



**ElSohly Laboratories, Inc. Policy
on Financial Conflict of Interest (FCOI)
in Research**



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Forms

Significant Financial Interest (SFI) Disclosure Form

PURPOSE

The purpose of this policy is to provide an operating procedure associated with identifying and managing financial conflict(s) of interest to safeguard the integrity of ElSohly Laboratories, Inc. (ELI: Company) research. 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.

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 the National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator's FCOIs.

KEY DEFINITIONS

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

HHS: the Department of Health and Human Services

Institutional responsibilities: an Investigator's professional activities on behalf of ELI (e.g., administration, research or consulting).

Investigator: 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 award, or proposed for such funding, which may include, for example, collaborators or consultants. ELI's Principal Investigator/Project Director, upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

PHS: 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).

Significant Financial Interest (SFI):

- i. 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 appear to be related to the Investigator's institutional responsibilities on behalf of UL.

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 for the investigator, investigator's spouse and dependent children, 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 including any stock, stock option, or other ownership interest, as determined through reference to public prices

or other reasonable measures of fair market value;

- a. 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
 - b. With regard to intellectual property rights and interests (e.g., patents, copyrights), a significant financial interest exists upon receipt of income of greater than \$5,000 related to such rights and interests.
- ii. The term significant financial interest does not include the following types of financial interests:
- a. Salary, royalties, or other remuneration paid by ELI to the Investigator if the Investigator is currently employed or otherwise appointed by ELI, including intellectual property rights assigned to ELI and agreements to share in royalties related to such rights;
 - b. 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;
 - c. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education; or
 - d. Income from service on advisory committees or review panels for a federal, state, or local government agency located in the U.S., a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.
- iii. Investigators must disclose the occurrence of any foreign or domestic 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 the Investigator's institutional responsibilities. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:
- 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.

Foreign Financial Interests: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

DISCLOSURES

Prior to the submission of an application to the NIH Grantee for funding, the Principal Investigator and all other Investigators at ELI must have disclosed to ELI's designated official an up-to-date listing of their Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application to NIH for funding from NIH, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to ELI's designated official promptly and prior to participation in the project.

Each Investigator who is participating in research under an NIH award must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to ELI pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a NIH funded project directly as a NIH Grantee and/or indirectly through a subaward) that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in research under an award from NIH must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Review by ELI's Designated Official: The designated official will conduct reviews of disclosures. The designated official will review any SFI that has been identified in a disclosure; these interests will be compared to each research award 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 award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award. The designated official has been designated as ELI's President, Dr. Mahmoud A. ElSohly.

Guidelines for Determining "Relatedness" and Financial Conflict of Interest:

The designated official will determine whether an Investigator's SFI is related to the research under a NIH award and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to the research under the NIH award when the designated official reasonably determines that the SFI: could be affected by the research conducted under the award; or is in an entity whose financial interest could be affected by the research. The designated official may involve the Investigator in the determination of whether a SFI is related to the research supported by the award.

A financial conflict of interest exists when the designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. In determining if an Investigator's SFI is related to the research under a NIH award, and if so, whether the relationship creates a FCOI, the designated official considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the designated official may also consider the following factors:

- Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
- Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or

- Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
- Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
- Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
- The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
- Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
- The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
- Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
- Whether other scientific groups are independently pursuing similar questions; or
- Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
- Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or
- Whether the project involves a subaward to an entity in which the Investigator has a SFI.

Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest: If a conflict of interest exists, the designated official will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the designated official will be guided by the principles discussed in this Policy. The designated official will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the Institution Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document;
- 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 disqualification 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);
- Severance of relationships that create financial conflicts;
- For research projects involving human subjects research, use of a data and safety monitoring board;
- Double-blind conditions;
- Provisions to conduct the work simultaneously at multiple sites;
- Written disclosure of the conflict to all individuals working on the research project;
- Annual reports on the research progress to the designated official.
- Disclosure at any presentation of information related to the FCOI.

If the designated official determines that a conflict exists, the determination will be communicated and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The designated official will keep a record of the disclosure and other relevant information for at least three years. If the designated official prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on a NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated official necessary to manage the Conflict of Interest. The designated official will communicate, in writing, with the NIH Grantee to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the NIH Grantee has reported the FCOI to NIH. The NIH Grantee will notify ELI when it may incur expenditures.

The designated official will keep a record of Investigator disclosures of financial interests and the designated official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations.

Public Accessibility to Information Related to Financial Conflicts of Interest:

Prior to the expenditure of any funds under a NIH award, ELI will ensure public accessibility, by written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- The SFI was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by ELI in the award application, progress report or any other report submitted to the NIH Grantee;
- ELI has determined that the SFI is related to the research funded through an award; and
- ELI has determined that the SFI is a financial conflict of interest.

The information that ELI will make available via a publicly accessible Web site or in a written response to any requestor within five days of request will include, at a minimum, the following:

- The Investigator's name;
- The Investigator's title and role with respect to the research project;
- The name of the entity in which the Significant Financial Interest is held;
- The nature of the Significant Financial Interest; and
- The approximate dollar value of the Significant Financial Interest in the following ranges: \$0-\$4,999; \$5,000-9,999; \$10,000 - \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If ELI uses a publicly accessible Web site to comply with the public disclosure requirements of the NIH regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the NIH-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the NIH-funded research project, if it is determined by the designated official that the Significant Financial Interest is related to the research and is a financial conflict of interest.

Information concerning the SFI of an individual, as limited by this Policy, will remain available, for responses to written requests or for posting via ELI's publicly accessible Web site for at least three years from the date that the information was most recently updated.

Reporting of Financial Conflicts of Interest:

Prior to the expenditure of any funds under an award funded by NIH, ELI will provide to NIH a FCOI report compliant with NIH regulations regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan.

While the award is ongoing (including any extensions with or without funds), ELI will provide to NIH an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing NIH-funded research project (e.g., upon the participation of an Investigator who is new to the research project), ELI will provide to NIH, within 60 days, an FCOI report regarding the financial conflict of interest and ensure that ELI has implemented a management plan and the Investigator has agreed to the relevant management plan.

Training Requirements

Each Investigator must complete training on ELI's Financial Conflict of Interest Policy Applicable to an Award

Issued by Public Health Services prior to engaging in research related to any NIH award and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- (1) ELI revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);
- (2) An Investigator is new to ELI research under a NIH award (training is to be completed prior to his/her participation in the research); or
- (3) ELI finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the designated official).

In fulfillment of the training requirement, UL requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> acting 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.

Failure to Comply with ELI's Conflict of Interest Policy Applicable to Public Health Service Funded Award:

When a FCOI is not identified or managed in a timely manner, including, failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a FCOI; failure by the Institution to review or manage such a FCOI; and failure by the Investigator to comply with a management plan; then ELI will within 120 days:

- Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct or reporting of research;
- Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B);
- Document ELI's determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this Policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research;

If bias is found, ELI shall notify NIH promptly and submit a mitigation report to NIH via the eRA Commons FCOI Module that shall address the following:

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

Thereafter, UL shall submit FCOI reports annually to NIH, in accordance with the regulation and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest, UL may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of UL's independent retrospective review.

Subrecipient FCOI Compliance:

A subrecipient relationship is established when federal funds flow down from or through ELI to another individual or entity and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to ELI for programmatic outcomes and compliance matters.

Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors and subawardees, are subject to ELI's terms and conditions, and as such, ELI will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation. ELI will incorporate, as part of a written agreement with the subrecipient, terms that establish whether ELI's FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator.

If the subrecipient's FCOI policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with ELI that it is in compliance with the federal FCOI regulation, and that the institution's portion of the project is in compliance with the FCOI policy. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigator is subject to ELI's FCOI Policy for disclosing SFI that are directly related to the subrecipient's work for ELI. ELI will, if applicable, submit a FCOI report to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to ELI. Such time period must be sufficient to enable ELI to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module.

If the subrecipient Investigator is subject to ELI's Investigator FCOI Policy, the agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of SFI to ELI. Such time period shall be sufficient to enable ELI to comply with its review, management, and reporting obligations under the regulation. ELI will submit any NIH FCOI reports for a subrecipient Investigator through the eRA Commons FCOI Module.

Maintenance of Records:

Records of financial disclosures and any resulting action will be maintained by the Institution 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. L will retain records for each competitive segment as provided in the regulation.

Failure to Comply with This Policy:

No expenditures of funds on an award supported by NIH will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any designated official-approved FCOI management plan.

Significant Financial Interest (SFI) Disclosure Form

| | |
|---|---------------|
| Employee Name: | |
| Telephone: | Email: |
| Proposal Submitted To: | |
| Investigator's Statement | |
| <p>I am disclosing the following significant financial interests (check below) and attaching a detailed explanation (in an envelope which may be marked <i>confidential</i>) that identifies 1) the business enterprise or entity involved, 2) the nature and amount of the interest, and 3) my relationship and duties within the entity's corporate structure.</p> <p><input type="checkbox"/> Salary or other payment services (e.g., consulting fees or honoraria).</p> <p><input type="checkbox"/> Equity Interests (e.g. stocks, stock options, or other ownership interests).</p> <p><input type="checkbox"/> Intellectual Property Rights (e.g. patents, copyrights, royalties, or other income from such rights)</p> <p><input type="checkbox"/> Other significant financial interests of the Investigator that possibly could directly and significantly affect or be perceived to affect the results of the research, educational, or service activities funded or proposed for funding.</p> | |
| <p>Further I agree:</p> <ul style="list-style-type: none"> ▪ To update this disclosure during the pendency of the award, either on an annual basis, or as new reportable significant financial interests are obtained; ▪ To cooperate in the development of a Memorandum of Understanding (MOU) that constitutes a conflict of interest "resolution plan"; ▪ To comply with any conditions or restrictions imposed by ELI to manage, reduce, or eliminate conflicts of interest. | |
| Investigator's Signature | |
| Signed: _____ | Date: _____ |