

# OnLume's Financial Conflict of Interest (FCOI) Policy

Updated: August 31, 2021

## Purpose

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest (FCOI) to ensure public trust and meet scientific, program, and ethical goals of our National Institutes of Health (NIH) grant efforts). The intent of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under contracts with the Public Health System ("PHS") of the U.S. Department of Health and Human Services ("HHS") will be free from bias resulting from any financial conflicts of interest. OnLume believes we have fully addressed the requirements of the rulings of PHS and HHS; we will continue to update this policy as needed.

Effective June 27, 2018, OnLume's policy requires that each investigator, subrecipients, subgrantees, and collaborators affiliated with OnLume, by NIH or any other applicable grant or contract, be in compliance with U.S. federal requirements pertaining to "Objectivity in Research" promulgated by the PHS which are published in U.S. regulations 42 CFR Part 50, Subpart F and 45 CFR Part 94.

This FCOI policy are also available at [OnLume.com/FCOIpolicy](http://OnLume.com/FCOIpolicy) so that all interested parties, including the general public, have access to this Company policy.

## Summary of Process

Significant Financial Interests (SFI) (as defined below in *Key Definitions*) shall be disclosed on the Significant Financial Interest Disclosure Form by an Investigator requesting government-sponsored or company-sponsored funds for a research project or by an Investigator when a Significant Financial Interest arises during the course of research. Regardless of whether a SFI exists, all Investigators and key personnel are required to submit a SFI Disclosure Form annually.

It is the Principal Investigator's responsibility to ensure those with financial interests in research are identified and make the required disclosures in conjunction with submission of a research proposal or application for human subjects' approval.

The Significant Financial Disclosure Form and supporting materials are forwarded to the Research Integrity Officer (RIO) for review. RIO will be responsible for evaluating and instituting a plan for managing any disclosed financial interests, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

Advance approval by the RIO is required prior to engaging in government-sponsored research. A SFI review must be completed before any expenses are incurred under an award.

Annual updates are required of all Investigators and key personnel participating in research. Any Investigator who has acquired a new or increased financial interest during the course of a research project shall report it immediately to the RIO. Annual updates and newly acquired interests are reported using the Significant Financial Interest Disclosure Form.

It is the shared responsibility of the RIO and Chief Executive Officer (CEO) to ensure that all appropriate employees, consultants, or other representatives of the Company are trained on this policy.

## Training

All employees, consultants, and other representatives of the Company who are or may in the future be involved with PHS-funded research must read and understand this policy. The RIO and/or CEO will ensure that the policy is provided to all appropriate individuals before they commence work on PHS-funded research.

The NIH Financial Conflict of Interest tutorial is required for anyone involved with an PHS-funded project, which includes all Investigators, consultants and employees engaged in PHS-funded research or its compliance (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>). This course was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. This training must be completed:

- prior to engaging in research relating to any NIH-funded grant
- when there are changes to the FCOI policy
- by an Investigator who is new to the Company
- if an Investigator is not in compliance with the FCOI policy or management plan, as determined by the RIO
- at least once every four (4) years

Upon completion of the training, a certificate of completion must be filed in the appropriate project file with a copy forwarded to the RIO.

## Key Definitions

The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI. A complete list of official definitions can be found at 42 CFR 50.603.

*Institution* means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for or receiving NIH research funding.

*Investigator* means the project director or principal investigator 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.

*Institutional responsibilities* means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research,

research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

*Financial interest* means anything of monetary value, whether or not the value is readily ascertainable.

*Financial conflict of interest (FCOI)* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

*Manage* means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

*Research* is defined at 42 CFR 50.603, where the regulation applies to basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug) 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.

*Senior/Key Personnel* means the Program Director (PD)/Principal Investigator (PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the regulation.

*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
  - (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) Upon receipt of income related to intellectual property rights and interests (e.g. patents, copyrights)
- (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. For example, if

the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination and duration. The Company is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes a FCOI with NIH-funded research.

- (3) The term significant financial interest does not include the following types of financial interests:
- (i) salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
  - (ii) intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
  - (iii) any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
  - (iv) 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;
  - (v) 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 (vi) 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.

## Procedures

- A. Identification of Persons Required to Disclose a Significant Financial Interest** It shall be the responsibility of the Principal Investigator or designated official(s) of a Research project to identify all Investigators who have a SFI requiring disclosure under this policy and to ensure that a SFI Disclosure Form is prepared and submitted. This review must take place no later than the time of application for PHS-funded research. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.
- B. Submission and Review of Significant Financial Interest Disclosure Form** Every individual having a SFI requiring disclosure under this policy shall prepare a fully completed SFI Disclosure Form that shall be submitted to the RIO. An initial review of the SFI Disclosure Form will be conducted by the RIO to determine whether a SFI could directly and significantly affect the design, conduct, or reporting of NIH-funded research exists. If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFI identified in the SFI Disclosure Form.
- C. Management of a FCOI** A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy to ensure, to the extent possible,

that the design, conduct, and reporting of research will be free from bias. The management plan may require one or more of the following actions (but not limited to) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests;
- Review of research protocols by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflicts

All management plans are required to be signed by the Investigator and the RIO. Compliance of the management plan shall be monitored by the RIO.

**D. Annual Reporting and After-Acquired Significant Financial Interests** All Investigators shall provide annual SFI Disclosure reports or more frequently if required by the management plan. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFI Disclosure Form within thirty (30) days of discovering or acquiring the new SFI. It will be put on the FCOI report through the eRA Commons FCOI Module prior to expending any funds. OnLume will then report it to the PHS awarding component that has issued the award within sixty (60) days. Each investigator must submit an updated disclosure of an SFI not less than annually. If a PHS-funded project is conducted by an Investigator or SO with a conflict that was not disclosed or managed, OnLume is required to disclose the conflict in each public presentation related to the results of the research. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research project submits the required SFI report to the RIO.

**E. Violations of Conflict of Interest Policy** Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the RIO shall make recommendations to Company management regarding the impositions of sanctions or disciplinary proceedings against the violating individual. In addition, the Company shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. If an investigator fails to comply with OnLume's FCOI policy, OnLume shall complete a retrospective review of the Investigator's activities within 120 days to determine bias. If a bias is found, OnLume shall submit a mitigation report to the NIH in accordance with 42 CFR 50.605(b)(3) that shall address the impact of the bias on the research project and actions taken to mitigate bias. OnLume will work with the Investigator to set up an FCOI management plan to mitigate the situation. The federal agency may take its own action as it deems appropriate, including the suspension of the right to work on the project or the funding for the Investigator until the matter is resolved.

**F. Record Keeping** Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the RIO for three (3) years from the date the final expenditure report is submitted to the NIH, or as required by 45 CFR 74.53(b) and 92.42(b) for different situations.

- G. **Sub-recipient Requirements** Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F) and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. If a SFI is identified by the sub-award recipient, they are required to notify the RIO of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations.
- H. **Federal Reporting** The RIO is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:
- a. Initial report – prior to the Company’s expenditure of any funds under a NIH-funded research project, the Company must provide to the NIH an FCOI report regarding any Investigator SFI found by the Company to be a financial conflict of interest in accordance with the regulation.
  - b. During on-going NIH-funded research projects – the Company shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, the Company shall submit a FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.
  - c. Annual FCOI report – For any FCOI previously reported to the NIH, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

## Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the OnLume Signing Official, Adam Uselmann (adam.uselmann@OnLume.com).