

FINANCIAL CONFLICT OF INTEREST POLICY

Luceome Biotechnologies LLC (LUCEOME) strives to create a research climate that promotes objectivity in research by establishing standards such that the design, conduct and reporting of Public Health Service (PHS, which includes NIH) funded research is free from bias resulting from financial conflict of interest (FCOI).

POLICY

This policy is applicable to each employee who is planning to or is participating in research activity that is either partially or wholly supported by PHS funds. Under this policy, each such employee must:

1. **disclose** his or her significant financial interests (SFI) in entities that would appear to be related to the employee's professional responsibilities on behalf of Luceome;
2. **comply** with a FCOI management plan, if a FCOI is identified; and
3. **undergo** FCOI training, at least once every four years.

Disclosure of SFI is essential for LUCEOME to determine if a FCOI exists, and in cases of FCOI determine how it will be managed and reported in full compliance with government regulation. Non-disclosure of SFI or non-compliance with FCOI management plan may subject the employee to employment discipline including, without limitation, suspension or termination of employment.

DEFINITIONS

- A. *Employee's professional responsibilities on behalf of LUCEOME* means conducting research, submitting patent applications, publication, technical committee membership and, teaching as adjunct faculty at an Institute of higher education.
- 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. *Investigator* refers to PD/PI and any other person regardless of title or position, who is responsible for design, conduct or reporting of PHS funded research, including subgrantees, contractors, consortium participants, collaborators or consultants
- D. *Institution* means Luceome Biotechnologies, LLC
- E. *Regulation* means FCOI Regulation 42 CFR Part 50 Subpart F
- F. *Significant Financial Interest (SFI)* means 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:
 - 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:
 - a) 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;

- b) 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
- c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (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 excluded sources provided in regulation.

SFI Exclusions

- a) Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- b) Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;
- c) Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- d) 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;
- e) Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an 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 an Institution of higher education; or
- f) Income from service on advisory committees or review panels for a federal, state or local government agency, 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 an Institution of higher education.

PROCEDURE

Employees who are planning to or participating in research activity that is either partially or wholly supported by PHS funds must disclose their SFI in a timely fashion, either to a member of the LUCEOME Management Team (LUCEOME MT) or the designated LUCEOME FCOI official. The designated LUCEOME FCOI official will determine whether the SFI constitutes an FCOI, based on guidance set by the LUCEOME MT. Consistent with the attached, Protocol for Handling Financial Conflict of Interest, if the SFI is determined to be an FCOI, the LUCEOME MT will take actions to discuss and approve the implementation of an FCOI management plan consistent with

government regulation and, furthermore, to promptly notify the PHS funding component (e.g., NIH) via a FCOI report.

As a part of the FCOI management plan, the LUCEOME MT will decide one or more actions depending upon the situation, including requiring certain disclosure in public presentations, employee role reassignment, reduction or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that create financial conflicts. Employees with an identified FCOI must comply with the FCOI management plan.

ADMINISTRATION

The designated LUCEOME FCOI official is responsible for administration of this policy.

PROTOCOL FOR HANDLING FCOI

This protocol outlines the procedure that will be followed as per regulation (Title 42 CFR 50 Subpart F).

1. Who is required to disclose financial interests

Employees planning to or participating in research activity that is either partially or wholly supported by PHS funds are required to disclose financial interests (“PHS-funded Investigators”).

2. SFI disclosure

PHS-funded Investigators are required to disclose SFIs to either a member of the LUCEOME MT or the designated LUCEOME FCOI official, as follows:

1. Employees planning to participate in PHS-funded research are required to disclose all SFI's prior to submission of an application for PHS-funded research.
2. Once the research project has been funded all PHS-funded investigators shall submit SFI Disclosures within thirty (30) days of acquiring any new or increased SFI,
 - When a new investigator joins an ongoing PHS-funded project, the investigator shall submit SFI disclosures within thirty (30) days of joining the project.
3. All PHS-funded investigators shall submit an updated SFI disclosure annually.
4. SFI disclosures (except travel) must include the following information:
 - Identity of the sponsor/organizer; and
 - Nature of SFI (e.g., salary, license income, stock).
5. Externally funded travel also constitutes SFI, and therefore PHS-funded investigators shall submit SFI Disclosures for externally funded travel: prior to submission of an application for PHS-funded research; and for PHS-funded projects within thirty (30) days of externally funded travel and in an annual update. The following travel related information must be disclosed:
 - Purpose,
 - Identity of the sponsor/organizer,
 - Destination, and,

- Duration.

3. Review of disclosures

All SFI disclosures, including those submitted by a new investigator who joins an ongoing PHS-funded project, will be reviewed by the designated LUCEOME FCOI official. The review will determine whether an SFI is related to the PHS-funded research and therefore an FCOI. The designated LUCEOME FCOI official may involve the relevant investigator in the review and request additional information from the investigator.

When an SFI that was not disclosed by a PHS-funded Investigator in a timely manner is identified, the designated LUCEOME FCOI official will determine if FCOI exists, develop and implement a management plan within sixty (60) days after the identification of the SFI. In addition, the designated LUCEOME FCOI official will conduct a retrospective review of SFIs for the PHS-funded investigator within one hundred twenty (120) days and document it.

4. Management of FCOI

For each disclosure that leads to determination of FCOI, the LUCEOME MT will discuss and approve the implementation of a management plan developed by the designated LUCEOME FCOI official. PHS-funded Investigators with an identified FCOI must comply with the management plan. The management plan will include the following elements at a minimum:

1. The role and principal duties of the conflicted PHS-funded Investigator in the research project;
2. Conditions of the management plan (see examples below);
3. How the management plan is designed to safeguard objectivity in the research project;
4. Confirmation of the PHS-funded Investigator's agreement to the management plan; and
5. How the management plan will be monitored to ensure PHS-funded Investigator compliance.

Examples of conditions or restrictions that might be imposed to manage a PHS-funded Investigator's FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s));
- For research projects involving human subjects research, disclosure of financial conflicts of interest 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 Financial Conflict of Interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

5. Reporting FCOI to PHS Awarding Component (e.g. the NIH)

Based on the FCOI management plan, the designated LUCEOME FCOI official will submit an initial FCOI report to the PHS-funding component, for example NIH. The report will be submitted, for example using eRA Commons for NIH, and consist of all elements required by the regulation.

The FCOI report for will be submitted prior to the expenditure of funds under the Notice of Award. FCOIs identified during the period of award will be submitted to NIH within sixty (60) days of identification, including for new investigators joining an ongoing PHS-funded project.

Annual FCOI reports (or revised reports as a result of retrospective reviews) will also be submitted and will include the status of financial conflict, i.e., whether the financial conflict is still being managed or explains why the financial conflict no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

6. Training for FCOI

PHS-funded Investigators must undergo training with respect to this Policy and PHS FCOI rules and regulations, as follows:

1. When a new employee joins LUCEOME;
2. Prior to participating in PHS-funded research, and at least once every four years;
3. When the LUCEOME FCOI policy changes in a manner that effects PHS-funded Investigator disclosure or compliance requirements; and,
4. Immediately when LUCEOME MT determines that a PHS-funded Investigator is not compliant with the FCOI Policy or an FCOI Management Plan.

7. Sanctions for violation of policy

Disclosure of SFI is essential for LUCEOME to implement its FCOI policy. If a PHS-funded Investigator fails to comply with this policy (with regard for instance to the SFI disclosure requirement or implementation of an FCOI management plan), and appears to have biased the PHS-funded research, the LUCEOME MT will implement a mitigation plan and require that the Investigator disclose the FCOI in each public presentation of the results of the research, and to remedy previously published presentations with an FCOI disclosure addendum. In addition, the employee may be subject to employment discipline including, without limitation, suspension or termination of employment. In any case, the PHS-funding agency will be promptly notified.

8. Retention of records

Records of financial disclosures and any resulting action will be maintained for three (3) years from the date of submission of the final expenditures report.

9. Subrecipient compliance

When working with a subrecipient, a written agreement will be put in place to clarify: (a) which organization's (prime awardee or subrecipient) FCOI policy will be followed, and, (b) in either case, clarify the timeline for disclosure and reporting. Note that the prime awardee is

responsible for monitoring subrecipient' s compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest.

10. Public Accessibility

As required by PHS regulation, the LUCEOME FCOI policy is being made accessible on LUCEOME web site.

If a PHS-funded investigator holds financial interests that are determined to be FCOI, as required by PHS regulation, these will also be posted on the web site, as follows:

1. Include the minimum elements required by the regulation;
2. Update within sixty (60) days of a newly identified FCOI;
3. Update annually; and
4. Remain available for three (3) years.