

Policy for Managing Financial Conflicts of Interest

1. POLICY STATEMENT

A. General Policy

The principles articulated herein are intended to provide guidance in the management of formal relationships between employees of Oleolive, Inc. (“Company”) and their external constituencies to ensure that the design, conduct, and reporting of sponsored research will not be biased by any conflicting financial interests. Under the Public Health Service (PHS) final rules on *Promoting Objectivity in Research* (Federal Register, August 25, 2011), each Investigator is required to disclose a listing of his/her significant financial interests, as well as those of his/her spouse and dependent children, that would reasonably appear to affect the research proposed for funding by the PHS. If, after review of these disclosures, it is determined that the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, the Company will report the existence of such conflicting interests to the sponsor and act to protect the resulting research from bias owing to the conflict. This policy statement is intended to satisfy current Federal rules for disclosure with regard to projects funded by the PHS involving conflict of interest situations.

B. Scope

This policy and the associated procedures are applicable immediately to all sponsored program activity at Oleolive, Inc. carried out by Company employees, consultants, scientists, trainees, technicians and other agents or research collaborators (“Company employees”). The policy and the associated procedures are derived from the final rules on Objectivity in Research promulgated by the PHS that were published in the Federal Register of August 25, 2011. The procedures described in this policy were created and designed primarily to comply with the specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research but are also intended to provide a basic framework and standards for identifying, evaluating, and managing potential financial conflicts of interest relating to Oleolive’s other research activities. These procedures will be followed whenever Oleolive, Inc. or its employees submit a request for funding from any external agency, whether it is the PHS or another Federal agency.

C. Research and Responsibility

Company research is facilitated and/or made possible through external funding from private as well as public sources. It is the Company's responsibility to assure the integrity of all aspects of such sponsored research while, simultaneously, taking care not to discourage the development of external funding opportunities.

D. Managing Financial Conflicts of Interest

This document and the accompanying procedure, SOP-25 Procedure for the disclosure of FCOI articulates Company policy on the management or elimination of financial conflicts of interest between outside constituencies and the associated funded activities carried out by Company. While this policy focuses on avoiding, or

at least managing, financial conflicts of interest, its primary purpose is to promote compliance with the standards of Objectivity in Research.

2. DEFINITIONS AND ACRONYMS

- A. Company means Oleolive, Inc.
- B. Company Employee is any individual employed on a full- or part-time basis by Oleolive, Inc. and is receiving, or will receive, compensation for such employment. (Includes Consultants, Agents and Research Collaborators of Company).
- C. Designated Official is the individual designated by Oleolive to oversee the financial conflicts of interest process, including solicitation and review of disclosures of Significant Financial Interests.
- D. Family member includes the Company employee's spouse and children or other adults who qualify as dependents under the Internal Revenue Code definitions.
- E. Financial Conflict of Interest (FCOI) is considered to occur whenever a Company employee, or a family member of the Company employee, has an existing or potential financial or other material interest that impairs, or appears to impair, the Company employee's independence and objectivity in the discharge of his/her responsibilities to and/or for the Company; or, alternatively, FCOI is considered to occur whenever a Company employee receives financial or other material benefit through inappropriate use of knowledge or information confidential to the Company. Moreover, an FCOI occurs when that interest could directly and significantly affect the design, conduct, or reporting of NIH-funded research.
- F. Investigator is the Principal Investigator, Co-Investigators, or any other Company employee responsible for the design, conduct, or reporting of externally funded scientific research activities.
- G. 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.
- H. Negative Finding means a determination has been made that no conflict of significant financial interest exists.
- I. PD/PI is a project director or principal Investigator of a PHS-funded research project.
- J. PHS is 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).
- K. Positive Finding means a determination has been made that a conflict of significant financial interest does exist and, therefore, appropriate administrative action will be required as given under 3.d. below.
- L. Project implies any externally funded activity such as basic, applied, or developmental research, or other activity conducted by Company employees on behalf of the Company.

- M. Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Company in the grant application, progress report, or any other report submitted to the PHS by the Company.
- N. Significant Financial Interest (SFI) is any item of monetary value including, but not limited to:
- i. Salary or other payments for services rendered such as consulting fees;
 - ii. Equity interests such as stocks, stock options, or other ownership interest; and
 - iii. Intellectual property rights such as patents, copyrights, and royalties from such intellectual property rights.
 - iv. SFI does not include:
 - a. Company remuneration such as salary or royalties;
 - b. Intellectual Property Rights assigned to the Company and agreements to share in royalties related to such rights;
 - c. Consulting fees from service on advisory committees or review panels for public or nonprofit entities; or
 - d. Any ownership interest in the Company held by the Investigator if the Company is a commercial or for-profit organization.
- O. Subrecipient means any individuals or entities that will perform part of the PHS-funded project, including contractors, academic institutions, consortium members, and contract research organizations.

3. PROCEDURE

A. Responsibilities of the Designated Official

The **Chief Operating Officer** as the Designated Official will be responsible for the following:

- i. Informing **Investigators** of their obligations under this policy and any related regulations;
- ii. Reviewing disclosures of SFI to determine whether they are related to the subject research and, if so, whether they constitute FCOIs as defined above;
- iii. Making a final determination involving an administrative action for positive findings of SFIs;
- iv. Maintaining all records relating to disclosures of financial interests, the Company's review and responses to such disclosures, and any related actions under this policy;
- v. Reporting and disclosure as required under this policy and applicable regulations;
- vi. For PHS-funded projects, ensuring that **Investigators** for subrecipients (e.g., contractors, academic institutions, consortium members, and contract research organizations) fully comply with this policy or provide the Company with sufficient assurances to enable the Company's compliance with all applicable regulations. To this end, the written agreement between the Company and the subrecipient will specify whether the FCOI policy of the Company or that of the subrecipient will apply to the subrecipient's **Investigators**, and if the subrecipient's policy will apply, the **Chief Operating Officer** will:
 - a. Establish time periods for subrecipient reporting of FCOIs to the Company that will enable the Company to report such conflicts in a timely manner, as required under its policy and the applicable regulations; and
 - b. Obtain certification from the subrecipient that its policy complies with 42 CFR 50.604 (c)(1)(i)-(iii).

1. If the subrecipient cannot provide such certification, the Company's policy will apply to the subrecipient's **Investigators**, and the Company will be responsible for meeting the requirements of this policy and the reporting obligations reflected in the applicable regulations.
- c. If the **Chief Operating Officer** is the subject of a FCOI, the Designated Official shall be the **Chief Executive Officer** who will assume all duties assigned to this position until the FCOI has been resolved, after which the position is returned to the Chief Operating Officer.

B. Internal Reporting Requirement

For PHS-funded research, as part of the funding application or proposal and prior to performing any work on the research, each **Investigator** who is planning to participate in the research is required by regulation to complete a Financial Conflict of Interest Disclosure (FCOID) Form and submit the FCOID Form to the **Chief Operating Officer**. This requirement also applies to **Investigators** who are or who work for subrecipients on PHS-funded research.

- i. FCOID Forms will be provided to **Investigators** in conjunction with annual training and will be otherwise made available.
- ii. The **Chief Operating Officer** will review FCOID submissions. The information reported on the FCOID Form includes a listing of the **Investigator's** known SFIs and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research. For travel, this will include, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- iii. **Investigators** in non-PHS-funded research who have any SFI that may reasonably appear to be affected by the research are also expected to complete the FCOID Form and submit it to the **Chief Operating Officer**.
- iv. **Investigators** are expected to submit an updated FCOID Form:
 - a. No later than the time of application for PHS-funded research;
 - b. At least annually during the period of the award;
 1. The annual update will typically be completed in conjunction with completion of annual training.
 - c. Within 30 days of discovery or acquisition of any new SFI (e.g., an interest acquired through purchase, marriage, or inheritance).
- v. For an SFI that was not disclosed timely by an **Investigator** or not previously reviewed by the Company, the **Chief Operating Officer** will, within sixty (60) days, review each disclosure and make the determination of whether an FCOI exists and is related to PHS-funded research. Management of the FCOI will follow the Company's procedure.

C. Determination and Management of Financial Conflicts of Interest

Upon receipt of a completed FCOID Form, the **Chief Operating Officer** will determine whether an **Investigator's** SFI is related to the subject research and, if so, whether the interest constitutes an FCOI under this policy and any applicable regulations. The **Investigator** may be required to submit additional information as part of the process. For travel, this may include a determination or disclosure of monetary value to determine whether the travel constitutes an FCOI with the PHS-funded research.

- i. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is in an entity whose financial interest could be affected by the research.
- ii. An FCOI exists if the SFI could directly and significantly affect the design, conduct, or reporting of the research.
- iii. Disclosures are categorized as a Negative Finding or a Positive Finding.
 - a. A negative finding indicates no FCOI exists, no further review is needed, and the disclosure will be filed in the Company's Human Resources files.
 - b. A positive finding indicates that a conflict of SFI does exist and requires appropriate administrative action.
 - c. The **Investigator** may appeal within 5 days of the positive finding to the **Board of Directors, excluding the Chief Operating Officer**, for a review of the FCOI determination.
- iv. Appeal of Positive Findings of Significant Financial Interests
 - a. The review of an appealed positive finding must be completed prior to the expenditure of any funds under an award. In reviewing positive findings, the **Board of Directors** will be guided by the following principles:
 - 1. Assure adherence to all relevant Company policies;
 - 2. Give full considerations to the nature and extent of the financial interests in the relationship of the **Investigator**, and/or the **Investigator's** family members, with the external constituencies;
 - 3. Give special consideration to the terms and conditions of sponsored project agreements that mitigate or complicate the given situation; and
 - b. Consult fully with the **Investigator** and obtain additional information from the **Investigator**, as deemed appropriate to the management of the apparent FCOI.

D. Managing Positive Findings of Significant Financial Interests

Following the determination of a positive finding, or upon confirmation of an appealed positive finding via review by the **Board of Directors**, an FCOI management plan will be implemented and monitored on an ongoing basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The **Chief Operating Officer** will make a final determination involving one of the following administrative actions:

- i. Accepting the sponsored project award;
- ii. Not accepting the sponsored project award; or
- iii. Accepting the sponsored project award subject to suitable modifications in the award documentation or in the **Investigator's**, or his/her family's, affiliation with the external constituencies involved. Reasonable modifications might include one or more of the following actions:
 - a. Requiring that public disclosure of the identified financial interests be made;
 - b. Requiring the disclosure of financial conflicts of interest directly to participants for research projects involving human subjects research;
 - c. Requiring that the data and research results be reviewed by independent reviewers identified by the **Board of Directors**;
 - d. Requiring that the research plan be modified;

- e. Requiring that the **Investigator** be disqualified from participation in a portion of the research;
- f. Requiring that the **Investigator** and/or her/his family member(s) divest certain SFIs related to the positive finding; or
- g. Requiring that the **Investigator** and/or his/her family members(s) sever relationships that create the FCOI.

E. External Reporting Requirements

The Company will disclose FCOIs as required by applicable laws or regulations.

- i. The **Chief Operating Officer** will provide to the PHS Awarding Component an FCOI report regarding any **Investigator's** SFI found by the Company to be conflicting and ensure that the Company has implemented a management plan.

The FCOI report will include the following key elements:

- a. Project number;
 - b. **PD/PI** or **Contact PD/PI** if a multiple PD/PI model is used;
 - c. Name of the **Investigator** with the FCOI;
 - d. Name of the entity with which the **Investigator** has an FCOI;
 - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - f. Value of the financial interest (dollar ranges are permissible: \$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;
 - g. A description of how the financial interest relates to the PHS-funded research and the basis for the Company's determination that the financial interest conflicts with such research; and
 - h. A description of the key elements of the Company's management plan, including:
 - 1. Role and principal duties of the conflicted **Investigator** in the research project;
 - 2. Conditions of the management plan;
 - 3. How the management plan is designed to safeguard objectivity in the research project;
 - 4. Confirmation of the **Investigator's** agreement to the management plan;
 - 5. How the management plan will be monitored to ensure **Investigator** compliance; and
 - 6. Other information as needed.
- ii. The Company will submit an FCOI report:
 - a. Prior to the expenditure of any funds;
 - b. Within 60 days of identification for an **Investigator** who is newly participating in the project;
 - c. Within 60 days for new, or newly identified, FCOIs for existing **Investigators**;
 - d. At least annually (concurrent with the annual progress report, multi-year progress report, if applicable, or at time of extension) to

provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.

- iii. In cases in which the Company identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, the Company will not submit an FCOI report to the PHS Awarding Component.
- iv. If the FCOI report involves an SFI that was not disclosed by an **Investigator** or not previously reviewed or managed by the Company (e.g., not reviewed or reported by a subrecipient in a timely manner), the **Chief Operating Officer** will, within one hundred twenty (120) days of the Company's determination of noncompliance, complete a retrospective review of the **Investigator's** activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
 - a. The retrospective review will include the following key elements:
 1. Project number;
 2. Project title;
 3. **PD/PI** or contact **PD/PI** if a multiple **PD/PI** model is used;
 4. Name of the **Investigator** with the FCOI;
 5. Name of the entity with which the **Investigator** has an FCOI;
 6. Reason(s) for the retrospective review;
 7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 8. Findings of the review; and
 9. Conclusions of the review
 - b. If bias is found in the retrospective review, the **Chief Operating Officer** will promptly notify PHS and submit a mitigation report. The mitigation report will include the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Company's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

F. Confidentiality

The Company will, to the extent possible, protect the confidentiality of disclosures. In every instance, the Company will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to employees of the Company only on a need-to-know basis and will not be disclosed outside of the Company unless necessary to comply with contractual, legal, or regulatory requirements.

G. Investigator Noncompliance

If an **Investigator** knowingly fails to comply with this policy (e.g., fails to identify an actual or potential FCOI), the Company may take appropriate disciplinary action, which may include, without limitation, termination of the **Investigator's** participation in the

research. In addition, for PHS-funded research, failure to comply with this policy or the applicable regulations will result in the following:

- i. If an **Investigator** knowingly fails to comply with this policy (e.g., fails to identify an actual or potential FCOI), the Company may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In addition, for PHS-funded research, failure to comply with this policy or the applicable regulations will result in the following:
- ii. The Company will make available to HHS all records pertinent to FCOIs and the management of those conflicts; and
- iii. If HHS determines that a clinical PHS-funded research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an **Investigator** with an FCOI that was neither disclosed nor managed, the Company will require disclosure of the conflicting interest in each public presentation of the results of the research and will request an addendum to previously published presentations, if necessary.

H. Training

- i. Upon hiring, each **Investigator** will be informed of the Company's policy on FCOIs, the **Investigator's** responsibilities regarding disclosure of SFIs, and of the requirements of the FCOI Regulation, Promoting Objectivity in Research, 42 CFR Part 50 Subpart F.
- ii. Each **Investigator** will be required to complete FCOI training. Each **Investigator** will complete the interactive training module offered by NIH (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) and submit a certificate of completion to the Company's Chief Operating Officer. This training module, by itself, does not meet all the requirements of the FCOI Regulation. As such, following the Company's Quality Management System policy, each Investigator will also be trained on this document, which details the Investigator's responsibilities for disclosure of SFIs and of the Company's specific FCOI policy. Each Investigator will sign and date this policy to acknowledge notification and training. Any changes to this policy will require re-training.
- iii. Each PHS-supported **Investigator**, including subrecipient **Investigators**, must complete FCOI training:
 - a. Prior to engaging in research related to any PHS-funded grant;
 - b. At least every 4 years;
 - c. Immediately, if:
 1. Revisions to the Company's FCOI policy affect requirements of **Investigators**
 2. An **Investigator** is new to the Company; or
 - d. The Company finds that an **Investigator** is not in compliance with the Company's FCOI policy or management plan.

I. Maintenance of Records

The Company will maintain records relating to all **Investigator** disclosures of financial interests and the Company's review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of an FCOI) and all actions under the Company's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from

other dates specified in 45 CFR 75.361.

J. Public Accessibility

i. Company Policy

This policy will be posted and publicly available on the Oleolive, Inc. website at www.oleo.live/fcoi

ii. Identified FCOIs

All identified FCOIs held by senior/key personnel will be made available within 5 business days of a written request. The information will include:

- a. the **Investigator's** name;
- b. the **Investigator's** title and role with respect to the research project;
- c. the name of the entity in which the significant financial interest is held;
- d. the nature of the significant financial interest;
- e. and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$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.

All information will be up to date and will remain available for three (3) years from the date the information was most recently updated.