

NIH Financial Conflict of Interest Policy

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1. Purpose

The purpose of this Policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard research integrity funded by the National Institute of Health ("NIH"). This policy has been developed to address and comply with the specific federal agency requirements as defined in the 2011 Revised Regulations 42 CFR part 50 subpart F "Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Final Rule." ("FCOI Regulation"). This regulation was developed to promote objectivity in research by establishing standards that provide a reasonable expectation, ensuring the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

2. Scope

This Policy applies to investigators applying for and working on NIH-funded research. Investigators must disclose significant financial interests related to the Investigator's responsibilities. Investigators are all people, regardless of title or position, responsible for the design, conduct, or reporting of research proposed for funding by the NIH, including collaborators or consultants. This Policy provides the framework to identify, evaluate, and correct or remove real, apparent, and potential conflicts of interest.

3. Definitions

Shall – The use of the word "shall" in this document indicates that the requirement or procedure step is mandatory.

May – The use of the word "may" in this document indicates that there are options for the requirement or procedure step. In all cases where options exist, a complete set of acceptable options will be listed.

Investigator: The Project Director (PD), Principal Investigator (PI), Key Personnel, and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the NIH, which may include, for example, collaborators or consultants.

Institutional responsibilities: An Investigator's professional responsibilities on behalf of Estenda, and as defined by Estenda, including but not limited to, activities such as research, research consultation, teaching, professional practice, committee memberships, and service on panels such as Review Boards or Data and Safety Monitoring Boards.

FCOI Officer: The individual designated by Estenda to oversee this policy, including solicitation and review of SFI Disclosure Forms, or such individual's designee. This individual also files reports to the NIH via the FCOI module of ERA Commons.

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

Significant Financial Interest (SFI): A financial interest of the Investigator consisting of one or more of the interests described below (including those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's responsibilities.

Financial conflict of interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Management Plan: A plan between Estenda and an Investigator with a financial conflict of interest. The terms, conditions, and restrictions of this plan ensure compliance with this policy, and manage, reduce, or eliminate any actual or potential conflict of interest. These plans ensure that the design, conduct, and reporting of research will be free from bias.

Key Personnel: The PD/PI and any other person identified as senior/key personnel by Estenda in the grant application, progress report, or any other report submitted to the NIH by Estenda.

Signing Official (SO): The SO has the authority to legally bind Estenda in grant administration matters by providing signature approval on grant application submissions. The SO also submits the FCOI policy and policy updates to the NIH via the FCOI module on ERA Commons.

4. Responsibility

Responsibilities for this procedure are defined as follows:

Initiator:

Senior Management

Authoring

This policy shall be authored and edited by Senior Management or someone familiar with NIH Financial Conflict of Interest Policies.

Approvals

This procedure requires the following approval:

- Senior Management (At least 2 individuals designated as Senior Management)

Training

See Section 5.7 Training for the training requirements for this policy.

5. Policy

5.1 Determination of a Significant Financial Interest (SFI)

5.1.1 What is an SFI?

A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's responsibilities:

- With regard to any publicly traded entity, an SFI exists if the value of any remuneration received by the Investigator (or the Investigator's spouse or dependent children) from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity, subject to the Exemptions defined below, as of the date of disclosure, when aggregated, exceeds \$5,000.
- With regard to any privately held company, an SFI exists if the value of any remuneration received by the Investigator (or the Investigator's spouse or dependent children) from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest in the entity (e.g., stock, stock options, or other ownership interest).
- For purposes of the definition of an SFI, remuneration includes, subject to the Exemptions defined below, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); and equity interest includes stock, stock options, or other ownership interest, as valued through reference to the public trading price or other reasonable measures of fair market value.
- An SFI exists, subject to the Exemptions defined below, with respect to intellectual property rights and interests (e.g., patents, trademarks, copyrights) upon receipt of (or right to receive) any income or other value related to such intellectual property rights and interests.
- With respect to a Significant Financial Interest, Investigators also must disclose (and such disclosure shall constitute an SFI Disclosure) any reimbursed or sponsored travel (i.e., travel which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Estenda of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Estenda of higher education. This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Upon receipt of this disclosure, the Policy Coordinator will

determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI.

5.1.2 Exemptions to an SFI

An SFI does not include the following types of financial interests

- Salaries, royalties, or other remuneration paid by Estenda to the Investigator if the Investigator is currently employed or otherwise appointed by Estenda, including with respect to intellectual property rights assigned to Estenda and agreements to share in royalties related to such rights;
- Any ownership interest in Estenda held by the Investigator;
- Income from investment vehicles, such as mutual funds and retirements accounts, as long as the Investigator does not directly control the investment decisions made by these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institute of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institute of higher education; or
- Income from service on advisory committees or review panels for a federal, state or local government agency, an Institute of higher education as defined at 20 USC001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institute of higher education.

5.2 Identification of SFI Disclosure

The Principal Investigator of a Research project shall be responsible for identifying all Investigators with an SFI requiring disclosure under this policy and ensuring that an SFI Disclosure Form is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.

The FCOI Officer shall review all SFI Disclosures and determine if there is a potential FCOI. If there is, they shall take steps to address the potential FCOI. This may include an FCOI Management Plan. See Section 5.5. FCOI Management Plan.

5.3 Reporting Process

The FCOI Officer is responsible for reporting the disposition of matters involving disclosures of SFI in accordance with applicable federal requirements to the NIH via the eRA Commons FCOI Module for Estenda and its sub-recipients.

The NIH requires the following reports:

- Initial report: Prior to the expenditure of any funds under an NIH-funded research project, Estenda must provide to the NIH an FCOI report regarding any Investigator SFI found by Estenda to be a financial conflict of interest in accordance with the regulations
- During on-going NIH-funded research projects: Estenda shall submit an FCOI report within 60 days after its determination that a new FCOI exists or within sixty (60) days of identification for an Investigator who is newly participating in the project.
- Annual FCOI report: For any FCOI previously reported to the NIH, Estenda shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan. The report shall be submitted at the same time as when Estenda is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension. The annual report shall provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project

5.4 FCOI Management Plan

If a management plan is necessary, it shall outline the terms, conditions, and any restrictions to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken to manage, reduce, or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests
- Review of research protocols by independent reviewers
- Monitoring of research by independent reviewers
- Modification of research plan
- Disqualification from participation in all or a portion of the research funded
- Divestiture of significant financial interests
- Severance of relationships that create actual or potential conflicts

The Investigator and the FCOI Officer shall sign all management plans. The FCOI Officer shall monitor compliance of the management plan.

5.5 Public Disclosure

This policy shall be posted on Estenda's public website. Estenda shall make available information concerning identified FCOIs held by Key Personnel publicly accessible prior to the expenditure of funds. This publicly accessible information will:

- Include the minimum elements as provided in the regulation
- Be made available within five (5) business days of a written request
- Remain available for three (3) years from the date the information was most recently updated

The responses in written requests will contain the most up-to-date information.

5.6 Record Keeping

Estenda shall maintain for three (3) years from the date the final expenditure report is submitted to the NIH, or, where applicable, from other dates specified in 45 CFR 75.361 for different situations:

- All FCOI-related records relating to all Investigator disclosures of financial interests and Estenda's review of, and response to, such disclosures (whether a disclosure resulted in Estenda's determination of a financial conflict of interest)
- All actions under Estenda's policy or retrospective review
- Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest.

5.7 Training

All Investigators shall complete training related to this Policy and applicable law as follows

- Upon joining Estenda
- Prior to engaging in NIH Funded Research
- At least every four years
- In the event of any modifications to this policy that affects an Investigator's obligations
- In the event Estenda determines that an Investigator is not in compliance with this policy or any FCOI management plan.

5.8 Sub-award Recipient Requirements

When Estenda is the primary award recipient, sub-award funding recipients shall comply with this policy. The sub-awardee shall establish, via subcontract agreements, that the sub-award recipient shall either follow the FCOI policy of Estenda or their own FCOI policy. In the case of a sub-award recipient following their own FCOI policy, Estenda shall obtain documentation from the sub-award recipient that its FCOI policy complies with the regulation.

The sub-contract agreements shall require that if the sub-award recipient identifies an SFI, they must notify the FCOI Officer of the existence of the conflicting interest within 30 days of identifying the interest. In addition, the sub-award recipient shall certify and assure that any reported conflicting interest has been managed, reduced, or eliminated in accordance with federal regulations.

5.9 Noncompliance of FCOI Policy

Whenever an Investigator has violated this policy—including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan—or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the FCOI Officer shall make recommendations to Human Resources and the Chief Executive Officer (CEO) regarding the impositions of sanctions or disciplinary proceedings against the violating individual.

In addition, Estenda shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved. Estenda shall notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation.

In addition, Estenda shall complete a CAPA investigation within 120 days when an SFI is not disclosed or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a significant financial interest that Estenda determines to constitute a financial conflict of interest
- Failure by Estenda to review or manage such a financial conflict of interest
- Failure by the Investigator to comply with the financial conflict of interest management plan

Estenda will ensure that in any case in which the Department of Health and Human Services determines that an NIH-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by Estenda as required by the regulation, Estenda shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research, and to request an addendum to previously published presentations.

6. References

NIH FCOI Training https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

7. Related Forms/Templates

QMS011_SOP-Template_v-2.0

MM004_SOP-CAPA_v-9.0

RES023_SFI Disclosure Form_v-1.0

8. Regulatory Standards

45 CFR part 46 – Protection of Human Subjects <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

Code of Federal Regulations, Title 42, Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought <https://www.govinfo.gov/content/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

9. Revision History

Version	Date	Author	Description of Change	Justification for Change
0.1	15-JAN-2025	RJ Kedziora	Created New	Creation of SOP
1.0	17-Jan-2025	Jeff Stainback	Updated for approval	Preparation of document for approval signatures.

10. Document Approval

The following signatures indicate approval of this document and any related Forms/Templates.

Role	Print Name	Signature	Date (DD-Mon-YYYY)
Senior Management			
Senior Management			