

**University of La Verne Policy and Procedure on
Financial Conflicts of Interest
Enacted November 12, 2020**

I. Policy Statement

This policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in research performed on behalf of University of La Verne (“University”).

This policy provides requirements for the disclosure of financial interests that comply with the requirements of federal regulations 42 CFR§ 50.603-50.606 of the U.S. Department of Health and Human Services (HHS) and the HHS Public Health Service (PHS), but this policy is not limited in application to PHS-funded research. Rather, this policy applies broadly to research performed at, or on behalf of the University, without regard to whether the research has external funding and, if externally funded, regardless of the funding source. It also establishes the process for the management and reporting of financial conflicts of interest in research.

This policy applies in addition to general University policies, such as policies on standards of conduct, those that belong to ethics committees such as the Institutional Review Board (IRB), as well as other policies governing disclosure of activities and financial interests. If a specific federal law or regulation provides different requirements than this policy, the more stringent requirement applies.

II. Scope & Audience

This policy applies to Covered Individuals and Covered Family Members, as defined below in Section III, during the course of conducting research at, or on behalf of the University.

This policy does not contemplate any other compliance or ethics responsibilities that may be required by applicable law, policy, or agreement, including those related to conflicts of commitment and conflicts of interest unrelated to research.

III. Definitions (specific to this policy)

Conflict of Interest Official: an employee within the University’s Office of General Counsel charged with making determinations related to conflicts of interest, establishing management plans, and ensuring compliance with other obligations established by this policy.

Covered Family Member includes:

- a. a spouse;

b. a dependent child or stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the disclosure statement; and

c. a related or non-related, unmarried adult who resides in the same household as the Covered Individual, and with whom the Covered Individual is financially interdependent, as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

If the Covered Individual is in doubt about whether an individual is a covered family member, the Covered Individual should resolve the doubt in favor of disclosure.

Covered Individual: is an individual who, regardless of title or position, is responsible for the design, conduct, reporting, review, or oversight of research, including a principal investigator, co-investigator, or project director, and who must file and update financial disclosure statements under this policy.

This definition also applies to any student enrolled at the University who is responsible for the design, conduct, or reporting of research as defined in this section. A student's supervising faculty member who is in doubt about whether the student is a Covered Individual must request a determination by the Conflict of Interest Official appointed under Section IV(c)(1).

Institutional Responsibilities: means any of the professional responsibilities of a Covered Individual performed on behalf of the University, including consultation, teaching, professional practice, research, University committee membership, or service on a University panel such as an Institutional Review Board (IRB).

Research: means any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term includes both basic and applied research and product development.

Financial Interest: is an interest with monetary value which is subject to disclosure under Section IV(b) of this policy.

Financial Conflict of Interest (FCOI): is a financial interest which:

a. has been determined by the Conflict of Interest Official as having potential for directly and significantly affecting the design, conduct, or reporting of the research or is in an entity whose financial interest appears to be affected by that research, and

b. is subject to the University's development of a management plan to avoid any direct and significant impact to the Covered Individual's research.

Management Plans: A management plan is a written agreement that may impose conditions and prescribe actions necessary to manage a financial conflict of interest, including an action reducing or eliminating the financial conflict of interest, to ensure that the design, conduct or reporting of the research is free from bias or the appearance of bias.

IV. Responsibilities & Procedures

a. GENERAL PROVISIONS

1. Collaborators and Contractors

i. If research is carried out in cooperation with or through a subrecipient (subrecipients or consortium members), the University will enter into a written agreement with the subrecipient that provides legally enforceable terms requiring that a financial conflicts of interest policy acceptable to the University applies to the researchers of the subrecipient.

ii. If the policy of the subrecipient applies to its researchers, the subrecipient must certify its policy is consistent with the requirements of any applicable federal regulations.

iii. If the policy of the subrecipient applies to its researchers, the agreement must specify the time periods for the subrecipient to report identified financial conflicts of interest to the University. The time periods must be sufficient for the University to make any reports required by federal regulation.

2. Education

i. Each Covered Individual must acknowledge annually that he or she has read this policy and is aware of the Covered Individual's responsibilities regarding disclosure of financial interests and of applicable federal regulations.

ii. A Covered Individual must complete training in regard to this policy and applicable policies, regulations, and laws before engaging in research at the University and at least once every four years thereafter.

A. A Covered Individual who is new to the University must complete the training before engaging in research at the University, including research related to any PHS-funded grant.

B. A Covered Individual must complete the training immediately if the University finds that the individual is not in compliance with this policy or the individual's management plan, or if the University revises this policy in a manner that affects the individual's duties.

C. A Covered Individual must complete the training immediately if the University revises its Financial Conflict of Interest policy in a way that affects Covered Individuals.

b. DISCLOSURE OF FINANCIAL INTERESTS RELATED TO INSTITUTIONAL RESPONSIBILITIES

1. Extent of Disclosure

i. As often as required by subsection 10 of this section, a Covered Individual must complete or update a financial interest disclosure statement that:

A. identifies all research in which the Covered Individual is engaged at the time of the disclosure; and

B. discloses, as provided by Section IV(c), each financial interest of the Covered Individual and Covered Family Members that reasonably appears to be related to the individual's institutional responsibilities.

ii. In determining whether research or a financial interest should be disclosed, the Covered Individual should resolve the doubt in favor of disclosure.

2. Contents of Disclosure: Financial Interests

i. The following interests are considered to be financial interests and, subject to the exclusions provided by subsection 3 of this section, a Covered Individual's disclosure statement must include the following information related to the Covered Individual and Covered Family Members, but only in regard to interests that reasonably appear to be related to the individual's institutional responsibilities:

A. PAYMENTS RECEIVED FROM OR EQUITY INTEREST IN A PUBLICLY TRADED ENTITY: the total amount and source of payments received in the preceding twelve months from a publicly traded entity and the value of any equity interest held in the entity on the date of disclosure that, when aggregated, exceed \$5,000, including:

a) as to payments received in the form of salary and /or any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and

b) as to equity interests held, any stock, stock options, or other ownership interest or entitlement to such an interest, valued by reference to public prices or other reasonable measures of fair market value;

B. PAYMENTS RECEIVED FROM A NON-PUBLICLY TRADED ENTITY OR EQUITY INTEREST IN A NON-PUBLICLY TRADED ENTITY:

a) the total amount and source of payments received in the preceding twelve months from an entity that is not publicly traded that, when aggregated, exceed \$5,000, including salary and/or any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and

b) a description of any equity interest held in an entity that

is not publicly traded, including any stock, stock options, or other ownership interests or entitlement to such an interest;

C. INTELLECTUAL PROPERTY (E.G., PATENTS AND COPYRIGHTS) AND ROYALTIES:

a) a description of intellectual property rights held and any agreements to share in royalties related to those rights; and

b) the amount and source of royalty income that the Covered Individual or Covered Family Member received or had the right to receive in the preceding twelve months;

D. TRAVEL: reimbursed or sponsored travel in the preceding 12 months, including the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip;

E. GIFTS: the value and source of a single gift that the Covered Individual received in the preceding twelve months that exceeds \$250 in value, or multiple gifts from a single entity that in the aggregate exceed \$250 in value, other than gifts from a Covered Family Member; and

F. FIDUCIARY POSITIONS: a fiduciary position the Covered Individual held in a for-profit or nonprofit entity in the preceding twelve months, including a position as a member of the board of directors, an officer, or other executive or management position, for which the individual received any form of remuneration or reimbursement for expenses, and the name and principal address of the entity.

3. Exclusions. The following interests are not financial interests and need not be disclosed on the disclosure statement:

i. salary, royalties, or other remuneration paid by the University to the Covered Individual, if the Covered Individual is currently employed or otherwise appointed by the University;

ii. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;

iii. income from service on an advisory committee or review panel for a federal, state, or local government, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical

center, or a research institute affiliated with an institution of higher education;

iv. income from investment vehicles, such as mutual funds or retirement accounts, as long as the Covered Individual does not directly control the investment decisions made in those vehicles; or

v. travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined by 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.

4. In making disclosures under this section, the Covered Individual must disclose the value of a financial interest within the following ranges:

i. \$0 - \$4,999;

ii. \$5,000 - \$9,999;

iii. \$10,000 - \$19,999;

iv. amounts between \$20,000 - \$100,000 by increments of \$20,000; or

v. amounts above \$100,000 by increments of \$50,000.

5. When describing a source, the Covered Individual must provide the name and principal address for the source.

6. The Covered Individual must distinguish among information pertaining to the Covered Individual and Covered Family Members whose financial interests and activities are also disclosed by the Covered Individual.

7. Any appropriate University official, such as the Conflict of Interest Official, a vice president, dean or department chair, may request further information about a Covered Individual's travel, including the monetary value of the travel, in order to determine whether the travel constitutes a financial conflict of interest.

8. Disclosure of Financial Interests of Other Persons: Covered Family Member

i. In disclosing financial interests, the interest of any legal entity, including a foundation or a trust that is controlled or directed by the individual or by the individual and Covered Family Members, is considered to be the interest of the Covered Individual or Covered Family Member as if the separate legal entity did not exist.

9. Text of Documentation to be provided on Request

i. If a Covered Individual discloses payments, intellectual property

interests, or royalties, the Covered Individual must permit review of any related agreement, contract, offer letter, or other documentation on request of:

A. the president of the University;

B. the Conflict of Interest Official; or

B. any other person or entity with administrative responsibility in regard to reviewing financial interest disclosure statements or approving a related management plan.

10. When to Disclose; Period Covered by Statement

i. A Covered Individual must submit or update a financial interest disclosure statement:

A. not later than the 30th day of initial employment, covering the 12 months preceding the date of disclosure;

B. annually not later than date mandated by the University;

C. prior to the submission of a proposal for research funding

D. not later than the 30th day after acquiring a new financial interest that requires disclosure under IV(b)(2); and

E. within 30 days from date of travel.

11. A Covered Individual who is funded under a PHS-funded research project must ensure his or her financial interest disclosure statement is current at the time of application for research funding from the PHS entity, except that an individual who is new to the University and who is planning to participate in an on-going PHS-funded research project must submit the statement not later than the 30th day of initial employment.

12. The president of the University or the Conflict of Interest Official may require a Covered Individual to submit additional disclosures.

c. CONFLICT OF INTEREST OFFICIAL; DISCLOSURE STATEMENT REVIEW

1. Conflict of Interest Official

i. The University's General Counsel will designate a member of the Office of General Counsel to serve as the Conflict of Interest Official.

2. Disclosure Statement Review; Determination of Financial Conflict of Interest

i. The appropriate Conflict of Interest Official will solicit disclosure of Financial Conflict of Interests at the times noted in section IV(b)(10)

ii. The appropriate Conflict of Interest Official will review each financial interest disclosure statement and make two determinations.

A. whether any financial interest disclosed is related to research in

which the Covered Individual is engaged; and

B. if so, whether a financial conflict of interest exists.

iii. A financial conflict of interest is related to research in which the Covered Individual is engaged if the Conflict of Interest Official reasonably determines the financial interest appears to be affected by the research or is in an entity whose financial interest appears to be affected by the research.

iv. A financial conflict of interest exists when the Conflict of Interest Official reasonably determines that a financial interest could directly and significantly affect the design, conduct, or reporting of the research.

3. No Expenditure of Funds Prior to Review and Determination

i. Neither the University nor a Covered Individual may expend research funds unless the Conflict of Interest Official has determined that no financial conflict of interest exists or that any financial conflict of interest is manageable in accordance with the terms of a management plan that has been adopted and implemented in accordance with Section IV(d) of this policy.

4. Cooperation with Institutional Committees

i. The Conflict of Interest Official and the appropriate IRB, Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), and/or other relevant University committees will cooperate in the consideration of whether a Covered Individual has a financial conflict of interest in regard to research and in the development and implementation of a management plan for that conflict of interest.

d. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

1. Management Required for Financial Conflicts of Interest

i. If the Conflict of Interest Official determines that a Covered Individual has a financial conflict of interest, the official, in cooperation with the Covered Individual and other appropriate individuals designated by the Conflict of Interest Official, such as an appointed Objectivity in Research Committee, must develop a management plan governing that conflict of interest.

A. Examples of conditions or restrictions in the plan may include: public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research); 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 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); or severance of relationships that create financial conflicts (42 CFR§ 50.605(a)(1))

ii. If research is ongoing and a new Covered Individual discloses a financial interest related to that research or any other Covered Individual discloses a new or newly identified financial interest related to that research, the Conflict of Interest Official must, not later than the 60th day after the filing of the disclosure statement:

A. review the disclosure statement to determine if a financial conflict of interest exists; and

B. if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research.

C. File a new, annual, or revised FCOI disclosure with the NIH, as appropriate and following the requirements listed in 42 CFR§ 50.603-50.606.

iii. If the Conflict of Interest Official learns of a financial interest that was not timely disclosed or was not timely reviewed, the Conflict of Interest Official must, not later than the 60th day after learning of the interest:

A. determine whether the financial interest is a financial conflict of interest; and

B. if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research going forward.

C. File a new, annual, or revised FCOI disclosure with the PHS, as appropriate and following the requirements listed in 42 CFR§ 50.603-50.606.

iv. In addition, if a financial conflict of interest was not identified or managed in a timely manner, or if a Covered Individual fails to comply with a management plan, the Conflict of Interest Official must, not later than the 120th day after determining noncompliance:

A. complete and document a retrospective review and determination as to whether research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research; and

B. implement any measures necessary with regard to the Covered Individual's participation in the research between the date that the

noncompliance is identified and the date the retrospective review is completed.

C. File a new, annual, or revised FCOI disclosure with the PHS, as appropriate and following the requirements listed in 42 CFR§ 50.603-50.606.

v. For PHS-covered research projects, the retrospective review must cover key elements as specified by federal regulations at 42 CFR§ 50.605 (a)(3)(ii)(B) and may result in updating the Financial Conflict of Interest Report, notifying the PHS, and submitting a mitigation report as required by federal regulation (42 CFR§ 50.605 (a)(3)(iii)).

2. Management Plan Design and Agreement

i. A management plan must be in the form of a written agreement and must:

A. provide that the Covered Individual acknowledges receipt of the plan, understands the requirements of this policy, and understands and agrees to comply with the required actions and other terms of the plan, including the time frames for required actions; and

B. clearly identify each specific person responsible for monitoring compliance with the management plan.

3. Monitoring and Compliance

i. Each person conducting research under a management plan must comply fully and promptly with the plan, and each person identified in the management plan as having responsibility for monitoring compliance with the plan must carefully and fully monitor that compliance.

E. WEB POSTING OF FINANCIAL CONFLICT OF INTEREST INFORMATION

1. Posting of this Policy - This policy and each update of this policy must be publicly accessible through the Internet. Policy updates will take effect upon such online publication.

a. Posting of Information Regarding Specific Financial Conflicts of Interest in Research Funded by PHS

i. For each financial conflict of interest in PHS-funded research that is found to exist by the Conflict of Interest Official, the University will make the following information available to the public through the Internet in regard to each Covered Individual who contributes to the scientific development or execution of the research project in a substantive, measureable way, including a Covered Individual who is the project director or principal investigator:

A. the Covered Individual's name;

B. the Covered Individual's title and role with respect to the research;

C. the name of the entity in which the financial interest is held;

D. the nature of the financial interest that constitutes a financial conflict of interest; and

E. the approximate value of the financial interest by range or, if the dollar value cannot be determined by reference to public prices or other reasonable measures of fair market value, a statement to that effect.

ii. The approximate dollar value of the financial interest must be provided within the following ranges if it can be determined by reference to public prices or other reasonable measures of fair market value:

A. \$0 - \$4,999;

B. \$5,000 - \$9,999

C. \$10,000 - \$19,999;

D. amounts between \$20,000 - \$100,000 by increments of \$20,000; or

E. amounts above \$100,000 by increments of \$50,000.

iii. The University will update the information required by this section annually. In addition, for any financial conflict of interest of a Covered Individual whose information must be posted under this section and for which the information was not previously posted, the University will make the information required by this section available not later than the 60th day after the financial conflict of interest is identified.

iv. The website on which the information is posted must note that the information is current as of the date listed and is subject to updates.

vi. The information required by this section must remain available on the Internet for three years after its most recent update.

vii. For PHS-funded research, in regard to project directors, principal investigators, and other senior or key personnel, this information must be available through the Internet before expending PHS funds.

Conflict of Interest Official

F. CERTIFICATION AND REPORTS

1. Certification and Report Requirement

a. The University will comply with all federal regulations that require certifications and reporting including that each application for funding to the PHS include specific certifications and agreements in regard to this policy and financial conflicts of interest.

2. Financial Conflict of Interest Report

a. Before the expenditure of any funds under a PHS-funded research project, the appropriate University officials will make the Financial Conflict of Interest Report to the PHS awarding component in compliance with 42 CFR§ 50.605(b). In general, those regulations require a Financial Conflict of Interest Report regarding those interests that the University determines are financial conflicts of interest, including financial conflicts of interest of subrecipients. The reporting will include specified information sufficient to enable the awarding component to understand the nature and extent of the financial conflict and to assess the appropriateness of the management plan related to the conflict of interest. The federal regulations require reporting within a specified period of financial conflicts of interest identified subsequent to an earlier report and require annual updating of reports regarding previously disclosed financial conflicts of interest.

G. ENFORCEMENT

1. Disclosure is a Condition of Employment or Relationship to University

i. Timely, complete, and accurate disclosure of activities and financial interests consistent with this policy is a condition of employment at the University, and a Covered Individual who does not comply with this policy is subject to discipline, which may include termination of employment.

ii. For a Covered Individual who is not an employee of the University, compliance with this policy is a condition of participating with the University in the capacity that qualifies the person as a Covered Individual. The University may require the individual to execute a document certifying that the individual knows that compliance with this policy is a condition of participation.

2. Federal Enforcement

i. Federal regulations, 42 CFR§ 50.605(a)(3)(iii), require the institution to notify the PHS of instances in which the failure of a Covered Individual to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research. The PHS awarding component may take enforcement action or require the institution to take action appropriate to maintaining objectivity in the research. The institution must make information available to HHS or the PHS awarding component as required by federal regulation.

ii. If the HHS determines clinical research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a Covered Individual with a financial conflict of interest that was not managed or reported by the institution as required by federal

regulation, the institution will require the Covered Individual involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

H. ADMINISTRATION OF CONFLICTS POLICIES; RECORDS

1. Oversight and Authority

i. The president or his or her designee will appoint a Conflict of Interest Official who is responsible for overseeing implementation of this policy and who may provide additional procedures and supplementary forms, as appropriate, consistent with this policy and applicable sponsor regulations.

2. Records

i. Records regarding the disclosure of financial interests and the management of a conflict of interest, including financial interest disclosure statements, a reviewing official's determinations, and other records of University actions, must be retained for the longest of at least three years after:

a. the date of creation;

b. the date of termination or completion of a research award or contract, or the submission of the final expenditures report, for research identified in a disclosure statement; or

c. the date of final resolution of any investigation, audit, or similar action involving the records.

d. any other condition as defined in 42 CFR§ 75.361

ii. The University will provide for a centralized repository for financial interest disclosure statements, management plans, and related records.

iii. The Conflict of Interest Official, or another person designated by the president, will provide the Provost with copies of all guidelines, procedures, and forms used by the University relating to financial conflicts of interest and must ensure that the Provost receives copies of any revised guidelines, procedures, and forms simultaneously with the implementation of the revision.

3. Audits

i. The University will provide for regular audits of financial interest disclosure statements to determine individual and University compliance with this policy