when such allegations warrant inquiries, conducting inquiries and investigations or staffing any committees constituted to undertake inquiries and investigations, and overseeing inquiries and investigations.

Research Misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or difference of opinion.

Respondent means an individual or group of individuals against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

III. POLICY STATEMENT

A. Scope

This Policy applies to all individuals who are engaged in research at SES, or who are otherwise, in their SES capacity, involved in or perceived to be involved in research.

B. Obligation to Report an Allegation of Research Misconduct

All allegations of research misconduct must be reported to the Research Integrity Officer unless they are clearly frivolous. Allegations should be as specific as possible. Ideally, allegations should be substantiated with documented observations, documents of facts, and/or any other form of proof from which the Research Integrity Officer can begin a formal review. The Research Integrity Officer is available to discuss any circumstances that may raise issues regarding the integrity of research.

C. Review of Allegations

The Research Integrity Officer shall review all allegations brought to his or her attention to determine the veracity of the allegation. Allegations may be submitted to the Research Integrity Officer by any means of communication. The Research Integrity Officer shall oversee the internal review process.

If an allegation pertains to an individual who is affiliated with multiple entities, the Research Integrity Officer of the entity at which the research in question was conducted shall be primarily responsible for overseeing the internal review process, or, alternatively, the entities may decide among themselves which one should be primarily responsible. The Research Integrity Officer of the lead entity may consult with the Research Integrity Officers of other affiliates as appropriate.

Allegations of research misconduct can vary significantly due to the nature of the misconduct alleged, the severity of the allegations, disputes over facts related to the allegation, and other factors. Due to these potential variations, this Policy allows for flexibility, where possible, so that each allegation of research misconduct can be resolved equitably.

D. Time Limitations

The Research Integrity Officer may dismiss an allegation brought more than six (6) years after the alleged misconduct occurred. The six year limitation does not apply when the research in question involves funding from the Public Health Service and either (a) the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication, or other use for the potential benefit of the respondent, of the research

record that is alleged to have been fabricated, falsified, or plagiarized; or (b) the Program Management Department (PMD)or , following consultation with PMD, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public. In the case of (a), the six-year limitation period would begin at the time of the last citation, republication, or other use for the potential benefit of the respondent.

E. Finding of Research Misconduct

A finding of research misconduct under this Policy requires that: (a) there be a significant departure from accepted practices of the relevant research community; (b) the misconduct be committed intentionally, knowingly, or recklessly; and (c) the allegation be proven by a preponderance of the evidence.

F. Protections for Individuals Involved with the Allegation; Retaliation

The protection of those who in good faith report concerns or allegations is a priority. It is against SES policy for SES to retaliate against any other individual who in good faith reports concerns under this Policy and cooperates in research misconduct proceedings. Reporting in good faith an issue or concern under this Policy and cooperating in research misconduct proceedings will not reflect negatively on the employee or affect his or her employment. The Research Integrity Officer shall make reasonable and practical efforts to protect or restore the positions and reputations of respondents, good faith complainants, witnesses, committee members, and other individuals cooperating in the proceedings, as appropriate. Any concerns about retaliation should be directed to the Research Integrity Officer or SES Human Resources who will review all instances of alleged retaliation for appropriate action.

G. Confidentiality; Anonymity

All individuals involved in research misconduct proceedings, including the respondent, complainant, witnesses, and panel members, are responsible for maintaining confidentiality. Disclosure of an allegation and the institutional review of an allegation should be limited to those with a need to know about them. The identity of research subjects, if any, should be kept confidential. Any concerns about breaches of confidentiality should be directed to the Research Integrity Officer or SES Human Resources who will review all concerns for appropriate action.

If a complainant requests anonymity, the Research Integrity Officer will make reasonable and practical efforts to honor that request, where appropriate. However, anonymity may not be possible in all instances.

H. Conflicts of Interest

Individuals involved in a research misconduct proceeding shall have an opportunity to raise concerns regarding personal, professional, or financial conflict of interest that they may have with the complainant, the respondent, any witness, or any individual responsible for carrying out any part of a research misconduct proceeding. Any concerns regarding such conflicts should be addressed by the Research Integrity Officer. If the concern relates to a conflict with the Research Integrity Officer, such concern should be addressed by the Deciding Official.

I. Safety Concerns

Any relevant institutional, state or federal agency (as appropriate) should be notified if, during the course of a research misconduct proceeding, any concerns are raised pertaining to the health or safety of the public (including an immediate need to protect human or animal research subjects), there is reason to believe that research activities should be suspended, there is reasonable indication of violation of any law, or any other concern that warrants such notification. If the research implicated in the research misconduct proceeding involves funding from the Public Health Service, there are special notification requirements when exigent circumstances arise (see Part IV, Section E(1)(b)).

IV. PROCEDURES

A. Preliminary Assessment

The Research Integrity Officer, or his/her designee, shall conduct a preliminary assessment to determine if (a) the allegation falls within the definition of research misconduct, and (b) the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

The Research Integrity Officer need not conduct an exhaustive review of the evidence or conduct interviews. If the allegation falls within the definition of research misconduct and the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified, further institutional review must be conducted pursuant to Section E.

If the Research Integrity Officer determines that he or she needs to consult with the respondent to conduct the preliminary assessment, the relevant research records should be preserved in accordance with Section B and the respondent should be notified of the allegations in accordance with Section C. If the Research Integrity Officer can conduct the preliminary assessment without consulting with the respondent, he or she does not necessarily need to preserve the research record or notify the respondent of the allegation.

If the Research Integrity Officer concludes that the allegation does not fall within

the definition of research misconduct or the allegation is not sufficiently credible and specific so that potential evidence of research misconduct may be identified, the Research Integrity Officer shall prepare a report that summarizes the allegation(s) and the reasons for closing the matter. This report shall be retained pursuant to Section F.

B. Preservation of Relevant Research Records

The Research Integrity Officer, or his/her designee, shall sequester all relevant research records or take other steps as determined appropriate to preserve the integrity of the records. Such actions should occur as early in the process as feasible, and prior to, or concurrently with, notification to the respondent. As noted in Section A, the Research Integrity Officer need not preserve the relevant research records during a preliminary assessment if he or she can conduct the preliminary assessment without consulting with the respondent. During the inquiry and investigation, to the extent not done so already, the Research Integrity Officer shall sequester all relevant research records or take other steps as determined appropriate to preserve the integrity of the records, including sequestering and preserving additional items that become known or relevant to the inquiry or investigation.

C. Notice of Allegation(s) to Respondent

Prior to the beginning of an inquiry (and during a preliminary assessment, if appropriate), the Research Integrity Officer shall inform the respondent of the allegations. If the allegations change throughout the course of the internal review, the Research Integrity Officer shall inform the respondent of such new or altered allegations. As noted in Section A, the Research Integrity Officer need not notify the respondent of the allegations during a preliminary assessment if the Research Integrity Officer can conduct the preliminary assessment without consulting with the respondent.

D. Further Institutional Review

The nature of the further institutional review depends on the funding source of the research in question, as determined by the Research Integrity Officer. Certain additional regulatory procedural requirements are required if the research involves funding from the Public Health Service (see Subsection 1), and there may be additional procedural requirements imposed by a funder other than the Public Health Service (see Subsection 2). Where appropriate, changes to these procedures may be implemented to ensure compliance with any requirements imposed by the funding entity.

The Research Integrity Officer shall conduct further review to determine whether the respondent committed research misconduct. The Research Integrity Officer may create a panel of one or more individuals to review the allegation(s) and evidence,

and to report its findings and recommendations to the Research Integrity Officer. Throughout the review, the Research Integrity Officer, or his or her designee, is responsible for ensuring that the respondent has an opportunity to present his or her case, including being interviewed if desired, and an opportunity to review and comment on any reports generated by the Research Integrity Officer or any panel before they are finalized.

The Research Integrity Officer shall relay the findings to the responsible office, who will make a final determination as to whether research misconduct did or did not occur, and what sanctions or other actions are appropriate. If the investigation results in a finding that research misconduct occurred, but that there was not a preponderance of the evidence that an identifiable respondent committed the research misconduct, the responsible office may still determine that sanctions (e.g., notification to the applicable journal) are appropriate. Sanctions will be addressed and adjudicated within applicable disciplinary policies and procedures of SES.

1. Research Involving Public Health Service Funding

a. Process

If the Research Integrity Officer determines that the research involves funding from the Public Health Service, specifically falling in the categories of research outlined in 42 C.F.R. §93.102(b), the internal review must comply with 42 C.F.R. §93 (the "PHS Rule"). The following provides a general outline of the procedures; the PHS Rule should be consulted for further specificity. If the inquiry or investigation is conducted with a non-SES institution(s), any discrepancy or conflict between this Policy and such institution's policy will be resolved by consultation with the PHS Rule.

i. Inquiry

If the Research Integrity Officer determines that the allegation constitutes research misconduct and there is sufficient credible and specific evidence so that potential evidence of research misconduct may be identified, the Research Integrity Officer shall conduct an inquiry consistent with the requirements of the PHS Rule. The purpose of the inquiry is to determine if an allegation warrants an investigation. An investigation is warranted if there is (a) a reasonable basis for concluding that the allegation falls within the definition of research misconduct; and (b) preliminary information- gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance. The Research Integrity Officer may appoint an individual or a panel to make recommendations as to whether an investigation is warranted.

If the Research Integrity Officer determines that an investigation is not warranted, he or she shall make a recommendation to the Deciding Official to conclude the review, and the Deciding Official shall make the final determination to conclude

the review. If the Research Integrity Officer determines that an investigation is warranted, he or she shall inform the Deciding Official as the Research Integrity Officer deems appropriate, and the matter shall proceed to investigation.

The findings of the inquiry shall be included in a written report, completed within 60 days of the initiation of the inquiry, unless circumstances clearly warrant a longer period.

If an investigation is warranted, PMD must be notified in writing within 30 days of such finding. PMD need not be notified if an investigation is not warranted. However, PMD must be notified in advance if the institution seeks to close a case prior to investigation due to the respondent admitting guilt or the respondent reaching a settlement with the institution.

Regardless of whether PMD is notified or not, all records relating to the inquiry must be retained consistent with Section F.

ii. Investigation

Within 30 days of determining an investigation is warranted, the Research Integrity Officer, or an individual or panel appointed by the Research Integrity Officer, shall investigate consistent with the requirements of the PHS Rule. The purpose of the investigation is to determine, for each allegation, whether research misconduct did or did not occur, and if so, who was responsible.

The findings of the investigation shall be included in a written report, which will include information as required by 42 C.F.R. §93.313 and shall be transmitted to the Deciding Official. The Deciding Official shall make the final determination as to whether to accept the investigation report, its findings, and the recommended actions (if any). PMD shall be provided with a copy of the final investigation report and notice of any institutional administrative actions within 120 days of the initiation of the investigation, unless PMD has granted an extension.

b. Exigent Circumstances

PMD or other relevant institutional, state or federal entities (as applicable) should be notified promptly if any of the following concerns are identified during the course of a research misconduct proceeding:

- The health or safety of the public is at risk, including an immediate need to protect human or animal research subjects;
- Resources or interests of the U.S. Department of Health and Human Services are threatened;
- Research activities should be suspended;

- There is 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 institution believes the research misconduct proceeding may be made public prematurely; or
- The research community or public should be informed.

2. Research Involves Funding from Sources That Have Specific Requirements for the Handling of Research Misconduct Allegations

If the research involves funding from an entity other than the Public Health Service, and such entity mandates specific requirements when assessing research misconduct allegations, the Research Integrity Officer shall comply with such requirements.

E. Record Retention

The Research Integrity Officer will keep all documents and other evidence relating to all research misconduct proceedings for seven (7) years after the completion of the matter or the completion of any Public Health Service proceeding involving the research misconduct allegation.

CONTROL OF CHANGES

Review	Date	Description
1.0	04-05-2024	The policy is created for the first time within the Quality Management System.