



Financial Conflicts of Interest Policy

ENALARE THERAPEUTICS INC.



Table of Contents

SECTION 1.0 SCOPE & PURPOSE	3
SECTION 2.0 DEFINITIONS	3
SECTION 3.0 CERTIFICATION AND OVERSIGHT	6
SECTION 4.0 TRAINING REQUIREMENTS	6
SECTION 5.0 DISCLOSURE, REVIEW, AND MONITORING	7
SECTION 6.0 REPORTING FCOIs	8
SECTION 7.0 MANAGEMENT OF FCOI AND REMEDIES FOR NON-COMPLIANCE	9
SECTION 8.0 PUBLIC ACCESS	10
SECTION 9.0 RECORD RETENTION	11
SECTION 10.0 SUBRECIPIENT REQUIREMENTS	11
SECTION 11.0 REVISION HISTORY	12
REFERENCES AND APPENDICES	12



SECTION 1.0 SCOPE & PURPOSE

This Financial Conflicts of Interest Policy for PHS-funded research ("FCOI Policy") implements U.S. federal requirements pertaining to "Objectivity in Research" promulgated by the Public Health System ("PHS") of the U.S. Department of Health and Human Services ("HHS"), including but not limited to the U.S. National Institutes of Health ("NIH") and the Biomedical Advanced Research and Development Authority ("BARDA").

Financial Conflict of Interest ("FCOI") requirements related to PHS-funded research are published in U.S. regulations 42 CFR Part 50, Subpart F and 45 CFR Part 94. These regulations describe the actions an individual and an organization must take to promote objectivity in PHS-funded research. The intent of this FCOI Policy is to promote objectivity and transparency in research by establishing standards to help ensure that the design, conduct, and reporting of research performed with funds received from PHS Organizations will not be biased by any conflicting financial interest. Further, pursuant to this FCOI Policy, if an actual, potential or the appearance of a conflicting financial interest is identified, Enalare Therapeutics will perform a reasonable investigation of the alleged conflicting financial interest and, if appropriate, properly disclose the FCOI.

This Policy is applicable to all projects implemented by Enalare Therapeutics and funded by PHS Organizations.

SECTION 2.0 DEFINITIONS

- A. *Disclosure of significant financial interests* means an Investigator's disclosure of significant financial interests to Enalare.
- B. *Financial conflict of interest (FCOI)* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- C. *FCOI report* means Enalare's report of a financial conflict of interest to a PHS Awarding Component.
- D. *FCOI Committee* means the Nominating & Corporate Governance Committee of Enalare's Board of Directors. The FCOI Committee is designated by Enalare to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests and identify FCOIs per the regulatory criteria provided in 42 CFR 50.604(f) and as stated within the Policy below.
- E. *Financial interest* means anything of monetary value, whether or not the value is readily ascertainable.
- F. *HHS* means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- G. *Institutional responsibilities* means the professional activities an Investigator performs on behalf of Enalare (e.g., administration, research, or consulting).



- H. *Investigator* means the project director (PD) or principal Investigator (PI) 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, which may include, for example, collaborators or consultants.
- I. *PD/PI* means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator as defined herein.
- J. *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- K. *PHS Awarding Component* means the agency or organizational unit of the PHS that funds the research.
- L. *Research* means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- M. *Senior/key personnel* means the PD/PI and any other person identified as senior/key personnel by Enalare in the grant application, progress report, or any other report submitted to the PHS by Enalare.
- N. *Significant financial interest* (SFI) means:
- 1) 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 institutional responsibilities:
 - i. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other



- ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - ii. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received 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 (e.g., stock, stock option, or other ownership interest); or
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income greater than \$5,000 related to such rights and interests.
- 2) Investigators also must disclose the occurrence of any 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 their institutional 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 located in the United States, a United States Institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education. Enalare's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with Enalare's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by Enalare to the Investigator if the Investigator is currently employed or otherwise appointed by Enalare, including intellectual property rights assigned to Enalare and agreements to share in royalties related to such rights; any ownership interest in Enalare held by the Investigator; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency located in the United States, a United States Institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, a United States Institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.



SECTION 3.0 CERTIFICATION AND OVERSIGHT

A. CERTIFICATION

To apply for funding with PHS Organizations, Enalare Therapeutics (“Enalare”) must be able to certify, in each application for funding, that Enalare:

- has in effect, an up-to-date, written, and enforced process to identify and manage FCOI;
- will promote and enforce compliance with applicable regulations;
- will manage FCOI and provide initial and ongoing FCOI reports;
- will make FCOI and significant financial interest information available to the PHS Organization, promptly, upon request; and
- will fully comply with the regulatory requirements.

B. OVERSIGHT

To comply with applicable regulations and to successfully manage FCOI, Enalare shall maintain an FCOI Committee. The FCOI Committee shall have the primary responsibility to:

- Implement this Policy;
- Review, analyze, and report instances of perceived/possible FCOI;
- Ensure compliance with Policy for all PHS-funded projects.

FCOI Committee Members shall comply with the training requirements of this Policy. The Committee Members shall recuse themselves if they serve as a Principal Investigator on a project.

SECTION 4.0 TRAINING REQUIREMENTS

Unless covered by a third-party FCOI policy as agreed with Enalare, Investigator and Senior /Key Personnel named in the PHS-funded federal award are required to complete training on Enalare’s FCOI Policy as follows:

- At the start of the project, prior to engaging in PHS-funded research;
- At least every 4 years; and
- Immediately, if (a) Enalare revises the FCOI Policy that affects requirements of PD/PI/Senior/key Personnel, (b) an Investigator is new to Enalare research under a PHS-funded federal award (training is to be completed before his/her participation in the research), or (c) a PD/PI/Senior/Key Personnel is determined to be in non-compliance with Enalare’s FCOI Policy (training is to be completed within 30 days in the manner specified by the FCOI Committee).

In fulfillment of the FCOI training requirement of the FCOI regulation, Enalare requires its Investigators to complete the National Institutes of Health’s Financial Conflict of Interest tutorial located at: [FINANCIAL CONFLICT OF INTEREST - NEWEST](#) in accordance with the requirements and expectations of this Policy. All Investigators must print a certification of completion at the end of training and retain it for audit purposes.



Additionally, all FCOI Committee Members shall be required to take this training before starting their assignment on the FCOI Committee.

SECTION 5.0 DISCLOSURE, REVIEW, AND MONITORING

Each PD/PI/Senior/Key Personnel and all other individuals who meet the definition of “Investigator” are required to disclose to the FCOI Committee any actual or potential SFIs (and those of said PD/PI/Senior/Key Personnel’s Immediate Family) that meet or exceed the definition of SFI. Any new Investigator who, after applying for a PHS-funded award or during the research project, plans to participate in the project must similarly disclose any actual or potential SFI(s) to the FCOI Committee promptly and before participation in the project. This disclosure must occur:

- Before starting engagement on a PHS-funded award;
- At least annually during the period of the PHS-funded research; and
- Within 30 days of discovering or acquiring a new SFI.

For each Investigator who must submit an updated disclosure of all SFIs at least annually, such disclosure must include any information that was not disclosed initially to Enalare according to this Policy or in a subsequent disclosure of an SFI and must include updated information regarding any previously disclosed SFI. In addition, Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

The FCOI Committee will review all SFI disclosures. Each interest identified in the disclosure will be compared to each PHS-funded research application, award, and/or contract 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 PHS-funded research and, if so, whether the SFI creates an FCOI related to that research award.

The FCOI Committee will determine whether an Investigator’s SFI is related to the research under a PHS-funded award and, if so, whether the SFI is an FCOI.

An Investigator’s SFI is related to the research when the FCOI Committee reasonably determines the SFI:

- could be affected by the PHS-funded research; or
- is in an entity whose financial interest could be affected by the PHS-funded research.

An FCOI exists when the FCOI Committee reasonably determines that the Investigator’s SFI is related to a PHS-funded research project (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the PHS-funded research. (“Significantly” means that the financial interest would have a material effect on the research).

The FCOI Committee will determine if an FCOI exists, and develop and implement management plans, as needed, to manage FCOIs:

- Before work on a particular PHS-funded research project begins; and
- Within 60 days whenever Enalare is made aware of or identifies a new SFI not previously disclosed or not previously reviewed.



If an FCOI is found, the FCOI Committee must establish a process to monitor the impacted PD/PI/Senior/Key Personnel's compliance with management plans until completion of the PHS-funded research project. For any report of an SFI involving travel reimbursement or sponsorship, the FCOI Committee must be provided information relating to the purpose, destination, and duration of each trip and the identity of the relevant sponsor or organizer. If requested by the FCOI Committee, additional information, including the monetary value of the trip, must be disclosed to determine whether the reimbursement or sponsorship constitutes an FCOI.

SECTION 6.0 REPORTING FCOIs

A. PERIODIC REPORTING

Enalare will send initial, annual, and revised reports listing FCOIs identified for PHS-funded research projects to the relevant PHS Organization:

- prior to expenditure of funds for PHS-funded research;
- within 60 days of identification of an FCOI for a PD/PI/Senior/Key Personnel who is newly participating in an on-going project;
- at least annually to provide the status of a previously reported FCOI and any changes to the management plan, if applicable, until the completion of the project; and
- following a retrospective review to update a previously submitted report, if appropriate.

Enalare will assign an institutional official to serve as the FCOI Signing Official ("FCOI SO") within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI reports to the relevant PHS Organization. The FCOI Module User Guide is available at: [Financial Conflict of Interest User Guide](#).

While the award is ongoing (including any extensions with or without funds), Enalare will provide the relevant PHS Organization with an annual FCOI report that addresses the status of the FCOI (i.e., an indication whether the FCOI is still being managed or if it no longer exists) and any changes in the management plan, if applicable.

For any SFI that is identified as conflicting after an initial FCOI report during an ongoing PHS-funded research project, Enalare will provide to the relevant PHS Organization within 60 days of identifying an FCOI, an FCOI report regarding the FCOI and ensure that Enalare has implemented a management plan and the Investigator has agreed to the relevant management plan.

Any initial FCOI report will include the information required in the regulation at 42 CFR Part 50.605(b)(3) or as outlined in NIH's FAQ H.5. at [Frequently Asked Questions \(FAQs\) | Grants & Funding](#).

Additional information on FCOI reporting can be found under this reference: Types of FCOI Reports Summary Chart for NIH and is available at required FCOI reports through eRA Commons.

B. AD-HOC REPORTING

Whenever Enalare identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner by the FCOI Committee, Enalare's FCOI Committee will, within 60 days, review and make the



determination of whether an FCOI exists, and report the FCOI if it exists to the relevant PHS Organization:

- If an FCOI exists: Enalare will, within 120 days of the Enalare's FCOI Committee's determination of noncompliance/nondisclosure, complete a retrospective review of the PD/PI/Senior/Key Personnel's activities and PHS-funded research to determine whether any of the PHS-funded Research conducted during the time period of the noncompliance/nondisclosure biased the design, conduct or reporting of such Research.
- Enalare's FCOI Committee will document the retrospective review as required by PHS regulations.
- Subsequent to the retrospective review, if applicable, Enalare's FCOI Committee will update the existing FCOI report and, if bias is found, will notify the relevant PHS Organization promptly and submit a mitigation plan with details required by PHS regulations.

C. REPORTING NON-COMPLIANT PD/PI/Senior/Key Personnel

Enalare will notify the relevant PHS Organization promptly if a PD/PI/Senior/Key Personnel assigned to a PHS-funded federal award fails to comply with this FCOI Policy or an FCOI management or mitigation plan and inform the relevant PHS Organization of the corrective action taken or to be taken.

SECTION 7.0 MANAGEMENT OF FCOI AND REMEDIES FOR NON-COMPLIANCE

A. MANAGEMENT AND MITIGATION PLAN

If the FCOI Committee determines an FCOI exists, prior to Enalare's expenditure of any funds under a PHS-funded research project, Enalare shall develop and implement a management plan that specifies the actions that have been, and shall be, taken to manage such FCOI. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- Public disclosure of FCOIs (e.g., when presenting or publishing the research, to research personnel working on the study, to Enalare's Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.);
- For research projects involving human subjects research, disclosure of FCOIs directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan to eliminate or mitigate the FCOI;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research to eliminate or mitigate the FCOI;
- Reduction or elimination of the SFI (e.g., sale of an equity interest); or
- Severance of relationships that create FCOIs.

B. REGULAR AUDITS

The FCOI Committee shall also include a periodic monitoring plan as a part of the management plan to ensure full compliance with the plan. Any non-compliance shall be reported to the PHS agency promptly in line with Section 6 of this Policy.



C. REMEDIES FOR NON-COMPLIANCE

When an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is determined by the Institution 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; Enalare will within 120 days of determining noncompliance:

1. Complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of research;
2. Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ 1.2. at [Frequently Asked Questions \(FAQs\) | Grants & Funding](#);

If bias is found, Enalare shall notify the relevant PHS Organization promptly and submit a mitigation report to the relevant PHS Organization that shall address the following:

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

Thereafter, Enalare shall submit FCOI reports annually to the relevant PHS Organization in accordance with the regulations and terms and conditions of the award agreement. Depending on the nature of the FCOI, Enalare may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the FCOI is identified and the completion of Enalare's retrospective review. If bias is not found, no further action is required.

Enalare will request the relevant PHS Organization to consider the situation and, as necessary, take appropriate action, or refer the matter to Enalare for further action, which may include directions to Enalare on how to maintain appropriate objectivity in the PHS-funded research project.

In addition to the above, in any case in which the PHS Awarding Component 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 has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by Enalare as required by applicable federal regulations, Enalare 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.

SECTION 8.0 PUBLIC ACCESS

Before expending funds on a particular PHS-funded research project, Enalare will establish procedures for public access to information concerning any SFI that is disclosed to Enalare and (a) continues to be held by a PD/PI/Senior/Key Personnel for a particular project, (b) is determined by Enalare to be related to the project, and (c) is determined by Enalare to constitute an FCOI.

Enalare will make required information about the applicable SFI(s) containing the minimum elements as provided by applicable regulation available within 5 business days of receiving a written request for at least 3 years after the information was most recently updated. Enalare will also make this FCOI Policy available on a publicly accessible website.



SECTION 9.0 RECORD RETENTION

Enalare will keep all records of all Investigator disclosures of SFIs and Enalare's review of, or response to, such disclosure (whether or not a disclosure resulted in Enalare's determination of an FCOI), and all actions under Enalare's policy or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained by Enalare for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations. Enalare will retain records as provided in the regulation.

SECTION 10.0 SUBRECIPIENT REQUIREMENTS

A subrecipient relationship is established when federal funds flow down from or through Enalare to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to Enalare 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 Enalare's terms and conditions, and as such, Enalare will take reasonable steps to ensure that any subrecipient Investigator complies with the federal FCOI regulation at 42 CFR Part 50 Subpart F.

Enalare will require any subrecipient or subcontractor performing PHS-funded research to either (a) mandate that its employees comply with this FCOI Policy or (b) comply with the subrecipient's or subcontractor's FCOI policy if the subrecipient or subcontractor certifies to Enalare that its policy complies with PHS regulations. Enalare will incorporate, as part of a written agreement with the subrecipient, terms that establish whether Enalare's FCOI Policy or that of the subrecipient's institution will 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 will certify as part of the agreement with Enalare that its policy complies with the federal FCOI regulation. In this situation, the agreement shall specify the period for the subrecipient to report all identified FCOI to Enalare in sufficient time to enable Enalare to provide timely FCOI reports, as necessary, to the relevant PHS Organization as required by the regulation (i.e., before 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 Enalare within 50 or 55 days of the subrecipient's identification of an FCOI to allow Enalare to report the FCOI within the 60 days. The Enalare assigned FCOI SO will submit the FCOI report (subrecipient report) to the relevant PHS Organization.

If the subrecipient cannot provide the certification of compliance with the FCOI regulation, the agreement shall state that the subrecipient Investigator is subject to Enalare's FCOI Policy for disclosing SFIs that are directly related to the subrecipient's work for Enalare. Therefore, Enalare will require the submission of all Investigator disclosures of SFIs to Enalare. The agreement will include sufficient periods to enable Enalare to comply timely with its review, management, and reporting obligations under the regulation. When an FCOI is identified, Enalare will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the relevant PHS Organization.



SECTION 11.0 REVISION HISTORY

Change History

Rev	Effective Date	Description of Change	Author	Change #
A	11/06/2024	Initial Release	Finance	N/A
B	12/6/2024	Revised to incorporate NIH feedback - clarifications and addition of procedures to identify and report SFIs.	Finance	01

REFERENCES AND APPENDICES

[eCFR :: 42 CFR Part 50 Subpart F -- Promoting Objectivity in Research](#)

*****<POLICYENDS>*****