



LOMA LINDA UNIVERSITY
ADVENTIST HEALTH SCIENCES CENTER

OPERATING POLICY

CATEGORY: Research Affairs/Grants

SUBJECT: Research Conflict of Interest

Effective: 8/13/2013

Implemented: 8/13/2013

Replace: 5/20/2012

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RELATED ENTITY SPECIFIC POLICIES:

Please note: Definitions are found at the end of the associated procedure. Words used will be underlined the first time they appear in a document.

1. Consistent with Public Health Service (PHS) regulation 42 CFR Part 50, Subpart F, this policy promotes “objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct or reporting of research... will be free from bias resulting from Investigator financial conflicts of interest.” Loma Linda University and affiliated institutions shall apply PHS investigator reporting requirements to all research projects without respect to the source of the funds (e.g. federal, nonfederal, and private). See also 45 CFR Part 94 and NSF Grant Policy Manual, Section 510.

Note: This policy is in addition to other conflict of interest disclosure requirements.

2. All significant financial interests (SFIs) require close scrutiny. Reported or identified SFIs that are determined to be financial conflicts of interest (FCOIs) shall be managed, reduced, or eliminated.
3. Each investigator, including investigators added to projects by amendment, shall be responsible for disclosing all significant financial interests to Research Affairs at least annually for him/herself and family members, that could reasonably be perceived to benefit from, or influence, his/her institutional responsibilities. More than annual disclosure may be required under certain circumstances. See Significant Financial Interests Limits of Disclosure (H-35B).

In addition to the annual SFI disclosure requirement, investigators must disclose under the following circumstances:

- a. Each investigator shall initiate and submit updated disclosures within 30 days of acquiring or discovering a new significant financial interest.

- b. Each investigator shall submit required conflict of interest information to the sponsor for FDA-regulated research. [21 CFR 54.4(b)]

Note: LLU will accept another institution's research conflict of interest policy for sub-recipients and external collaborators provided the other institution has a complaint policy and LLU verifies certification on the Federal Demonstration Partnership listing or receives certification from that institution's authorized representative.

4. The Research Conflict of Interest Committee (RCOIC) shall determine when an SFI interest constitutes a financial conflict of interest (FCOI) and shall develop a plan to manage, reduce, or eliminate the conflict.
5. The Institutional Review Board (IRB) for human subjects research, the Institutional Animal Care and Use Committee (IACUC) for animal research, and Financial Management (FM) for all other research, are charged with requiring the principal investigator to incorporate the conflict management plan defined by the RCOIC into the conduct of their study. The conflict management plan shall, at a minimum, require investigators to disclose to research subjects that a conflict exists. Any proposed modification to the plan requires approval by the RCOIC.
6. Research Affairs shall report research conflicts of interest and conflict management plans for all types of research (as described in H-35A, section 9).
7. Individuals who become involved in research shall complete an initial Research Conflict of Interest training session, and then renew their training no less than once every four years.
8. The institution may withhold approvals and/or access to funds during the SFI disclosure and FCOI review process, depending on circumstance:
 - a. Grant Submissions: SFI disclosure must be completed prior to grant submission.
 - b. Notice of Award: Management plan must be in place and investigator must agree to management plan and FCOI training must be completed prior to expending any research funds.
 - c. IRB/IACUC Approvals: Investigators or other personnel cannot be added to a project until disclosure and training are completed. When an FCOI is identified, a management plan must be in place and accepted by the investigator prior to expending any research funds. When the person is already listed as an investigator on a project they may be temporarily, but officially, suspended from conducting research activities until SFI disclosures have been submitted, reviewed, and FCOIs cleared or managed.

Note: Should updated disclosures reveal a new financial conflict of interest, research activities may be suspended and access to funds from affected research awards may be restricted until a conflict management plan is formulated, implemented, and appropriate reporting obligations have been met.

Note: This must be completed by the institution within 60 days of the institution's discovery of the financial conflict of interest.

9. Research Integrity may monitor compliance with this policy, by conducting random and for-cause audits, as necessary.
 - a. Investigators may be selected for monitoring of compliance with disclosure requirements.
 - b. Research involving an investigator with a conflict of interest may be monitored for compliance with the conflict management plan.
 - c. Audits may be conducted to ensure compliance with reporting requirements to sponsors and federal agencies.
 - d. Deviations from this policy shall be reported to the VPRA and the RCOIC.
 - e. Research Integrity may consult with the RCOIC or other advisors to determine whether bias exists and to develop a mitigation plan and report.
10. Serious deviations from this policy shall be reviewed by a committee appointed by the VPRA. (See Research Non-compliance policy - in progress).
 - a. Disciplinary action may include censure, suspension of research approvals, restrictions on applying for research funding, nonrenewal of appointment, or dismissal. The Investigator may appeal in accordance with the appropriate grievance policy.
 - b. Research Affairs shall promptly notify the PHS awarding component or other sponsors of any conflict management plan or mitigation plan, and of any investigator noncompliance, if required.
11. Disclosures shall be retained per Document Retention policy (in progress).

Approved: LLUAHSC President's Council – August 13, 2013