

## RG:12

### Conflict of Interest in Research Policy

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#### I. PURPOSE

LMU is committed to maintaining high standards of ethical conduct in research. Appropriate awareness of conflicts of interest and how it can affect the quality of research as well as sponsored awards receipt is critical for all faculty, staff, and students who are engaged in research. Likewise, federal regulations and guidelines regarding financial conflicts of interest in research mandate that research funded by federal grants, cooperative agreements, or contracts be conducted, designed, and reported without bias.

#### II. POLICY STATEMENT

All faculty, staff, and students engaged as a Primary Investigator in sponsored research at the University must disclose activities that cast doubt on the integrity of research design, conduct, and reporting. This includes activities that either create a conflict of interest or that produce the appearance of a conflict of interest.

When significant financial interests or other personal factors could jeopardize or appear to jeopardize professional judgment or integrity in the conduct or reporting of research or performance in administration, management, instruction, or other university obligations, there is a conflict of interest. According to federal regulations, participants in externally financed research must fully disclose any substantial financial interests. A conflict of interest is not an accusation and does not imply that an employee's judgment has been compromised.

Any Significant Financial Interest (SFI) must be disclosed by completion of the Office of Research, Grants, and Sponsored Programs (ORGSP) Conflict of Interest in Research form by the deadline for research funding applications. The PI must either annually submit an updated disclosure of SFIs or acknowledge no change to previous disclosures. Should a new SFI arise during the sponsored project period (including marriage, inheritance, or purchase), the PI must reach out to ORGSP within 30 days of knowledge to determine if the conflict of interest needs to be managed, mitigated, reduced, or eliminated. Should management be required, the Investigator, Chair of the Department, and the Dean of the Investigator's school must work with the Office of Research, Grants, and Sponsored Programs on the creation of a management plan.

After the management plan is approved by the Executive Director of ORGSP, it may be utilized. While this is under review by the ORGSP, the PI may not engage in the research until the PI agrees to comply with the finalized management plan.

#### III. DEFINITIONS

**Significant Financial Interest (SFI):** a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's

spouse/domestic partner and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities:

- *With regard to any publicly traded entity*, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure plus the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- *With regard to any non-publicly traded entity*, a SFI 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/ domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest). An Investigator does not need to know the specific dollar value of an ownership interest because any equity interest in a non-publicly traded entity is a SFI even if the value is unknown.
- *With regard to intellectual property rights and interests* (e.g., patents, copyrights), a SFI exists upon receipt of income of greater than \$5,000 related to such rights and interests.

#### IV. AUDIENCE

This policy applies to any faculty, staff, or student member who conducts research within the University.

#### V. COMPLIANCE

Failure to follow this policy can result in loss of grant funding, the ability to apply for future grant opportunities through the University, and/or disciplinary action by the Executive Vice President for Academic Affairs.

#### VI. ROLES AND RESPONSIBILITIES

**Investigator:** Completes RCR instruction through the Collaborative Institutional Training Initiative (CITI). Completes and regularly updates the Conflict of Interest Form and adheres to Management Plan if necessary.

**Dean/Chair:** Works with the ORGSP to mitigate any potential Conflicts of Interest and collaborates on Management Plans.

**Office of Research, Grants, and Sponsored Projects:** Provides access to CITI training, the Conflict of Interest Form, and guides the development and safekeeping of any

Management Plan. Notifies federal agencies if an SFI is determined during the course of an award.

**Executive Vice President for Academic Affairs:** Determines appropriate action if compliance for this policy is not met.

## VII. APPLICABLE STATUTES, REGULATIONS, AND RELATED POLICIES

Promoting Objectivity in Research, [42 CFR Part 50](#) and [45 CFR Part 94](#)  
[National Institutes of Health Financial Conflict of Interest Policy](#)

## IX. PROCEDURE

1. **CITI Training:** The University utilizes the Collaborative Institutional Training Initiative (CITI) to provide the LMU community with a general overview of conflict of interest policies and regulations. This overview is designed to assist faculty, staff and students with acquiring a basic level of understanding. The module takes approximately 45 minutes and includes a brief series of questions. This training is required for all Investigators conducting research at LMU.
2. **Disclosing Conflicts of Interest:** Key personnel on specific federal and other sponsored research projects must complete a Financial Conflict of Interest Form (see Forms) assessing their significant financial and personal interests and disclose any potential conflicts to LMU. This is the first step in identifying, evaluating, and managing situations involving a conflict of interest.
3. **Managing Conflicts of Interest:** If the ORGSP determines that a conflict of interest exists, the Investigator, Chair of the Department, and the Dean of the Investigator's school works with the Office of Research, Grants, and Sponsored Programs on the creation of a management plan. The management plan must be followed throughout the life of the award. All Conflict of Interest forms and management plans will be confidentially maintained within the ORGSP.
4. **New SFI:** Should a new SFI arise during the sponsored project period (including marriage, inheritance, or purchase), the PI must reach out to ORGSP within 30 days of knowledge.
5. **PHS-funded research:** When Investigators apply for U.S. Public Health Service (PHS)-funded research (directly or flowing through another agency), the University must abide by the Financial Conflict of Interest (FCOI) regulation set by the PHS. All Investigators (defined by the PHS as 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) applying for funds from the Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA),

Indian Health Service (IHS), National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA) will be subject to the following provisions:

5a.) *Disclosing Conflicts of Interest*

Each Investigator must submit a disclosure form before applying for a PHS grant. This form must list any financial interests that the investigator believes are reasonably related to their institutional responsibilities and are held by them, their spouses, or any dependent children. The ORGSP must receive the disclosure form. If the researcher receives PHS funding, they must additionally update the disclosure at least once a year throughout the grant's duration and within 30 days after learning about or acquiring a new substantial financial interest. The LMU Conflict of Interest in Research Policy shall be followed when reviewing and managing disclosures.

5b.) *CITI Conflict of Interest Training*

Investigators must finish the LMU-mandated CITI training for Conflicts of Interest before beginning a PHS-funded research study. If the Conflict of Interest Policy is changed to influence the requirements for Investigators, if an Investigator is new to the University, or if an Investigator is not in accordance with this policy or a management plan, this training must be redone at least every four years and must be finished right away.

5c.) *Public Access of Disclosed Significant Financial Interest*

Any significant financial interest disclosed to the University that fits the following criteria will have information about it made accessible to public request:

- The disclosed significant financial interest is still held by the senior/key personnel of the active PHS project; [NOTE: Senior/key personnel are defined as a PHS Project Director or Principal Investigator and any other person who makes a significant, quantifiable contribution to the scientific development or execution of a project and is mentioned in the grant application, progress report, or any other report submitted by the institution, regardless of whether they are paid through the grant.]
- The University determines that the significant financial interest is related to the PHS-funded research; and,
- The University determines that the significant financial interest is a financial conflict of interest.

The information request must be made to the Executive Director of ORGSP who will respond within five (5) business days of receipt of the request. Disclosed

information will be provided to the extent required by applicable PHS regulations and state law.

5d.) *Subrecipients*

If the University conducts the PHS-funded research through a subrecipient, the University will include provisions determining whether the University's or the subrecipient's policy on Conflict of Interest in Research will apply to the subrecipient investigators in a written agreement with the subrecipient. The subrecipient will attest as part of the agreement that its policy conforms with the PHS requirements on Objectivity in Research if the subrecipient's policy will be applicable. For the University to send reports to PHS on time, the agreement must also stipulate the time(s) during which the subrecipient must notify it of any financial conflicts of interest that are discovered. As an alternative, if the University's Conflict of Interest in Research Policy is in effect, the agreement should provide timeframes for the subrecipient to send the University all subrecipient investigator declarations of substantial financial interests. These time frames must be long enough to allow the University to meet the PHS regulations-required deadlines for evaluation, administration, and reporting.

**X. CONTACT INFORMATION**

For more information regarding this policy, please contact the Office of Research, Grants, and Sponsored Programs.

**XI. DOCUMENT HISTORY**

Effective: 10-16-2024

➤ [CITI Training](#)