FINANCIAL CONFLICT OF INTEREST POLICY

Purpose:

This Corporate Operating Procedure establishes a Financial Conflict of Interest (FCOI) policy for the company, across all Departmental or Divisional lines. This procedure is written to ensure compliance with the 2011 FCOI regulation, promoting objectivity in research (42 CFR Part 50 Subpart F) and supersedes any other similar procedures in effect at the date of implementation.

Rationale:

The 2011 FCOI regulation (42 CFR Part 50 Subpart F) promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator FCOIs. To be eligible for NIH funding, Lifordi Immunotherapeutics ("Lifordi") must maintain and enforce an FCOI policy that meets or exceeds the regulatory requirements.

Definitions: In this procedure:

1. Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of the Public Health Service funded research.
2. Significant Financial Interest (SFI) means
    a. 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 company responsibilities:
        i. With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 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. 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, an SFI exists if the value of any remuneration received from the entity in the 12 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 options, or other ownership interest); or
        iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests in excess of $5,000.
    b. Investigators also must disclose the occurrence of any reimbursed or sponsored travel in excess of $5,000 received in the preceding 12 months (initial disclosure) related to their company 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, an academic teaching hospital, a medical

center, or a research institute that is affiliated with a United States institution of higher education. Note: Reimbursed or sponsored travel from a foreign government, which includes local, provincial, or equivalent governments of another country or foreign institutions of higher education must be disclosed when such income is more than $5,000. The details of the disclosure will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

c. The term SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by the company to the Investigator if the Investigator is currently employed or otherwise appointed by the company, including intellectual property rights assigned to the company and agreements to share in royalties related to such rights; any interest in the company held by the Investigator, if the company is a commercial or for-profit organization; 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, 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 any service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education. Note: Income from seminars, lectures, or teaching engagements and from service on advisory committees or review panels received from a foreign government, which includes local, provincial, or equivalent governments of another country or foreign institutions of higher education must be disclosed when such income meets the threshold for disclosure (e.g., income more than $5,000). See NIH's FAQs E.36. and E.37. for more information.

3. Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the Public Health Service, or proposed for such funding, which may include collaborators or consultants.

Scope/Applicability:

This procedure is applicable to: 1) all NIH grants and cooperative agreements, excluding Phase I Small Business Innovative Research (SBIR) applications and awards, and 2) each Investigator, as defined by the regulation, who is planning to participate in or is participating in Public Health Service (PHS) funded research.

Regulation Applicability:

This procedure is mandated by 42 CFR Part 50 Subpart F available at eCFR :: 42 CFR Part 50 Subpart F — Promoting Objectivity in Research.

Procedure:

1. Training Requirements

a. All Investigators who plan to participate in or are participating in PHS-funded research must be informed of Lifordi's FCOI policy, the Federal regulation 42 CFR Part 50 Subpart F, and the Investigator's responsibility to disclose significant financial interests.
b. Investigators must be trained:
    i. Prior to engaging in PHS-funded research.
    ii. Every four years, thereafter.
    iii. Immediately, if:
        - Lifordi's FCOI policy is revised.
        - Investigator is new to the company.
        - Investigator does not comply with the FCOI policy or management plan.
c. Training constitutes Investigators certifying they have read and reviewed:
    i. Lifordi Financial Conflict of Interest Policy
    ii. NIH's "FCOI Training" on Regulation 42 CFR Part 50 Subpart F at FCOI Training | grants.nih.gov.
d. The FCOI Policy has been implemented in the following ways:
    i. Each Investigator has been provided a written copy;
    ii. The FCOI Policy has been added to the company website.

2. Disclosure, Review, and Monitoring Requirements
    a. Each Investigator has a responsibility to disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigator's company responsibilities that meet or exceed the definition of SFI as provided in this policy using the company's Significant Financial Interest Form.
        i. No later than at the time of application for PHS-funded research
        ii. At least annually during the period of the award
        iii. Within 30 days of discovering or acquiring a new SFI
    b. Lifordi's Designated Institutional Official (DIO), will solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to the Investigator's company responsibilities for determination of FCOI.
        i. An SFI is related to PHS-funded research if the DIO reasonably determines that the SFI is related to the PHS/NIH-funded research and is an FCOI. An SFI is related to the research if the SFI:
            1. Could be affected by the PHS/NIH-funded research; or
            2. Is in an entity whose financial interest could be affected by the research.
        ii. An Investigator may be involved in making the determination of whether the SFI is related to PHS/NIH-funded research.
        iii. An FCOI exists when the DIO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
    c. In the case an SFI is determined to be an FCOI, the company will manage the FCOI at its discretion. This may include full public disclosure of the FCOI (e.g., in

presentations, publications, to research personnel working on the study, etc.), appointment of an independent monitor, modification of the research plan, removal of the Investigator from the PHS- funded research, etc. See NIH's FAQ F.1. for more strategies that may be imposed to manage an FCOI.

d. Prior to the company's expenditure of PHS funds, the DIO must:
    i. Review all Investigator SFI disclosures.
    ii. Determine if any SFIs related to PHS-funded research.
    iii. Determine if an FCOI exists, and if so
    iv. Develop and implement a management plan to manage the FCOI(s).
e. In the case a new Investigator begins to work on the PHS-funded research project or an existing Investigator discloses a new SFI, the DIO shall within 60 days review the SFI disclosures, determine whether an FCOI exists, and, if so, implement a management plan that specifies the actions that have been and will be taken to manage the FCOI.
f. In the case the company identifies an SFI that was not disclosed timely by an Investigator or was not previously reviewed by the company during an ongoing PHS- funded research project, the DIO shall within 60 days review the SFI disclosures, determine whether an FCOI exists, and, if so, implement a management plan that specifies the actions that have been and will be taken to manage the FCOI going forward.
g. The company will manage FCOIs of all Investigators, including those of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

3. Reporting Requirements to NIH
    a. Lifordi must send initial, annual, and revised FCOI reports, if applicable, including all required information defined in 42 CFR 50.605(b)(3) or NIH's FAQ H.5., to the NIH via the eRA Commons FCOI Module for the Institution and its subrecipients, if applicable, as follows:
        i. Prior to the expenditure of funds.
        ii. Within 60 days of identification for an Investigator who is newly participating in the project.
        iii. Within 60 days for new, or newly identified, FCOIs for existing Investigators.
        iv. At least annually, at the same time as when the company is required to submit the annual progress report. The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until completion of the project. FCOI reporting will end during the period of an award if a submitted annual FCOI report indicates that the FCOI "No Longer Exists."
        v. After a retrospective review to update a previously submitted report if new information is discovered following completion of the review.
    b. Lifordi must notify NIH promptly if bias is found with the design, conduct, or reporting of PHS-funded research. A Mitigation Report will be submitted to detail

the action(s) taken to mitigate the effects of the bias in accordance with 42 CFR Part 50.605(b)(2).
    i. The company will report all elements (e.g., entity name, Investigator with the FCOI, nature of the SFI(s), value of the SFI(s), etc.) as required by 42 CFR Part 50.605(a)(3)(iii).
c. Lifordi must notify NIH promptly if an Investigator fails to comply with Lifordi's FCOI policy or if an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research.
    i. The company will take corrective action for noncompliance with Lifordi's FCOI policy or the management plan.

4. Maintenance of Records
    a. Lifordi will maintain all FCOI-related records relating to all Investigator disclosures of financial interests and the company's review of and response to such disclosures (regardless of whether a disclosure resulted in the Institution's determination of an FCOI) and all actions under the Institution's policy or retrospective review, if applicable:
        i. For at least 3 years from the date the final expenditure report is submitted to NIH.
        ii. Or, where applicable, from other dates specified in 45 CFR 75.361.
5. Enforcement Mechanisms and Remedies and Noncompliance
    a. In the case an Investigator fails to comply with Lifordi's FCOI policy or an FCOI management plan, employee sanctions or other administrative actions will be implemented. These may include a letter of reprimand, restriction on the use of funds, loss of wages, or termination from the company.
    b. Lifordi will perform a retrospective review within 120 days of a determination of noncompliance when either an SFI is not disclosed timely or not previously reviewed or when an FCOI is not identified or managed in a timely manner, including:
        i. Failure by the Investigator to disclose a significant financial interest that is determined by the company to constitute an FCOI.
        ii. Failure by the company to review or manage an FCOI.
        iii. Failure by the Investigator to comply with the FCOI management plan.
    c. The retrospective review will be documented and will include, at minimum, the following:
        i. Project number
        ii. Project title
        iii. PD/PI and contact information
        iv. Name of Investigator with the FCOI
        v. Name of the entity with which the Investigator has an FCOI
        vi. Reasons for the retrospective review
        vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed)
        viii. Findings of the review

ix. Conclusions of the review

d. In the case where a PHS-funded project includes clinical research with the purpose to evaluate the safety or effectiveness of Lifordi's medical device or treatment and said PHS-funded project was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the company as required by 42 CFR 50.606(c), Lifordi will require the Investigator involved to:
    - Disclose the FCOI in each public presentation of the results of the research, and
    - Request an addendum to previously published presentations.

6. Subrecipient Requirements
    a. When applicable, Lifordi will comply with all subrecipient requirements according to 42 CFR 50.604(c) and NIH Grants Policy Statement 15.2.1.
    b. Lifordi will establish, via a written agreement, whether the subrecipient will follow Lifordi's FCOI policy or the FCOI policy of the subrecipient. In the case of the latter:
        i. Lifordi will obtain a certification from the subrecipient that its FCOI policy complies with 42 CFR Part 50 Subpart F.
        ii. Lifordi will include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the company to report identified FCOIs to the NIH as required by 42 CFR Part 50.605(b)(1) and (2) (i.e., prior to the expenditure of subrecipient funds under a new award or within a certain period of time of identifying an FCOI during the period of award (e.g., 50 days) to allow the institution to report the FCOI to the NIH prior to the 60-day reporting period.
        iii. Alternatively, Lifordi will include in the written subrecipient agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the company to identify, manage, and report identified FCOIs to the NIH.
7. Public Accessibility Requirements
    a. Lifordi's FCOI policy is publicly accessible on the company's website.
    b. Information concerning identified FCOIs held by senior/key personnel, as defined by 42 CFR Part 50.603, will be made publicly accessible prior to the expenditure of funds. The publicly accessible information will:
        i. Include the minimum elements as provided in 42 CFR Part 50.605(a)(5)(ii).
        ii. Be made available within 5 business days of a written request.
        iii. Be updated at least annually, but a response to a written request must be current.
        iv. Be updated within 60 days of a newly identified FCOI, but a response to a written request must be current.
        v. Remain available for 3 years from the date the information was most recently updated.

Forms:

- Lifordi Significant Financial Interest Form

Training:

The following employees or agents of the company are required to read this procedure and sign to acknowledge understanding and intent to comply:

- All Investigators participating in or planning to participate in PHS-funded research.

Date of Implementation:

Effective April 4, 2024

Expiration or Review:

This procedure and associated forms extend into perpetuity, unless:

1) Revised, in accordance with the procedures on revision.

2) Made obsolete by the implementation of a procedure that specifically supersedes this procedure.