SAGICO VA USA, LLC

Financial Conflict of Interest Policy

Promoting Objectivity in Research
Complies with 42 CFR Part 50, Subpart F

Effective date: August 27, 2026

Approved by: James J. Gibson, Jr., Founder and Signing Official

Review cycle: Annually *(Note: or as needed by federal law or material changes)*

1. Purpose and Scope

This policy establishes the standards and procedures by which SAGICO VA USA, LLC (the "Company") identifies, manages, reduces, or eliminates financial conflicts of interest that could directly and significantly affect the design, conduct, or reporting of research funded by the Public Health Service, including the National Institutes of Health.

This policy implements 42 CFR Part 50, Subpart F. It applies to the Company as an Institution applying for or receiving PHS research funding, and to each Investigator who plans to participate in or participates in such research. Consistent with 42 CFR 50.602, this policy does not apply to SBIR or STTR Phase I applications. It does apply to SBIR and STTR Phase II and Direct to Phase II applications and awards.

2. Definitions

Investigator 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. This may include subrecipients, collaborators, and consultants.

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

Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following, held by the Investigator or by the Investigator's spouse or dependent children, that reasonably appears related to the Investigator's institutional responsibilities:

- With regard to a publicly traded entity, remuneration received in the twelve months preceding disclosure plus the value of any equity interest as of the date of disclosure, where the aggregate exceeds $5,000.
- With regard to a non-publicly traded entity, remuneration received in the twelve months preceding disclosure that exceeds $5,000, or any equity interest of any value.
- Intellectual property rights and interests, including patents and copyrights, upon receipt of income related to those rights and interests.
- Reimbursed or sponsored travel related to institutional responsibilities, excluding travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

Significant Financial Interest does not include salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed by or otherwise appointed by the Company; income from investment vehicles such as mutual funds and retirement accounts in which the Investigator does not directly control investment decisions; or income from seminars, lectures, or teaching engagements sponsored by, or service on advisory or review panels for, a federal, state, or local government agency or an institution of higher education.

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

3. Public Accessibility

The Company shall maintain this policy in current, written, and enforced form and shall make it available on a publicly accessible website. If the Company does not maintain a public website, it shall provide this policy to any requestor within five business days of a request.

Requests for this policy may be directed to the Designated Official identified in Section 5.

4. Investigator Disclosure Requirements

Each Investigator shall disclose to the Designated Official all Significant Financial Interests, and those of the Investigator’s spouse and dependent children, that reasonably appear related to the Investigator’s institutional responsibilities.

Disclosures shall be made using the Company’s Investigator Financial Interest Disclosure Form and shall be submitted:

- No later than the time of application for PHS-funded research.
- At least annually during the period of the award.
- Within thirty days of discovering or acquiring a new Significant Financial Interest.

Investigators shall disclose the existence of any interest and, on request, provide sufficient information for the Designated Official to determine whether the interest is related to the research and whether it constitutes a Financial Conflict of Interest.

5. Designated Official and Review

The Company designates [NAME AND TITLE] as the Designated Official responsible for soliciting and reviewing disclosures, determining relatedness, identifying Financial Conflicts of Interest, and developing and monitoring management plans.

Where the Designated Official is also the Investigator making a disclosure, the disclosure shall be referred to an independent reviewer who is not subject to the Investigator’s supervision or control. The Company shall document the identity of that reviewer and the basis of the determination. An independent reviewer may be an outside advisor, counsel, or a member of the Company’s governing body without a financial interest in the research.

The Designated Official shall review each disclosure and determine whether the Significant Financial Interest is related to the PHS-funded research and, if so, whether it could directly and significantly affect the design, conduct, or reporting of that research.

6. Management of Financial Conflicts of Interest

Where a Financial Conflict of Interest is identified, the Company shall develop and implement a written management plan before expenditure of any funds under the award. Management measures may include:

- Public disclosure of the financial interest in presentations and publications arising from the research.
- Disclosure of the financial interest directly to participants, where applicable.
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research from bias.
- Modification of the research plan.
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- Reduction or elimination of the financial interest.
- Severance of relationships that create the conflict.

The Investigator shall acknowledge the management plan in writing. The Designated Official shall monitor compliance on an ongoing basis until completion of the research.

7. Reporting to the PHS Awarding Component

The Company shall provide an initial FCOI report to the PHS Awarding Component prior to expenditure of funds under the award, and shall not permit expenditure until the report is submitted and a management plan is in place.

Thereafter, the Company shall provide an annual FCOI report for the duration of the award, and shall report within sixty days any Financial Conflict of Interest identified subsequent to the initial report, including those arising from newly acquired interests or from Investigators newly participating in the research.

Where bias is found in the design, conduct, or reporting of research, the Company shall promptly notify the PHS Awarding Component and submit a mitigation report.

8. Subrecipients

Where the Company carries out PHS-funded research through a subrecipient, the written agreement with that subrecipient shall specify whether the Company's policy or the subrecipient's policy will apply to the subrecipient's Investigators.

Where the subrecipient's policy applies, the agreement shall require the subrecipient to certify that its policy complies with 42 CFR Part 50, Subpart F, and to report identified Financial Conflicts of Interest to the Company in sufficient time for the Company to meet its own reporting obligations.

Where the Company's policy applies, the agreement shall specify the time period for the subrecipient to submit disclosures to the Company.

Note: the University of Miami maintains its own FCOI policy compliant with 42 CFR Part 50, Subpart F. The subaward agreement should specify that the University of Miami policy governs its Investigators, and should require reporting to the Company in time to meet federal deadlines.

9. Investigator Training

Each Investigator shall complete training on this policy, on the Investigator's disclosure responsibilities, and on the requirements of 42 CFR Part 50, Subpart F prior to engaging in PHS-funded research, and at least every four years thereafter.

Training shall additionally be required immediately when the Company revises this policy in a manner affecting Investigator requirements, when an Investigator new to the Company begins participation, or when the Company finds that an Investigator has not complied with this policy or with a management plan.

10. Recordkeeping

The Company shall maintain records of all Investigator disclosures and of all actions taken to review, manage, reduce, or eliminate Financial Conflicts of Interest for at least three years from the date the final expenditure report is submitted, or longer where required by 45 CFR 75.361.

11. Enforcement and Noncompliance

Failure by an Investigator to comply with this policy or with an established management plan may result in suspension or removal from the research, withholding of compensation, or other action the Company determines appropriate.

Where the Company identifies noncompliance, it shall conduct a retrospective review within one hundred twenty days to determine whether the research conducted during the period of noncompliance was biased, and shall document and report the review as required.

12. Review and Revision

This policy shall be reviewed at least annually and revised as necessary to reflect changes in federal requirements or Company operations. The current version shall at all times be the version made publicly accessible under Section 3.

Signed and Adopted by: James Gibson, President, SAGICO VA USA, LLC

SAGICO VA USA, LLC
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