



Financial Conflicts of Interest Policy

Purpose:

Lynntech (Company) recognizes its responsibilities to encourage interaction between its employees and the public and private sectors as an important component of its research activities. The Company is committed to conducting research in a manner consistent with the highest standards of integrity and ethics. This policy is designed to promote objectivity in research and to ensure that our research activities are free from bias resulting from financial conflicts of interest (FCOI).

This policy implements federal law and regulations adopted by the Public Health Service (PHS) of the U.S. Department of Health and Human Services and the National Science Foundation (NSF) to address when a significant financial interest (SFI) reasonably appears to affect or bias the design, conduct, or reporting of research.

Process Steps:

1. PURPOSE AND BACKGROUND

This policy defines the general procedures used to identify, manage, and report financial conflicts of interest (FCOI) in research. The purpose of this policy is to protect the credibility and integrity of Company researchers and staff so the public trust and confidence in research activities is maintained. To that end, this policy adopts standards for the disclosure, management, and reporting of FCOI beyond those required by federal law.

Company has a responsibility to identify and manage, and reduce or eliminate conflicts of interest that may arise due to financial or other personal interests of an investigator. Therefore, the Company requires all investigators to disclose their financial interests related to their institutional responsibilities.

2. APPLICABILITY

Except as otherwise provided by federal law, this policy applies broadly to all externally sponsored research or research activities regardless of the funding source.

3. CONFLICT OF INTEREST OFFICIAL

COO, Bart Arndt has appointed Tony Giletto, Director of Research as the conflict of interest official (COI Official) who will be responsible for implementation this policy. The COI Official must perform the duties assigned by this policy and any other duties as assigned by the COO.

4. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS (SFI)

- 4.1. Each investigator, must submit or update a Financial Disclosure Statement as required in Section 4.2 of this policy that:
 - a. Identifies all research or research activities in which the investigator is engaged at the time the Financial Disclosure Statement is submitted; and
 - b. Discloses the following information for each SFI held by the investigator or a covered family member, as defined below, that is reasonably related to the investigator's responsibilities:

Doc: FCOI Policy	Page 1 of 7
By: 	Revision Date: 3/15/21



Lynntech

1. The total amount of salary or other payments received from the SFI in the preceding 12 months, in rounded, whole dollar amounts;
2. A description and the value of any equity interest (e.g., stock, stock options, or other ownership interest or entitlement to such an interest) in rounded, whole dollar amounts by reference to public prices or other reasonable measures of fair market value;
3. A description and the value of any intellectual property or royalty interests in rounded, whole dollar amounts;
4. The source of the SFI, including the source's name and principal address; and
5. For each occurrence of reimbursed or sponsored travel, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration of the trip. Each member, at its discretion, may require an investigator to disclose additional information in order to determine whether the travel at issue constitutes an FCOI.

4.2. Investigators must submit or update a Financial Disclosure Statement to the COI Official:

- a. Within 30 days of the investigator's initial employment date;
- b. Annually, not later than August 31st;
- c. Within 30 days after acquiring a new SFI requiring disclosure.

4.3. Investigators must also submit or update a separate Financial Disclosure Statement for each covered family member within the time periods specified in Section 4.2.

4.4. An investigator or covered family member must provide any additional documentation related to the SFIs disclosed on a Financial Disclosure Statement upon request of the COI Official.

5. REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

5.1. The COI Official must review the Financial Disclosure Statement(s) submitted by each investigator and determine:

- a. Whether an SFI is related to research in which an investigator is participating; and
- b. Whether an FCOI exists.

5.2. The COI Official may request additional information about an investigator's Financial Disclosure Statement to determine if an FCOI exists.

5.3. An FCOI exists when the COI Official reasonably determines that an SFI held by an investigator or a covered family member could directly and significantly affect the design, conduct or reporting of the investigator's research.

6. CERTIFICATION AND REPORTING

6.1. Federal regulations require members to include specific certifications and agreements regarding this policy and FCOI in applications for funding submitted for funded research.

6.2. Company must comply with the reporting requirements in 42 C.F.R. Part 50, Subpart F, and 45 C.F.R. Part 94, which requires us to submit reports to the appropriate federal funding agency within a certain period of time after the COI Official identifies an FCOI related to an applicable funded research project.

7. NO EXPENDITURE OF RESEARCH FUNDS

Doc: FCOI Policy	Page 2 of 7
By:	Revision Date:



There will be no expenditure of sponsored research funds by an investigator or member unless the COI Official has determined that no FCOI exists or that any identified FCOI is manageable under the terms of a management plan that has been adopted and implemented.

8. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

- 8.1. If the COI Official determines that an FCOI exists, the COI Official or designee must notify the investigator in writing and work with the investigator to develop a management plan specifying the steps to be taken to manage, reduce, or eliminate the FCOI.
- 8.2. Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate an investigator's FCOI include, but are not limited to:
 - a. Public disclosure of the FCOI;
 - b. For research projects involving human subjects, disclosure of the FCOI to the participants;
 - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research against bias resulting from the FCOI;
 - d. Modification of the research plan or research activities;
 - e. Requiring a change in personnel and/or responsibilities for all or a portion of the research activities;
 - f. Disqualification of personnel from participation in that portion of the research activities that would be affected by the FCOI;
 - g. Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
 - h. Severance of relationships that create an FCOI.
- 8.3. A management plan must include a description of the following key elements:
 - a. The research affected by the FCOI, including, if available, the project number;
 - b. The role and principal duties of the investigator who has the FCOI;
 - c. The conditions or restrictions to be implemented to manage, reduce, or eliminate the FCOI;
 - d. A statement explaining how the management plan will protect the research from bias resulting from the FCOI;
 - e. Confirmation of the investigator's agreement to abide by the management plan; and
 - f. A statement explaining how the management plan will be monitored to ensure compliance and identify the person responsible for monitoring compliance with the management plan.
- 8.4. The management plan must be signed by the investigator, the investigator's supervisor, and the COI Official.
- 8.5. For NSF-funded research, if the COI Official determines that imposing conditions or restrictions would be either ineffective or inequitable, and potential negative impacts arising from the FCOI are outweighed by the interests of scientific progress, technology transfer or the public health and welfare, the COI Official may allow the research to proceed without imposing such conditions or restrictions.
- 8.6. If an investigator disagrees with the COI Official's determination that an FCOI exists, the investigator may appeal the COI Official's determination to the COO or the COO's designee in writing within 10 business days after receiving the COI Official's determination. The decision of the COO or the COO's designee will be final.

Doc: FCOI Policy	Page 3 of 7
By:	Revision Date:



9. PUBLIC ACCESSIBILITY

9.1. This policy is available at Lynntech.com/fcoi/, a publicly accessible website and will be updated as needed.

9.2. National Institutes of Health (NIH) Funded Research

9.2.1.If COI Official determines that an FCOI exists that is related to NIH-funded research, the member will make the following information available to the public:

- a. The name of the investigator;
- b. The title and role of the investigator in relation to the affected research;
- c. The name of the entity in which the SFI is held;
- d. A description of the SFI that was determined to be an FCOI; and
- e. The approximate dollar value of the SFI. If the dollar value cannot be determined by reference to publicly available prices or another reasonable method, the member must include a statement to that effect. Dollar values may be provided within ranges, e.g., \$0-\$4,999; \$5,000-\$10,000; \$10,000-\$20,000; \$20,000-\$50,000; \$50,000-\$100,000. Amounts over \$100,000 may be stated in increments of \$50,000.

9.2.2.Members must make this information available in writing to any requestor within five business days after receipt of a request so long as the following criteria are met:

- a. The SFI was disclosed and is still held by the investigator;
- b. The COI Official has determined that the SFI is related to NIH-funded research; and
- c. The COI Official has determined that the SFI is an FCOI.

9.2.3.Alternatively, the Company may make this information available through a posting on a publicly accessible website. If Company chooses this option, the Company must update the information posted on the website on an annual basis. In addition, for each SFI that is required to be publicly available under this section, the information related to that SFI must be posted on the Company’s website within 60 days after the FCOI is identified. The website will contain a statement that the information posted is current and accurate as of the date listed and is subject to updates.

9.2.4.The information required under this section will remain available to any requestor or posted on the internet for three years after the date of the last expenditure on the research project.

10. RETROSPECTIVE REVIEW

10.1. Noncompliance, Retrospective Review, and Documentation for funded Research

10.1.1. If Company discovers an FCOI related to NIH-funded research that was not timely identified or managed, or if an investigator fails to comply with a management plan, the COI Official or designee must, within 120 days after determining noncompliance:

- a. Complete a retrospective review of the investigator’s research activities and any NIH-funded research project to determine if any NIH-funded research, or portion thereof, conducted during the period of noncompliance, was biased in the design, conduct or reporting of such research; and
- b. Implement any measures necessary, including but not limited to halting the investigator’s participation in any affected research project, to remediate the noncompliance between the date the noncompliance was identified and the date the retrospective review is completed.

10.1.2. The COI Official or designee must document each retrospective review including, but not limited to, the following key elements:

- a. Project number;

Doc: FCOI Policy	Page 4 of 7
By:	Revision Date:



Lynntech

- b. Project title;
- c. Investigator contact(s);
- d. Name of the investigator with the FCOI;
- e. Entity with which the investigator has an FCOI;
- f. Reason(s) for the retrospective review;
- g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- h. Findings of the review; and
- i. Conclusions of the review (i.e., determination, recommended actions and remedial measures implemented).

10.1.3. If bias is found, the COI Official must notify the NIH and submit a mitigation report as required by federal law. If necessary, the COI Official must update the FCOI Reports described in Section 9.2 of this policy.

10.2. Noncompliance, Retrospective Review, and Documentation for All Other Research: If a member’s COI Official discovers an FCOI related to non-NIH-funded research that was not timely identified or managed, the COI Official must conduct and document a retrospective review as described in Sections 10.1.1 and 10.1.2. If bias is found, the member’s COI Official must notify the COO and, if required by law, the COI Official must also notify the funding agency.

11. RESEARCH THROUGH SUBRECIPIENTS

11.1. If Company conducts research in cooperation with or through a subrecipient (e.g., a subcontractor, contractor or collaborator) who performs part of the statement of work described in the prime contract, Company must enter into a written agreement with the subrecipient to ensure compliance with this policy and federal law. The written agreement must incorporate legally enforceable terms that specify whether the Company FCOI policy or the subrecipient’s FCOI policy will apply to the subrecipient’s investigators who will participate in the research. The written agreement must also require the subrecipient to cooperate with Company to provide FCOI reports to a sponsoring agency as required by law.

11.2. If the subrecipient’s investigators must comply with the subrecipient’s FCOI policy, the subrecipient must certify that its policy complies with applicable federal law. If the subrecipient cannot provide this certification, the agreement must state that the subrecipient’s investigators are subject to this policy’s requirements for disclosing SFIs that are related to the work performed by the subrecipient’s investigators on behalf of Company.

11.3. If the subrecipient’s FCOI policy applies to its investigators, the agreement must specify the time periods for the subrecipient to report all identified FCOIs to Company. These time periods must be sufficient to allow Company to comply with the Company’s review and management requirements and all federal reporting requirements.

11.4. The requirements of this section apply only to:

- a. NIH-funded research; and
- b. Sponsored research in which an investigator subcontracts a portion of the research to a covered family member or an entity in which the investigator or a covered family member holds a financial interest.

12. TRAINING, EDUCATION, AND CERTIFICATION

Doc: FCOI Policy	Page 5 of 7
By:	Revision Date:



- 12.1. Company is responsible for complying with the training requirements under federal law, e.g., 42 C.F.R. §50.604(b); 45 C.F.R. §94.4(b).
- 12.2. Each investigator must certify annually that the investigator is aware of and has read this policy, the applicable member rule and any related procedures, and is aware of the investigator’s responsibilities regarding disclosure of SFIs and of applicable federal regulations.
- 12.3. Prior to engaging in research and at least once every four years thereafter, each investigator must complete training on this policy and other applicable policies, regulations, rules and laws. In addition, investigators must immediately complete training if the company changes this policy in a manner that affects investigator requirements.
- 12.4. An investigator who is newly employed must complete the requisite training before engaging in any research or research activity and at least once every four years thereafter.
- 12.5. If the COI Official determines that an investigator is not in compliance with this policy or a management plan agreed upon by the investigator and the Company, the investigator must immediately complete training on this policy and other applicable policies, regulations, rules and laws.
- 12.6. The COI Official or their designee must document an investigator’s compliance with applicable training requirements. The COI Official or their designee will maintain all documentation related to an investigator’s compliance with this training requirement in a central location.

13. ENFORCEMENT

- 13.1. Violations of this policy or applicable company rules must be brought to the attention of the investigator who will be given an opportunity to comply. The investigator must present a proposal for compliance to the COI Official for review and action within 10 business days of the notification of noncompliance. Failure to comply will constitute an intentional violation as discussed in the following section.
- 13.2. Repeated or intentional violations of this policy may be reported to the funding agency and the COO by the COI Official. Sanctions may be imposed by the COO or their designee and may range from a letter of reprimand to termination.
- 13.3. Cases involving investigators including appeals of impending sanctions, must be processed in a manner consistent with applicable company policies.
- 13.4. Cases, including appeals of impending sanctions, involving investigators not employed by or affiliated with the Company must be referred to the investigator’s home institution or organization for processing. However, company may remove an investigator not employed by or affiliated with the Company from participating in a particular research project or activity until any allegations involving an FCOI are resolved.

14. RECORDKEEPING

The COI Official must maintain all records related to investigators’ Financial Disclosure Statements and any FCOI determinations and/or management plans in a central location. These records must be kept for the longer of three years from the date of the last expenditure submitted in the case of sponsored research or as required by applicable federal law, e.g., 45 C.F.R. §74.53(b), 92.42(b).

15. AUDIT

Company will provide for regular audits of SFI disclosure statements and related documents and reports to determine individual and institutional compliance with this policy.

Other Pertinent Information:

Doc: FCOI Policy	Page 6 of 7
By:	Revision Date:



42 C.F.R. Part 50, Subpart F
45 C.F.R. § 74.53(b), 92.42(b) and Part 94
21 C.F.R. Parts 54, 312, 314, 320, 601, 807 and 812

Contact Office

Shawn Rhodes
(979) 764-2211

Doc: FCOI Policy	Page 7 of 7
By:	Revision Date: