



Financial Conflict of Interest Policy

Policy on objectivity in research funded by the U.S. Public Health Service, including the U.S. Food and Drug Administration

Item	Detail
Policy owner	Chief Executive Officer
FCOI Official	Chief Financial Officer
Approved by	Russell M. Webster, President and Chief Executive Officer
Effective date	October 30, 2026
Next review	October 2027, or sooner if federal rules change

1. Purpose

Food Enterprise Solutions, LLC (FES) is committed to research that is objective and free from bias. This policy explains how FES identifies, manages, and reports financial interests that could affect, or appear to affect, the design, conduct, or reporting of research funded by the U.S. Public Health Service (PHS), including the U.S. Food and Drug Administration (FDA).

This policy meets the requirements of the federal regulation on Promoting Objectivity in Research, 42 CFR Part 50, Subpart F. Where this policy and the regulation differ, the regulation applies.

2. Who This Policy Covers

This policy applies to every **Investigator** on research funded by PHS, or proposed for PHS funding, at FES. An Investigator is the Project Director or Principal Investigator (PD/PI) and any other person, whatever their title or position, who is responsible for the design, conduct, or reporting of that research. This includes FES employees, consultants, and contractors who meet this definition.

The FCOI Official decides who counts as an Investigator for each award and keeps a current list.

3. Key Terms

Term	Meaning
Significant Financial Interest (SFI)	A financial interest of the Investigator, or of the Investigator's spouse or dependent children, that reasonably appears related to the Investigator's work for FES. Section 4 lists what counts.
Financial Conflict of Interest (FCOI)	An SFI that the FCOI Official decides could directly and significantly affect the design, conduct, or reporting of PHS funded research.
Institutional responsibilities	An Investigator's professional duties for FES, such as research, consulting, teaching, and service on committees or panels.
Management plan	A written plan setting out the steps FES will take to manage an FCOI, such as public disclosure, independent monitoring, or a change in the Investigator's role.

4. What Must Be Disclosed

An SFI includes any of the following, when it reasonably appears related to the Investigator's work for FES:

- a. Publicly traded entities.** Payments received from the entity in the past 12 months, plus the value of any equity (such as stock or stock options) held in it on the day of disclosure, that together exceed \$5,000. Payments include salary, consulting fees, honoraria, and paid authorship.
- b. Entities not publicly traded.** Payments received from the entity in the past 12 months that exceed \$5,000, or any equity interest at all, whatever its value.
- c. Intellectual property.** Income over \$5,000 in the past 12 months from patents, copyrights, or licenses that are not paid through FES.
- d. Sponsored or reimbursed travel.** Any travel related to the Investigator's FES duties that someone else paid for or reimbursed, other than the Investigator's own employer. Investigators report the purpose, sponsor, destination, and length of each trip.

The following do **not** need to be disclosed: salary and other payments from FES; income from investment vehicles such as mutual funds and retirement accounts that the Investigator does not directly control; income from seminars, lectures, teaching, advisory committees, or review panels for a U.S. federal, state, or local government agency, a U.S. institution of higher education, or a research institute or medical center affiliated with one; and travel paid for by those same bodies.

5. Training

Each Investigator must complete FCOI training before starting work on PHS funded research, and at least every four years after that. Investigators must also retrain within a reasonable time if FES changes this policy in a way that affects them, if they are new to FES, or if FES finds that they did not comply with this policy. FES uses the free online FCOI training module from the National Institutes of Health (NIH) or an equivalent course. The FCOI Official keeps records of who completed training and when.

6. When to Disclose

When	What the Investigator does
Before work starts	Submits a disclosure form listing all SFIs, or confirming there are none, before working on PHS funded research and before FES spends award funds on that work
Every year	Updates the disclosure at least once a year during the award, on a date the FCOI Official sets
Within 30 days of a change	Discloses any new SFI within 30 days of acquiring or discovering it

Investigators use the FES Financial Interest Disclosure Form and send it to the FCOI Official.

7. Review and Management

The FCOI Official reviews each disclosure and decides whether any SFI relates to the PHS funded research and, if so, whether it is an FCOI. For new disclosures made during an award, the review is completed within 60 days. If the FCOI Official has a personal interest in a disclosure, or is the person disclosing, the Vice President for Programs carries out the review instead.

If the FCOI Official finds an FCOI, FES will put a management plan in place before any further award funds are spent on the affected work. The plan may include public disclosure of the FCOI, independent monitoring of the research,

changes to the Investigator's role, a reduction or end to the financial interest, or ending the relationship that creates the conflict. The Investigator must agree to and follow the plan, and the FCOI Official monitors it until the award ends.

8. Reporting to FDA

FES reports to FDA, through the eRA Commons FCOI module, as the regulation requires:

Before spending funds on a new award, for any FCOI identified at that time.

Within 60 days of identifying a new FCOI during the award.

Each year during the award, with the status of each FCOI and any change to its management plan, at the same time as the annual progress report or as FDA requests.

If FES finds that an FCOI was not disclosed or reviewed on time, or that an Investigator did not follow a management plan, FES will complete a review of the research within 120 days to find out whether it was affected by bias, update its report to FDA, and, where bias is found, submit a mitigation report as the regulation requires.

9. Public Access

Before spending funds on a PHS award, FES will respond within five business days to any written request for information about an FCOI held by senior or key personnel on that award. The response includes the person's name, title, and role on the project; the name of the entity in which the interest is held; the nature of the interest; and its approximate dollar value in the ranges set by the regulation. FES keeps this information available for at least three years from the date it was last updated. Requests should be sent to the contact in Section 13.

10. Contractors and Collaborators

When a consultant or contractor working on PHS funded research meets the definition of Investigator, FES will require them, in writing, to follow this policy or a policy of their own organization that meets the regulation, and to disclose SFIs to FES on the same schedule.

11. Records

FES keeps all disclosures, training records, reviews, management plans, and actions taken under this policy for at least three years from the date FES submits the final expenditure report for the award, or longer where the regulation requires.

12. Noncompliance

Failure to disclose an SFI, to complete training, or to follow a management plan is a breach of this policy. Depending on the case, FES may take corrective action, up to and including removing the person from the research or ending their employment or contract. FES will also take any action FDA requires.

13. Questions and Requests

Questions about this policy, and written requests under Section 9, should be sent to the FCOI Official, Food Enterprise Solutions, LLC, at shola.ajibola@foodsolutions.global.