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Conflict of Interest Policy – version 3.0

Scope: Research Members of Socios En Salud Peru Branch who conduct research funded by The National Institute of Health.

Responsible Office: Program Management Department

Responsible executive: Director of Program Management

Socios En Salud Sucursal Perú (SES) is an institution that promotes research, respecting the creative freedom of researchers; directing it towards the areas of its competence; and, ensuring that it is carried out within the standards of research ethics and responding to the needs of the country. To this end, it is of utmost importance to maintain objectivity in your investigations.


The main objective of this document is to promote the objectivity of research results by establishing a policy declaration of conflicts of interest (COI) that could affect the design, execution, and/or reports of the investigations that SES carries out. To this end, all researchers will be required to submit a COI declaration for all projects that they oversee or participate in the development of this project.

Financial conflict of interest is defined as a set of conditions in which the professional's judgment regarding the primary interest (patient well-being or validity of research or validity of research reporting), tends to be overly influenced by a secondary interest, such as financial gain.

The document is exclusively applicable to SES researchers who have and/or participate in projects or programs financed with federal funds from the Government of the United States of North America, excluding its application in other contexts. Nor does it generate any precedent nor is it binding for those SES researchers who carry out activities with funds from other funding sources than the one indicated.



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Leonid Lecca
Executive Director
Socios En Salud

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FINANCIAL CONFLICT OF INTEREST POLICY

INTRODUCTION

All researchers sponsored by the United States Public Health Service (PHS) are subject to this institutional policy that regulates financial conflicts of interest under the framework of regulation 42 CFR Part 50, Subpart F, Promoting Objectivity in Research (FCOI regulation) of the National Institutes of Health (NIH). Failure to comply with this policy may result in disciplinary action for the researcher.

DEFINITIONS

Clinical trial

It is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Conflict of Interest Committee (CDI Committee). This means the Institution Committee or the person who advises the SES Board of Directors on matters related to COI. The institution will not organize a committee; the SES Director of Program Management will assume a CDI committee role.

Financial Conflict of Interest (FCOI). This means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.


Disclosure of significant financial interests. This means the disclosure by an Investigator of significant financial interests to an Institution.

Family. Means any member of the Investigator's immediate family, specifically, dependent children and spouse.

Financial interest. This means anything of monetary value, whether or not the value is readily ascertainable.

For Researchers, the ***financial interests*** also include any reimbursed or sponsored travel undertaken by the Investigator and related to his or her institutional responsibilities. This includes trips that are paid for in the name of the Investigator, as well as trips that have been reimbursed, even if the exact monetary value is not readily available.

This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

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Investigator. It means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants.


Significant financial interest. Involves a financial interest of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities (those responsibilities that are performed on behalf of the Institution):

- a) In the case of a publicly traded entity, a SFI exists, if the aggregate value of any consideration received from the company during the 12 months prior to disclosure and the value of the equity of any holding company on the date of disclosure exceeds \$5,000. Such compensation includes salary and any payments for services not expressly deemed to be salary (e.g., consulting fees, royalties, royalties from authorship).
- b) In any non-publicly traded entity, a SFI exists, if the total value of compensation received from that entity in the 12 months prior to disclosure exceeds \$5,000, or if the investigator (or his or her spouse or dependent children) owns an equity interest (such as stock, stock options, or other ownership interests).
- c) In Intellectual property rights (e.g., patents, copyrights), a SFI exists, if your income upon the receipt of income exceeds US\$5,000 from intellectual property rights and interests that are not reimbursed by the Institution.
- d) A SFI exists if your travel is reimbursed or sponsored by an outside entity that is related to your institutional responsibilities (e.g., research, research consultation, teaching, clinical, etc.).

Institutional officer. Refers to the individual within the Institution who is responsible for the request and review of disclosures of SFIs, including those of the Investigator's family in connection with the Investigator's institutional responsibilities. For this policy, the Institutional Officer is designated as the Head of the SES Planning Unit, which is the area where regulatory documents are managed.

Institutional responsibilities. This means any professional responsibility performed by the covered individual on behalf of SES, including conducting research activities, teaching, professional practice, research consultation, institutional committee membership, and service on institutional research committees and panels (e.g. Institutional Review Board -IRB-SES)

Researcher. Means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research, or proposal for such financing, which may include, for example, collaborators or consultants.

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PD/PI. This means a project director or principal investigator of a PHS-funded research project; The PD/PI is included in the definitions of senior/key personnel and researcher in this subpart.

Public Health Service or PHS. This means the Public Health Service of the U.S. Department of Health and Human Services and any component of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Research. This means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge broadly related to public health, including social and behavioral science research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

CONFLICT OF INTERESTS


This policy is based on the expectation that researchers will manage their activities to avoid or minimize conflicts of interest and must respond appropriately when they arise. As a result, this policy informs researchers about situations that may give rise to conflicts of interest related to research and provides mechanisms for researchers and the institution to manage potential conflicts of interest. It also describes situations that are prohibited. Each researcher must familiarize himself with and comply with the provisions of this policy. If there is a conflict of interest, a researcher should speak with the Institutional Official.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their foreign and domestic SFIs to the Institution, as defined above, on an annual basis and an ad hoc basis, as described below. The Institutional Officer is responsible for the distribution, receipt, preparation, review, and maintenance of disclosure forms. The CDI Committee will assist in the review of forms and processes.

a) Annual Declarations

All Investigators must disclose their SFIs that relate to the Investigator's responsibilities to the Institution, through the Institutional Official, on an annual basis. All forms must be submitted to the Institutional Official or designee by April 30 for the preceding calendar year.

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b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All researchers must disclose their SFIs to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment.

Before entering or applying to PHS-sponsored projects where the Investigator has a SFI, the Investigator must affirm the validity of the annual declaration or submit to the Institutional Official the updated ad hoc disclosure of his or her SFI with the external entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.


Additionally, all Investigators must submit to the Institutional Official an ad hoc disclosure of any SFI acquired or discovered during the year, within thirty (30) days of discovering or acquiring the SFI.

c) Travel

Investigators must also disclose any reimbursed or sponsored travel related to their institutional activities (i.e., travel paid on behalf of the investigator but not reimbursed to the investigator, so the exact monetary value may not be available). institutional activities. liability; however, this disclosure requirement does not apply to travel reimbursed or sponsored by a local, state, or U.S. federal government agency (i.e., a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education). As part of disclosure, you are required to provide the following information: purpose of travel, identity of sponsor/organizer, destination, and duration. For the purposes of this policy, the Institutional Official will determine if additional information, including monetary value determinations or disclosures, is necessary to determine if the travel constitutes an FCOI (i.e., is related to PHS-funded research and could have a direct and significant affect on the design, conduct, or reporting of PHS-funded research). The threshold for disclosure is US\$5,000 or more.

2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICER

If the disclosure form reveals a SFI, it will be immediately reviewed by the Institutional Official or designee to determine if it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take measures to manage the financial conflict of interest, including reducing or eliminating the conflict, as appropriate. The Institutional Official may consult the CDI Committee for guidance in specific cases, or the

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application of the policy to particular situations.

If the Institutional Official determines that a manageable financial conflict of interest exists, he or she shall develop and implement a written management plan. The affected Investigator must formally commit to the proposed management strategies and sign the written management plan before any PHS-related or sponsored research moves forward.

The Institutional Officer will periodically review the ongoing activity, supervise the conduct of the activity, to ensure the open and timely dissemination of the research results, as well as supervise general compliance with the management plan.

A financial conflict of interest exists when the institution, through its Institutional Official, reasonably determines that an investigator's significant financial interest is related to an NIH-funded research project (i.e., The SFI could be affected by the research or the SFI in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

When the FCOI manager applies for a proposal funded by the NIH or other federal funds applicable to this FCOI, the manager will delegate his/her duties to the FCOI officer.

3) CLINICAL TRIALS


The specific requirements related to PHS-funded clinical research is as follows:

- a) In the event of failure to report and/or manage a financial conflict of interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the Investigator must disclose financial conflicts of interest in each public presentation of the results of the indicated PHS-sponsored research and request an addendum to previously published presentations.

4) REPORTS TO THE PHS

The Institutional Official will report financial conflicts of interest or noncompliance to PHS per PHS regulations.

Initial Reports: Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution must provide to the NIH an FCOI report regarding any Investigator Significant Financial Interest found by the Institution to be a Financial Conflict of Interest in accordance with the

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regulation.

During an Ongoing NIH-funded Research Project: The Institution must submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to the Institution during the period of award.

Annual FCOI Report: For any Financial Conflict of Interest previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists.

5) NON-COMPLIANCE BY THE INVESTIGATOR OR INSTITUTION

a) Investigator Disciplinary Action


If an Investigator fails to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action is taken as deemed appropriate by the Institutional Official.

An Institutional Official's decision to impose sanctions on an Investigator for noncompliance with this Policy, or failure to comply with the Institutional Official's decision, is described in a written explanation of the investigator's decision, to the CDI Committee and, where applicable, to the Institutional Ethics Committee, and will notify the individual of their right to appeal the decision. The Institution will promptly notify the PHS Granting Component of the action taken or to be taken. If funding for such research comes from a first beneficiary of the PHS, such notification must be made promptly to the first beneficiary, so that it can be reported to the PHS.

b) Retrospective Review when there is Non-Compliance

If the Institutional Official determines that a Financial Conflict of Interest has not been identified on time or managed promptly, including:

- Failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a Financial Conflict of Interest,
- Failure by the Institution to review or manage such a Financial Conflict of Interest,
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan

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SES will, within 120 days of the Institutional Official’s determination of noncompliance, complete a “retrospective review” of the Investigator’s activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

Documentation of the retrospective review will include the a) project number, b) project title, c) PI/PD, d) the name of the Investigator with the financial conflict of interest before the FCOI, e) the name of the entity with which the Investigator has the financial conflict of interest, f) the reason(s) for the retrospective review, g) the detailed methodology used for the retrospective review, and h) findings or results and review conclusions.




The Institutional Officer will update any report previously submitted to PHS or the first PHS recipient related to the investigation, specifying actions that will be taken to manage the financial conflict of interest in the future. This retrospective study will be completed in the manner and within the time frame established in the PHS regulations. If bias is found, the Institution will immediately notify the granting component of the PHS and submit a mitigation report per PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project, and the action plan to eliminate or mitigate the effects of the bias.

6) TRAINING

Before participating in PHS-funded research, and at least every four years thereafter, all researchers must receive training on this Policy, as well as researcher disclosure responsibilities and PHS regulations. Additionally, they must complete training within a reasonable time frame as determined by the Institutional Official if this policy is substantially modified in a manner that affects the requirements of investigators, if the investigator is new to the institution, or if determined that the investigator has not complied with this policy or a management plan related to his or her activities.

7) RECORDS RETENTION

All the investigator disclosures of financial interests and the Institution’s review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution’s determination of a Financial Conflict of Interest), and all actions under the Institution’s policy or retrospective review be retained for a period of three years from the date of submission of the final expenditure report. for Federal awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, respectively, as

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reported to the PHS and/or HHS awarding agency or pass-through entity in the case of a subrecipient. HHS awarding agencies and pass-through entities must not impose any other record retention requirements upon non-Federal entities. The exception for this statement will be:

- If any litigation, claim, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.
- When the non-Federal entity is notified in writing by the PHS and/or HHS awarding agency, cognizant agency for audit, oversight agency for audit, cognizant agency for indirect costs, or pass-through entity to extend the retention period.

For any other exception the Institutional Officer shall review 45 CFR Part 75.361.

8) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make that information available to the granting components of the PHS and/or HHS, to a requester for information regarding financial conflicts of interest related to funding by the PHS or to the primary entity that made the funding available to the Institution, if requested or required. If the Institution is requested to submit disclosure forms, conflict management plans, and related information to an external entity, the Investigator will be informed of this disclosure.

9) PUBLIC ACCESSIBILITY


Before the use of funds, SES has posted this policy on its publicly accessible website and will respond to requests, within five business days of the request, for information regarding any SFI that meets the following criteria:

- a) The SFI was disclosed and is still maintained by senior and key personnel; and
- b) The SFI has been determined to relate to PHS-funded research; and
- c) The SFI has been determined to be a financial conflict of interest.

The information that must be made available will be compatible with the requirements of the PHS regulations.

10) REGULATORY AUTHORITY

This policy applies the requirements of 42 CFR 50 Subpart F and 45 CFR 94. Where there are material differences between this policy and the requirements, those requirements must prevail.

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CONTROL OF CHANGES

Version	Date	Description	Elaboration	Review	Approval
1.0	03/19/2024	First version	Program Management Department	Director of Program Management	Executive Director
2.0	03/25/2024	Second version	Program Management Department	Director of Program Management	Executive Director
3.0	04/05/2024	Third version	Program Management Department	Director of Program Management	Executive Director



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