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 institutional responsibilities performed on behalf of Estenda. 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 manage financial 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 shall be listed.

Investigator: The Project Director (PD), Principal Investigator (PI), 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. Estenda shall consider the role and level of independence in which the person works to determine if they meet the definition.

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 institutional 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 to manage an identified Financial conflict of interest. These plans ensure that the design, conduct, and reporting of research will be free from bias.

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 5.8 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 domestic or foreign 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 institutional responsibilities. Note: The Investigator should not determine if the SFI is related to NIH-funded research as a condition for disclosure.

- **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 when aggregated, exceeds $5,000.
- Investigators must disclose the occurrence of any foreign or domestic reimbursed or sponsored travel that exceeds $5,000 (i.e., that 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 the Investigator's institutional responsibilities. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The details of this disclosure shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

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 since Estenda is a commercial or for-profit organization and such interest is excluded from the SFI definition per the regulation
- 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 located in the United States (U.S.), a U.S. Institute of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institute of higher education
- Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States (U.S.), a U.S. Institute of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institute of higher education.
- Travel reimbursed or sponsored by a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.

5.2 Identification of SFI Disclosure

The FCOI Officer shall be responsible for identifying all Investigators (e.g. Project Director (PD), Principal Investigator (PI) 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). The FCOI Officer may engage the PD/PI to help make the determination who on the project is an "Investigator" and is subject to the SFI disclosure requirements. The FCOI Officer is responsible for ensuring that an SFI Disclosure Form is prepared and submitted, when required. In addition, the FCOI Officer shall be responsible for ensuring that annual updates are provided and that Investigators understand the requirement to disclosure any newly acquired or discovered SFIs are disclosed and reviewed as required by the regulation and this policy.

5.3 Review of SFI Disclosure for Determination of FCOI

The FCOI Officer shall review any SFIs that have been identified in a disclosure and compare them to each NIH research application and/or award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the NIH funded research and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award.

- An SFI is related to the research if a "yes" response is provided to either of these questions:
  - Could the SFI be affected by the research?
  - Is the SFI in an entity whose financial interest could be affected by the research?

- A related SFI is an FCOI when the FCOI Officer determines that the SFI could directly and significantly affect the design, conduct or reporting of the NIH-funded research. "Significantly" in this statement means that the financial interest could have a material effect on the research.

If there is an FCOI, the FCOI Officer shall take steps to address or manage the FCOI. This shall include an FCOI Management Plan that must be agreed to by the Investigator. See Section 5.4. FCOI Management Plan.

5.4 FCOI Management Plan

An FCOI management plan shall outline the terms and conditions to manage the FCOI to promote objectivity of NIH-funded research. 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 identified financial conflict of interest:

- Public disclosure of significant financial interests (e.g., when presenting or publishing the research, to research personnel working on the study, to the Institutional Review Board associated with the research, and/or Data Safety and Monitoring Board, etc.)
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest
- Review of research protocols by independent reviewers
- Monitoring of the research by independent reviewers
- Modification of the research plan
- Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research funded
- Reduction or divesture of significant financial interests (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts

If the FCOI Officer determines that an FCOI exists, it shall communicate its determination and the means it has developed for managing the FCOI in writing to the individual, to the relevant Principal Investigator/Project Director, and to the appropriate direct supervisor.

No expenditures on an NIH award shall be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated official necessary to manage the Financial Conflict of Interest. The designated FCOI Officer shall submit the FCOI report to NIH via the eRA Commons FCOI Module.

The FCOI Officer shall monitor compliance with the management plan until the grant period expires or until the FCOI no longer exists during the period of NIH-funded research.

5.5 Public Disclosure

This policy shall be made publicly available on Estenda's website.

Prior to the expenditure of any funds under an NIH award, Estenda shall ensure public accessibility by written response to any requestor within five business days of a request of information concerning any SFI disclosed that meets the following three criteria:

i. The SFI was disclosed and is still held by the Investigator
ii. Estenda has determined that the SFI is related to the research funded through an award
iii. Estenda has determined that the SFI is a financial conflict of interest.

The information that Estenda shall make available in a written response to any requestor within five days of request shall include, at a minimum, the following:

i. The Investigator's name
ii. The Investigator's title and role with respect to the research project
iii. The name of the entity in which the Significant Financial Interest is held
iv. The nature of the Significant Financial Interest
v. The approximate dollar value of the Significant Financial Interest in the following ranges: $0-$4,999; $5,000-9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is

one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The written response shall include the following text: "The information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new Financial Conflict of Interest, which should be requested subsequently by the requestor."

Requests may be sent to info@estenda.com and reference this policy.

Information concerning an individual's SFI, as limited by this Policy, shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

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 conflicts of interest.

5.7 Reporting Process

Prior to the expenditure of any funds under an award funded by NIH, Estenda shall provide NIH a FCOI report compliant with NIH regulations regarding any Investigator's Significant Financial Interest found to be conflicting and shall ensure that the Investigator has agreed to and implemented the corresponding management plan. The report shall be submitted via the eRA Commons FCOI Module.

The FCOI Officer shall serve as the FCOI SO within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI reports to the NIH. The FCOI Module User Guide is available at Financial Conflict of Interest User Guide (nih.gov).

The NIH requires the following reports:

- Initial report: Prior to the expenditure of any funds under an NIH-funded research project, Estenda shall 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 ongoing NIH-funded research projects: For any Significant Financial Interest that is identified as conflicting after an initial FCOI report during an ongoing NIH-funded research project (e.g., a new SFI is identified for an Investigator who is participating in the NIH-funded research, upon the participation of an Investigator who is new to the research project, etc.), Estenda shall provide to NIH within 60 days of identifying an FCOI, an FCOI report regarding the financial conflict of interest and ensure that Estenda has implemented a management plan and the Investigator has agreed to the relevant management plan.

- Annual FCOI report: For any FCOI previously reported to the NIH, Estenda shall provide an annual FCOI report addressing the status of the FCOI (i.e., an indication of whether the FCOI is still being managed or if it no longer exists) 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

5.8 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.

Estenda requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html in accordance with the requirements and expectations of this Policy. All investigators shall complete a training record per Estenda's training policy (RES002_SOP-Training), print a certification of completion at the end of training, and retain it for audit purposes.

Estenda shall inform Investigators about the FCOI policy, training requirements, and their SFI disclosure requirements.

5.9 Subrecipient Requirements

- A subrecipient relationship is established when federal funds flow down from or through Estenda to another individual or entity, and the subrecipient will be conducting a substantive portion of a NIH-funded research project and is accountable to Estenda for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub- awardees, are subject to Estenda's terms and conditions, and as such, Estenda shall take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation at 42 CFR Part 50 Subpart F.
- Estenda shall incorporate, as part of a written agreement with the subrecipient, terms that establish whether Estenda's FCOI Policy or that of the subrecipient's institution shall apply to the subrecipient Investigator(s). See the NIH Grants Policy Statement Section 15.2.1 Written Agreement at 15.2 Administrative and Other Requirements.
- If the subrecipient's FCOI policy applies to the subrecipient Investigator, the subrecipient institution shall certify as part of the agreement with Estenda that its policy is in compliance with the federal FCOI regulation. In this situation, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to Estenda in sufficient time to enable Estenda to provide timely FCOI reports, as necessary, to the NIH as required by the regulation (i.e., prior to the subrecipient's expenditure of funds and within 60 days of the subrecipient's identification of an FCOI during the period of an award). Therefore, the written agreement may establish a reporting requirement of FCOIs identified during the period of an award to be submitted to Estenda within 45 days of the subrecipient's identification of an FCOI to allow Estenda to report the FCOI within the 60-day period. The FCOI Officer shall submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.
- If the subrecipient cannot provide the certification of compliance with the FCOI regulation, the agreement shall state that the subrecipient Investigator is subject to Estenda's FCOI Policy for disclosing SFI(s) that are directly related to the subrecipient's work for Estenda. Therefore, Estenda shall require the submission of all Investigator disclosures of SFIs to Estenda. The agreement shall include sufficient time period(s) to enable Estenda to comply timely with its review, management, and reporting obligations under the regulation. When an FCOI is identified, Estenda shall develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

5.10 Noncompliance of FCOI Policy

When an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a significant financial interest that the Institution determines to constitute a FCOI, failure by the

Institution to review or manage such an FCOI; and failure by the Investigator to comply with a management plan; Estenda shall within 120 days:

1. Complete an investigation per Estenda's Corrective Action Preventive Action (CAPA) process. This investigation shall include a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of research
2. In addition to Estenda's CAPA requirements documenting a nonconformity, Estenda shall also document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's Responsibility of Applicants for Promoting Objectivity in Research (2011 Revised Regulations) FAQ subsection Retrospective Review and Mitigation Report

If bias is found, Estenda shall notify NIH promptly and submit a mitigation report to NIH via the eRA Commons FCOI Module that shall address the following:

- Impact of the bias on the research project
- Estenda' s plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, Estenda shall submit FCOI reports annually to NIH in accordance with the regulations and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest, Estenda may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of Estenda's independent retrospective review.

If bias is not found, no further action is required.

5.11 Failure to Comply with this Policy.

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Therefore, such Investigators who fail to comply with this policy are subject to discipline, including letters of reprimand, restriction on the use of funds, termination of employment, or disqualification from further participation in any NIH-funded research, etc., as may be deemed appropriate.

Estenda shall 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

NIH Responsibility of Applicants for Promoting Objectivity in Research
https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm

NIH Administrative Requirements
https://grants.nih.gov/grants/policy/nihgps/html5/section_15/15.2_administrative_and_other_requirements.htm

7. Related Forms/Templates

QMS011_SOP-Template_v-2.0

MM004_SOP-CAPA_v-9.0

RES002_SOP-Training_v-11.0

RES023_SFI Disclosure Form_v-2.0

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.
1.1	22-JAN-2025	RJ Kedziora	Updated for clarity, ease of burden in compliance, and simplicity in execution	Per feedback from the NIH FCOI Policy reviewer
1.2	24-JAN-2025	RJ Kedziora	Additional clarifications for compliance, understanding and simplicity in execution	Per feedback from the NIH FCOI Policy reviewer and internal review
1.3	27-JAN-2025	RJ Kedziora	Additional clarifications for compliance, understanding and simplicity in execution	Per feedback from the NIH FCOI Policy reviewer and internal review
2.0	27-JAN-2025	RJ Kedziora	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	Drew Lewis	2025.01.27	15:37:27 -05'00'
Senior Management	Jeff Stainback	2025.01.27	15:38:20 -05'00'