



SOUTHERN CALIFORNIA EYE INSTITUTE

Policy on Financial Conflicts of Interest in Public Health Service (PHS)-Funded Research

Promoting Objectivity in Research: 42 CFR Part 50, Subpart F

Administrative Designations

Item	Entry
Policy number	SCEI-RSCH-001
Effective date	January 1, 2023
Supersedes	Original policy adopted January 1, 2023; reviewed, updated, and reaffirmed August 26, 2026
Designated Official	Raya Karelin, MBA, Executive Director, Institutional Official, and Designated FCOI Official SCEI administrative office 833-270-3937
Alternate Designated Official	Independent alternate designated by the SCEI President/CEO or Board of Directors when the Designated Official has a conflict
Approved by	SCEI Board of Directors; administered under the authority of Rohit Varma, MD, MPH, President and Chief Executive Officer
Annual disclosure due date	January 31 of each year, and at all additional times required by Section 5
Policy posted at	https://www.sceyes.org/fcoi
FCOI information requests to	Institutional FCOI Official, Southern California Eye Institute, 1300 North Vermont Avenue, Doctors Tower, Suite 101, Los Angeles, CA 90027 833-270-3937 www.sceyes.org

1. Purpose, Scope, and Applicability

The Southern California Eye Institute ("SCEI" or the "Institution") is committed to ensuring that the design, conduct, and reporting of research it conducts with funding from the Public Health Service ("PHS"), including the National Institutes of Health ("NIH"), is free from bias resulting from Investigator financial conflicts of interest.

This Policy establishes how SCEI identifies, reviews, manages, reports, and records Investigator financial conflicts of interest, in compliance with 42 CFR Part 50, Subpart F ("Promoting Objectivity in Research"), the NIH Grants Policy Statement Section 4.1.10, and NIH Guide Notice NOT-OD-21-002. It is maintained in writing, kept up to date, and enforced, as required by 42 CFR 50.604(a).

This Policy applies to every Investigator, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by, or proposed for funding by, the PHS at or through SCEI, and to subrecipient Investigators to whom it is extended under Section 11. It applies to all PHS grants and cooperative agreements, except that, consistent with 42 CFR 50.602, it does not apply to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications and awards.

Research funded by other sponsors is governed by the applicable sponsor requirements and any separate SCEI policies. This Policy is limited to PHS-funded research.

2. Definitions

These definitions are adopted from 42 CFR 50.603 and govern the interpretation of this Policy.

Designated Official. The individual designated under 42 CFR 50.604(d) to solicit and review disclosures of Significant Financial Interests, determine relatedness and the existence of a Financial Conflict of Interest, develop and monitor management plans, and submit FCOI reports to the PHS Awarding Component. The Designated Official and Alternate are identified on the Administrative Designations page.

Financial Conflict of Interest (FCOI). A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report. The Institution's report of a Financial Conflict of Interest to a PHS Awarding Component, submitted through the eRA Commons FCOI Module.

Financial interest. Anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities. An Investigator's professional responsibilities performed on behalf of SCEI, including research, research consultation, teaching or mentoring, scholarly activities, committee service, and institutional administration.

Investigator. 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, or proposed for such funding, including, for example, collaborators or consultants.

Manage. Taking action to address a Financial Conflict of Interest, which can include reducing or eliminating it, to ensure to the extent possible that the design, conduct, and reporting of research will be free from bias.

PD/PI. The project director or principal Investigator of a PHS-funded research project; the PD/PI is included within the definitions of senior/key personnel and Investigator.

PHS Awarding Component. The organizational unit of the PHS that funds the research subject to this Policy.

Research. A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, encompassing basic and applied research and product development.

Senior/key personnel. The PD/PI and any other person identified as senior/key personnel by SCEI in a grant application, progress report, or other report submitted to the PHS.

2.1 Significant Financial Interest (SFI)

A Significant Financial Interest is 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, consisting of one or more of the following:

- Publicly traded entity: remuneration received from the entity in the twelve (12) months preceding the disclosure plus the value of any equity interest as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (for example, consulting fees, honoraria, paid authorship). Equity interest includes stock, stock options, or other ownership interest.
- Non-publicly traded entity: remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or the Investigator (or spouse or dependent children) holds any equity interest of any value.
- Intellectual property rights and interests (for example, patents and copyrights), upon receipt of income related to such rights and interests.

Both foreign and domestic financial interests must be disclosed.

2.2 Reimbursed and sponsored travel

Investigators must also disclose reimbursed or sponsored travel related to their Institutional Responsibilities. This means travel paid on behalf of the Investigator and not reimbursed to the Investigator, such that the exact value may not be readily available. The initial disclosure must state the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration. The Designated Official will determine whether further information, including monetary value, is needed to determine whether the travel constitutes an FCOI.

This requirement does not apply to travel reimbursed or sponsored by a federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education.

2.3 Exclusions

Significant Financial Interest does not include: salary, royalties, or other remuneration paid by SCEI to a currently employed or appointed Investigator, including intellectual property rights assigned to SCEI and related royalty-sharing agreements; any ownership interest in SCEI held by the Investigator if SCEI is a commercial or for-profit organization; income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions; or income from seminars, lectures, teaching engagements, advisory committees, or review panels sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

3. Designated Official

SCEI designates a single Designated Official, with one Alternate, as identified on the Administrative Designations page. The Designated Official is responsible for soliciting, collecting, and reviewing SFI

disclosures; determining relatedness and the existence of an FCOI; developing, implementing, and monitoring management plans; conducting retrospective reviews and preparing mitigation reports; submitting FCOI reports through eRA Commons; responding to public requests under Section 8; maintaining records under Section 12; and ensuring Investigator training is delivered and documented under Section 4.

The Alternate acts as Designated Official where the Designated Official is the subject of a disclosure or otherwise has a conflict with respect to a particular review.

4. Investigator Training

SCEI will inform each Investigator of this Policy, of the Investigator's disclosure responsibilities, and of the requirements of 42 CFR Part 50, Subpart F. Each Investigator must complete FCOI training prior to engaging in research related to any PHS-funded grant, at least every four (4) years thereafter, and immediately when: (i) SCEI revises this Policy or its procedures in a manner that affects Investigator requirements; (ii) an Investigator is new to SCEI; or (iii) SCEI finds an Investigator is not in compliance with this Policy or a management plan.

Training consists of the NIH FCOI Tutorial together with SCEI-specific instruction on this Policy and its disclosure procedures. The Designated Official maintains documentation of each Investigator's training completion date.

5. Investigator Disclosure

Each Investigator must disclose to the Designated Official, using Form 1 (Investigator FCOI Certification and Disclosure), all Significant Financial Interests and all reimbursed or sponsored travel described in Section 2.2. Disclosure is required whether or not the Investigator believes the interest is related to the PHS-funded research; relatedness is determined by the Institution, not the Investigator. An Investigator with nothing to disclose submits a negative certification on the same schedule.

Trigger	Deadline
Investigator planning to participate in PHS-funded research	No later than the time of application for PHS-funded research
Investigator participating in PHS-funded research	At least annually during the period of the award, by the annual due date on the Administrative Designations page; must include any interest not previously disclosed and updated information on previously disclosed interests
New Significant Financial Interest discovered or acquired (for example, by purchase, marriage, or inheritance)	Within thirty (30) days of discovering or acquiring the interest
Investigator new to an ongoing PHS-funded project	Before assuming responsibility for the design, conduct, or reporting of the research

6. Institutional Review and Determination

The Designated Official reviews each disclosure in two steps, consistent with 42 CFR 50.604(f).

Relatedness. An SFI is related to PHS-funded research when the Designated Official reasonably determines that the SFI could be affected by the research, or is in an entity whose financial interest could be affected by the research. The Investigator may be involved in this determination.

Conflict. An FCOI exists when the Designated Official reasonably determines that a related SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Relevant factors include the nature and magnitude of the interest, the Investigator's role in the project, the degree to which the interest could be affected by the research outcome, the involvement of human subjects, and whether the research evaluates a product, technology, or service of the entity in which the interest is held.

The Designated Official documents the outcome of every review, including reviews that do not result in an FCOI determination, and notifies the Investigator in writing where an interest was disclosed. Documentation is recorded as follows: a disclosure that reports one or more financial interests or instances of sponsored travel is reviewed on Form 2 (Institutional FCOI Determination); a negative certification is recorded in the Project Disclosure Log, which also records receipt of every Form 1 submitted for the project.

6.1 Timing

Circumstance	Required action and timeframe
Before SCEI expends any funds under a PHS-funded research project	Review all disclosures; determine relatedness; determine whether an FCOI exists; and, if so, implement a management plan and submit an initial FCOI report
An Investigator new to an ongoing project discloses an SFI, or an existing Investigator discloses a new SFI	Within sixty (60) days: review the disclosure, determine relatedness and whether an FCOI exists, and, if so, implement at least an interim management plan
SCEI identifies an SFI that was not disclosed timely or not previously reviewed, including one not timely reviewed or reported by a subrecipient	Within sixty (60) days: review the SFI, determine relatedness and whether an FCOI exists, and, if so, implement at least an interim management plan. A retrospective review under Section 10 is also required

The Designated Official may impose interim measures on the Investigator's participation in the research between the date of disclosure and the completion of the review.

7. Management and Monitoring

Where an FCOI is identified, the Designated Official develops and implements a written management plan on Form 3 (Management Plan and Monitoring Record), specifying the actions taken and to be taken to manage the conflict. The Investigator must acknowledge in writing that they agree to its conditions. Conditions may include, but are not limited to:

- Public disclosure of the FCOI, for example when presenting or publishing the research;
- For research involving human subjects, disclosure of the FCOI directly to research participants, including in the informed consent process and documents as approved by the IRB of record;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or part of the research;
- Reduction or elimination of the financial interest (for example, sale of an equity interest); or
- Severance of the relationships that create the conflict.

Where SCEI conducts clinical research involving human subjects, the Designated Official coordinates with the IRB of record so that any plan condition affecting participant-facing materials is implemented in the approved protocol and consent documents.

Monitoring. The Designated Official monitors compliance with each management plan on an ongoing basis until the completion of the PHS-funded research project. The frequency and method of monitoring are specified in the management plan based on the nature of the conflict.

8. Public Accessibility of FCOI Information

Prior to the expenditure of any funds under a PHS-funded research project, SCEI ensures public accessibility of information concerning any Significant Financial Interest that meets all three of the following criteria: the SFI was disclosed and is still held by senior/key personnel; SCEI has determined that the SFI is related to the PHS-funded research; and SCEI has determined that the SFI is an FCOI.

Method. As permitted by 42 CFR 50.605(a)(5)(i), SCEI makes this information available by written response to any requestor within five (5) business days of a request. Requests are directed to the contact on the Administrative Designations page. Each written response will note that the information is current as of the date of the correspondence and is subject to updates on at least an annual basis and within sixty (60) days of SCEI's identification of a new FCOI, which the requestor should request subsequently.

Each response includes, at a minimum: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI, or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. Dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; \$20,000–\$100,000 in increments of \$20,000; and above \$100,000 in increments of \$50,000.

The Designated Official maintains this information in a form that permits a response within five business days, and keeps it available for at least three (3) years from the date it was most recently updated. If SCEI later elects to post individual FCOI information on a publicly accessible website instead, the posted information must be updated at least annually and within sixty (60) days of the identification of a new FCOI.

The Policy itself. Separate from individual FCOI information, this Policy is posted on SCEI's publicly accessible website at the address on the Administrative Designations page, as required by 42 CFR 50.604(a), and is submitted in the eRA Commons Institution Profile (IPF) Module under NOT-OD-21-002.

9. Reporting to the PHS Awarding Component

SCEI submits FCOI reports through the eRA Commons FCOI Module as follows:

Report	Timing
Initial	Prior to the expenditure of any funds under the project, for any SFI found to be conflicting, with confirmation that a management plan is implemented. If SCEI identifies an FCOI and eliminates it before expenditure of PHS-awarded funds, no report is submitted.
Subsequent	Within sixty (60) days of identifying any FCOI after the initial report, for example, upon the participation of an Investigator new to the project.
Revised	Following a retrospective review, if appropriate, specifying the actions to be taken going forward.
Mitigation	Promptly, if bias is found, together with prompt notification to the PHS Awarding Component.
Annual	For the duration of the project period, including extensions with or without funds, addressing the status of the FCOI and any changes to the

Report	Timing
	management plan, and stating whether the conflict is still being managed or why it no longer exists. Submitted at the same time the institution is required to submit an annual progress report or multi-year progress report, or at the time of an extension, as applicable.

Each report contains sufficient information for the PHS Awarding Component to understand the nature and extent of the conflict and to assess the management plan, including: project number; PD/PI or contact PD/PI; name of the Investigator with the FCOI; name of the entity; nature of the financial interest; value or dollar range, or a statement that the value cannot be readily determined; how the interest relates to the research and the basis for the conflict determination; and the key elements of the management plan, namely the Investigator's role and principal duties, the conditions of the plan, how the plan safeguards objectivity, confirmation of the Investigator's agreement, and how compliance will be monitored.

10. Retrospective Review and Mitigation

A retrospective review is required whenever an FCOI is not identified or managed in a timely manner, including failure by an Investigator to disclose an SFI that SCEI determines to be an FCOI, failure by SCEI to review or manage such an FCOI, or failure by an Investigator to comply with a management plan.

Within one hundred twenty (120) days of SCEI's determination of noncompliance, the Designated Official completes and documents a retrospective review of the Investigator's activities and the research project to determine whether any PHS-funded research conducted during the period of noncompliance was biased in its design, conduct, or reporting. The documentation includes the project number and title; the PD/PI or contact PD/PI; the name of the Investigator with the FCOI; the name of the entity; the reasons for the review; the detailed methodology used, including the review process, composition of any review panel, and documents reviewed; the findings; and the conclusions.

SCEI updates any previously submitted FCOI report as appropriate. If bias is found, SCEI promptly notifies the PHS Awarding Component and submits a mitigation report containing, at a minimum, the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and SCEI's plan of action or actions taken to eliminate or mitigate the effect of the bias, including the extent of harm and an analysis of whether the project is salvageable. Annual FCOI reports continue thereafter.

11. Subrecipients

Where SCEI carries out PHS-funded research through a subrecipient, the written subaward agreement will establish whether this Policy or the subrecipient's FCOI policy applies to the subrecipient's Investigators.

- If the subrecipient's policy applies, the subrecipient must certify in the agreement that its policy complies with 42 CFR Part 50, Subpart F. If it cannot so certify, the agreement will state that subrecipient Investigators are subject to this Policy for disclosing SFIs directly related to their work for SCEI.
- Where the subrecipient's policy applies, the agreement will require the subrecipient to report identified FCOIs to SCEI as follows: an FCOI existing at the time of award, before the subrecipient begins work or incurs project costs; a newly identified FCOI, within thirty (30) days after identification; and the annual report, at least thirty (30) days before SCEI's annual NIH reporting deadline.

- Where this Policy applies to the subrecipient's Investigators, the agreement will require the subrecipient to submit all Investigator SFI disclosures to SCEI on the same schedule set out in Section 5.

These time periods are set so that SCEI can meet its own federal obligations: reporting prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI. SCEI provides FCOI reports to the PHS Awarding Component for all FCOIs of all subrecipient Investigators.

12. Recordkeeping

The Designated Official maintains records of all Investigator disclosures; SCEI's review of and response to each disclosure, whether or not it resulted in an FCOI determination; management plans and monitoring documentation; retrospective reviews and mitigation reports; FCOI reports submitted to the PHS; and training records. Records are retained for at least three (3) years from the date the final expenditure report is submitted to the PHS or, where applicable, from other dates specified in 2 CFR 200.334.

Disclosure records are maintained confidentially and shared only with those who need them to administer this Policy, or as required by law or by HHS.

13. Enforcement and Sanctions

Compliance with this Policy is a condition of participation in PHS-funded research at SCEI. Failure to submit a required disclosure, submission of an incomplete or knowingly inaccurate disclosure, failure to complete required training, or failure to comply with a management plan may result in one or more of the following actions, imposed by the Designated Official in consultation with the approving official identified on the Administrative Designations page:

- Written warning and required retraining;
- Additional conditions on the Investigator's participation in the research;
- Required public disclosure or correction of prior presentations or publications;
- Suspension or removal of the Investigator from all or part of the project;
- Ineligibility to serve as PD/PI or senior/key personnel on future applications for a specified period;
- Suspension of expenditure authority on the affected project; and
- Disciplinary action up to and including termination of employment or appointment, in accordance with applicable SCEI personnel policies and California law.

14. Federal Remedies

If an Investigator's failure to comply with this Policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research, SCEI promptly notifies the PHS Awarding Component of the corrective action taken or to be taken.

The PHS Awarding Component and HHS may inquire at any time, before, during, or after award, into any Investigator disclosure and SCEI's review of and response to it, whether or not it resulted in an FCOI determination. SCEI will submit, or permit on-site review of, all pertinent records. The PHS Awarding Component may impose specific conditions under 2 CFR 200.208 or suspend funding or take other enforcement action under 2 CFR 200.339 until the matter is resolved.

If HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported as required, SCEI will require the

Investigator to disclose the FCOI in each public presentation of the results and to request an addendum to previously published presentations.

15. Institutional Certification

In each application for PHS funding to which 42 CFR Part 50, Subpart F applies, SCEI certifies that it: has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest for all research projects for which PHS funding is sought or received; shall promote and enforce Investigator compliance with the regulation, including disclosure of Significant Financial Interests; shall manage financial conflicts of interest and provide initial and ongoing FCOI reports consistent with the regulation; agrees to make information available promptly upon request to HHS relating to any Investigator disclosure and SCEI's review of and response to it, whether or not it resulted in an FCOI determination; and shall fully comply with 42 CFR Part 50, Subpart F.

16. Policy Administration

This Policy is maintained by the Designated Official. It will be reviewed periodically and whenever applicable federal requirements change. Material revisions require approval by the approving official identified on the Administrative Designations page and trigger immediate Investigator retraining under Section 4.

16.1 Associated forms

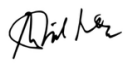
- Form 1: Investigator FCOI Certification and Disclosure
- Form 2: Institutional FCOI Determination (completed for each disclosure reporting a financial interest or sponsored travel)
- Form 3: Management Plan and Monitoring Record
- Form 4: Retrospective Review Record (used only if noncompliance occurs)
- Project Disclosure Log
- Designated Official Administrative Checklist

16.2 Authorities

- 42 CFR Part 50, Subpart F, Promoting Objectivity in Research (76 FR 53283, August 25, 2011), as currently codified.
- NIH Grants Policy Statement, Section 4.1.10, Financial Conflict of Interest
- NOT-OD-21-002, Required Submission of Financial Conflict of Interest Policy into the eRA Commons Institution Profile (IPF) Module
- NOT-OD-22-210, Financial Conflict of Interest (FCOI) and Other Support: Reminders
- 2 CFR 200.208, 200.334, and 200.339

Policy history: Originally effective January 1, 2023; reviewed, updated, and reaffirmed August 26, 2026. Next scheduled review no later than August 26, 2030, or earlier if federal requirements change.

16.3 Approval

Name and title	Signature	Date
Approved by: Rohit Varma, MD, MPH, President and Chief Executive Officer		08/26/2026
Acknowledged and accepted by: Raya Karelin, MBA, Executive Director, Institutional Official, and Designated FCOI Official		08/26/2026