 <p><b>Socios</b> En Salud Partners In Health</p>	<p><b>CONFLICT OF INTEREST POLICY</b></p>	<p>Code: SES-GR-PO-01 Version: 1.0 Effective date: 25-03-2024</p>
<p><b>QUALITY MANAGEMENT SYSTEM</b></p>		<p>Page 0</p>

### **Conflict of Interest Policy – version 1.0**

**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.



Leonid Lecca García  
General Director of SES

 <p><b>Socios</b> En Salud Partners In Health</p>	<p><b>CONFLICT OF INTEREST POLICY</b></p>	<p>Code: SES-GR-PO-01 Version: 1.0 Effective date: 25-03-2024</p>
<p><b>QUALITY MANAGEMENT SYSTEM</b></p>		<p>Page 1</p>

## 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 received or held by an Investigator or an Investigator's family, regardless of whether the value is easily verifiable, including, but not limited to: salary and other payments for services (for example, consulting fees, honoraria, or paid authorship for non-academic works); any participation rights (for example, shares, stock options or other ownership interests); and intellectual property rights and interests (for example, patents, trademarks, service marks and copyrights), upon receipt of royalties or other income related to intellectual property rights and interests.

**Financial interest.** NOT included:

- a) salaries, royalties, or other remuneration of the Institution, or
- b) income from the authorship of academic or schoolwork; income from seminars, conferences, and other teaching engagements sponsored by or on the advisory committees or review panels of U.S. federal, state, or local government agencies.; of institutions de education superior of the EE.UU.;

 <p><b>Socios</b> En Salud Partners In Health</p>	<p><b>CONFLICT OF INTEREST POLICY</b></p>	<p>Code: SES-GR-PO-01 Version: 1.0 Effective date: 25-03-2024</p>
<p><b>QUALITY MANAGEMENT SYSTEM</b></p>		<p>Page 2</p>

- from research institutes affiliated with higher education institutions, university teaching hospitals, and medical centers; or
- c) participations or income from investment vehicles, such as mutual funds and retirement accounts, if the Researcher does not directly control the investment decisions made in these vehicles.

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. Excludes travel reimbursed or sponsored by U.S. federal, state, or local government agencies, U.S. institutions of higher education, and research institutes affiliated with higher education institutions, university teaching hospitals, and medical centers.


**Significant financial interest.** Involves a financial interest that reasonably appears to be related to the institutional responsibilities of the Investigator, and:

- a) in the case of a listed entity, the aggregate value of any salary or other payments for services received during the 12 months before disclosure, and the value of any equity interest during the 12 months prior or as of the date of disclosure exceeds US\$5,000; or
- b) in the case of a non-listed entity, the aggregate value of any salary or other payments for services received during the 12 months before disclosure exceeds US\$5,000; or
- c) in the case of an unlisted entity, is an equity interest in any security during the 12 months preceding or from the date of disclosure; or
- d) if your income exceeds US\$5,000 about intellectual property rights and interests not reimbursed by the Institution; or
- e) if your travel is reimbursed or sponsored for activities related to your institutional responsibilities.

**Institutional officer.** Refers to the individual within the Institution who is responsible for the request and review of disclosures of significant financial interests, 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 the professional responsibilities of a Researcher on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include, for example: activities such as research, research consultation, teaching, professional practice, membership on institutional committees, and service on panels such as Data and Security Monitoring meetings.

**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

 <p><b>Socios</b> En Salud Partners In Health</p>	<p><b>CONFLICT OF INTEREST POLICY</b></p>	<p>Code: SES-GR-PO-01 Version: 1.0 Effective date: 25-03-2024</p>
<p><b>QUALITY MANAGEMENT SYSTEM</b></p>		<p>Page 3</p>

of PHS-funded research, or proposal for such financing, which may include, for example, collaborators or consultants.

**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).

## 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 financial interests 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 Significant Financial Interests 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.

#### b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All researchers must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30

 <p><b>Socios</b> En Salud Partners In Health</p>	<p><b>CONFLICT OF INTEREST POLICY</b></p>	<p>Code: SES-GR-PO-01 Version: 1.0 Effective date: 25-03-2024</p>
<p><b>QUALITY MANAGEMENT SYSTEM</b></p>		<p>Page 4</p>

days of their initial appointment or employment.

Before entering or applying to PHS-sponsored projects where the Investigator has a Significant Financial Interest, 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 Significant Financial Interest 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 Significant Financial Interest acquired or discovered during the year, within thirty (30) days of discovering or acquiring the Significant Financial Interest.


### c) Travel

Researchers must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interests and Significant Financial Interests. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the organizer/sponsor, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information (for example, monetary value if not disclosed) is necessary to determine if the trip constitutes Financial Conflict of Interest with the Investigator's research.

## 2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICER

If the disclosure form reveals a Significant Financial Interest, 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 application of the policy to particular situations.

A financial conflict of interest will exist when the Institutional Official or his/her designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting for PHS-sponsored research. 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.

 <p><b>Socios</b> En Salud Partners In Health</p>	<p><b>CONFLICT OF INTEREST POLICY</b></p>	<p>Code: SES-GR-PO-01 Version: 1.0 Effective date: 25-03-2024</p>
<p><b>QUALITY MANAGEMENT SYSTEM</b></p>		<p>Page 5</p>

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.

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

#### **Review of Significant Financial Interests Related to Clinical Trials**

Clinical trials involve especially sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

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. If research funding is made available to a first PHS recipient, such reports will be made to the first beneficiary before the expenditure of any portion of the funds and within 60 days of the identification of any financial conflict, so that the first beneficiary will be able to comply with its reporting obligations to the PHS.

### 5) NON-COMPLIANCE BY THE INVESTIGATOR

#### **a) 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

 <p><b>Socios</b> En Salud Partners In Health</p>	<p><b>CONFLICT OF INTEREST POLICY</b></p>	<p>Code: SES-GR-PO-01 Version: 1.0 Effective date: 25-03-2024</p>
<p><b>QUALITY MANAGEMENT SYSTEM</b></p>		<p>Page 6</p>

the PHS, such notification must be made promptly to the first beneficiary, so that it can be reported to the PHS.

**b) Retrospective Review**


Additionally, if the Institutional Official determines that a Financial Conflict of Interest has not been identified or managed promptly, including but not limited to failures by an Investigator to disclose a significant financial interest that is determined to be a financial conflict of interest, or failure to materially comply with a financial conflict of interest management plan, a committee designated by the Institutional Official will be charged with completing a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the research conducted during the period of noncompliance was biased in design, conduct, or investigation reporting.

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.

 <p><b>Socios</b> En Salud Partners In Health</p>	<p><b>CONFLICT OF INTEREST POLICY</b></p>	<p>Code: SES-GR-PO-01 Version: 1.0 Effective date: 25-03-2024</p>
<p><b>QUALITY MANAGEMENT SYSTEM</b></p>		<p>Page 7</p>

**7) RECORDS RETENTION**

Unless any litigation, claim, financial management review, or audit is commenced before the expiration of the three years, the institutional officer will retain all disclosure forms, conflict management plans, and related documents for a period of three years (digital or paper) from the date the final expense report was submitted to the PHS or the first PHS beneficiary. In these cases, the records will be retained until all disputes, claims, or audit findings related to the files have been resolved and a final decision has been made.

**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 may respond to requests, within five business days of the request, for information regarding any significant financial interest that meets the following criteria:


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



	<b>CONFLICT OF INTEREST POLICY</b>	Code: SES-GR-PO-01 Version: 1.0 Effective date: 25-03-2024
<b>QUALITY MANAGEMENT SYSTEM</b>		Page 8

Revision record					
Version	Date	Description	Elaboration	Review	Approval
1.0	03/22/2024	First version			
		-			



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