LOMA LINDA UNIVERSITY

ADVENTIST HEALTH SCIENCES CENTER

OPERATING PROCEDURE

CATEGORY:	**Research Affairs/Grants**	Effective:	8/13/2013
		Implemented:	8/13/2013
SUBJECT:	Procedures for Research Conflict of Interest	Replace:	8/14/2012
		Page:	Page **1** of **8**

RELATED ENTITY SPECIFIC POLICIES:

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

1. Principal Investigator's (PI) Responsibilities:

    a. Identifies all personnel responsible for the design, conduct, or reporting of research at the initiation of each new project. Such persons are required to submit Significant Financial Interest disclosures annually.

        Note: The PI must submit personnel changes as they occur.

    b. Completes and submits the Disclosure of Significant Financial Interests to Research Affairs, as applicable:

        (1) Annual Disclosure: Investigators may submit one annual disclosure for all projects in which they are involved, if they meet all of the following conditions for the preceding 12 months:

            (a) the investigator (including his/her family members) have not had any investments, income or personal connections to pharmaceutical, biotech, drug, medical instrument, healthcare, research, or clinically related companies.
            (b) the investigator (including his/her family members) has less than $5,000 in travel sponsored or reimbursed by entities other than this institution and government agencies.
            (c) the investigator (including his/her family members) has not received any income related to intellectual property rights and interests (e.g., patents, copyrights).

Note: Investigators who do not qualify for this option or whose financial interests have changed are required to submit disclosures described in sections 1.2.b – 1.2.d below.

(2) New research projects: At the time of each new grant submission, new contract execution, or at the time a new IRB or IACUC protocol is submitted a new disclosure or additional information may be required to assist Research Affairs in determining if a Financial Conflict of Interest exists.

(3) Annual renewal of established projects: Submits disclosures with the annual renewal of research grants, contracts, or protocols.

(4) Change in significant financial interests: Submits an updated disclosure within (30) thirty days of a change in significant financial interests.

c. Ensures that no research personnel conduct any sponsored research activities before disclosures are filed, identified conflicts have been managed, and appropriate institutional approvals have been obtained.

d. Maintains research conflict of interest training.

2. Research Conflict of Interest Coordinator Responsibilities:

a. Screens disclosures of significant financial interests (SFIs) for potential conflicts of interest.

b. Compiles disclosures that have identified potential conflicts of interest for review by the Vice President for Research Affairs (VPRA) or designee and the Research Conflict of Interest Committee (RCOIC), if applicable.

(1) Gathers additional information, as necessary, for review by the VPRA and RCOIC.

c. Notifies the appropriate oversight committee or body (IRB for human subjects research, IACUC for animal research, or Research Affairs – Financial Management [RAFM] for laboratory research) that:

(1) All disclosures have been received for a project and no SFIs were identified.

(2) Some disclosures have not yet been received; project approval and funds must be held.

(3) All disclosures have been received; one or more SFIs have been identified and are under review.

(4) Conflict(s) have been identified and remain unresolved; funds will not be released until the identified COI(s) have been managed.

d. If disclosures have not been received, contacts the PI or research coordinator to facilitate receipt of disclosures.

e. Documents findings of the Research Conflict of Interest Committee (RCOIC), the basis for their recommendations, the nature and extent of the financial interests and the management plan for the conflict. The plan will include basic strategies to protect human subjects, animal subjects, the integrity of the research and the reputation of the institution, as appropriate.

f. Prepares and distributes a summary of RCOIC deliberations and approved management plans to RCOIC members, the VPRA, and General Counsel.

3. Investigator and Associated Research Personnel Responsibilities:

a. Complete disclosure forms as described for the PI in section 1.2 above.

b. Maintains research conflict of interest training.

c. Potential exclusions from reporting: Some investigators identified by the PI as not having significant responsibility for the design, conduct, or reporting of a research project may be excluded from the SFI disclosure requirement. For example, study personnel who follow predetermined instructions or protocols provided by an investigator or are not significantly involved in designing or modifying these protocols, may be excluded from SFI disclosure if the PI identifies the personnel and adequately justifies their exclusion from reporting. In addition, consultants paid less than $5,000 from a research grant or contract are not required to submit disclosures.

4. Vice President of Research Affairs (VPRA) or Designee Responsibilities:

a. Reviews disclosures that have identified research-related SFIs and supporting documentation.

b. Makes one of the following determinations:

(1) No conflict of interests identified; report administratively to the RCOIC.

(2) Conflict of interest(s) identified, but can be handled administratively by the VPRA and reported to RCOIC.

(3) Conflict of interest identified and requires review by the RCOIC.

c. Provides RCOIC approved plan for managing the conflict(s) to the relevant oversight committee or body (IRB, IACUC, or RAFM) for integration into the approval process and distribution to the affected investigator and PI.

d. If the investigator petitions the conflict management plan, the VPRA will convene a committee to seek a resolution and will communicate the final ruling to the appropriate oversight committee. If no resolution can be made, an appeal will be sent to the President for final ruling. The VPRA will then communicate the President's final ruling to the appropriate oversight committee.

e. Appoints a hearing committee, as necessary, to address serious cases of non-compliance with the conflict management plan.

f. Notifies investigators of research conflict of interest training requirements.

5. Research Conflict of Interest Committee (RCOIC):

a. The committee shall include:

(1) The Vice President for Research Affairs (Chair), or designee

(2) Investigators experienced in human studies, animal or in vitro research

(3) Director of Research Integrity

(4) Director of Technology Management

(5) Experienced member of relevant oversight committees, if any

(6) Ethics faculty

(7) General Counsel

(8) Others as determined necessary by the VPRA

b. RCOIC Responsibilities:

(1) Reviews disclosures of SFIs.

(2) Reviews the extent of the financial conflict of interest and identifies compelling circumstances concerning the research.

(3) Makes a determination as to the existence and potential impact of a conflict.

(4) When the investigator provides evidence for compelling circumstances, the RCOIC will review the case to determine whether the original conflict management plan must be honored and whether the circumstances warrant a revision to the plan

6. IRB/IACUC/RAFM

a. Communicates the approved management plan to the PI and conflicted investigator, and requires its implementation before the initiation of the research project.

b. Returns proposed changes to an approved management plan to the RCOIC for approval.

7. President

When the Investigator and the RCOIC cannot come to an agreement:

a. Reviews investigator's written appeal, including a copy of the conflict management plan, and renders a final ruling.

b. Communicates the final ruling to the VPRA and RCOIC.

8. Hearing Committee for Non-Compliance (as appointed by the VPRA):

a. The committee may include the following individuals or their designee(s):

(1) Provost (Chair)

(2) VPRA

(3) Director, Research Integrity

(4) Executive Vice President for Medical Affairs (when human subjects are involved).

(5) Dean who is primarily responsible for supervising the investigator

(6) Department Chair who is primarily responsible for supervising the investigator

(7) General Counsel

(8) Invitees may include: the chair/representative of the IRB, IACUC, or RAFM (for human, animal or *in vitro* research, respectively).

b. Responsibilities:

(1) Evaluates the level of severity of the deviation from the conflict management plan and recommends corrective actions to the VPRA.

(2) The VPRA shall have final authority to accept or reject recommendations and communicates the mitigation plan to the appropriate oversight committee, investigator, and supervisor/department head and funding agencies, as appropriate.

9. Research Administration and Principal Investigator Reporting Responsibilities:

a. Research Affairs must report the existence of financial conflicts of interest as follows:

(1) To Research Sponsor: financial conflicts of interest shall be reported to the sponsor, as appropriate.

(2) To Government Agencies: The institution shall make information available, as required by regulation, to the United States Department of Health and Human Services (HHS) regarding all conflicting interests and how those interests have been managed.

Information shall be made available to state agencies that monitor research, as required by statute or regulation. For PHS funded research, reports must be made within 60 days.

(3) To the Department Chair or Center Director: A copy of the management plan shall be provided to the head of the unit in which the covered individual resides administratively.

(4) To General Counsel: A copy of the management plan shall be provided to the Office of the General Counsel.

(5) Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall ensure public accessibility, via a written response within five business days of a request, of information concerning any Significant Financial Interest disclosed to the Institution that meets the following three criteria:

a. The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the institution in the grant application, progress report, or any other required report submitted to the NIH;

b. The Institution determines that the Significant Financial Interest is reltated to the NIH-funded research; and

c. The Institution determines that the Significant Financial Interest is a **Financial Conflict of Interest.**

(6) The information that the Institution makes available shall include, at a minimum the following:

a. Investigator's name;

b. Investigator's title and role with respect to the research project;

c. Name of the entity in which the Significant Financial Interest is held;

d. Nature of the Significant Financial Interest; and

e. 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.

b. Principal Investigators must report the existence of conflicts of interest as follows:

(1) To the Research Community: investigators shall disclose the existence of conflicts of interest to editors considering publications of the research; and in any substantive public communication of the research results, whether oral or written.

(2) To Research Subjects: investigators shall disclose the existence of a conflict to research subjects.

c. The IRB shall ensure the PI discloses the existence of conflicts to research subjects, as indicated in the management plan.

Definitions:

Compelling circumstances: facts and conditions that may favor a decision to allow a conflicted Investigator to participate in a research project. For example, when the individual having such interests is uniquely qualified by virtue of expertise and experience and the research could not otherwise be conducted as safely or effectively without the individual, he or she may be permitted in the study to the extent prescribed by the RCOIC.

Family: immediate family members including spouse, children, step-children, siblings, parents and parental in-laws.

Honoraria: payments in recognition of a special service or distinguished achievements for which custom does not typically set a fixed price (e.g. panel participation, reviewing manuscripts, leading group discussions, making presentations, and similar services).

Income: salary, consulting payments, honoraria, royalty payments, dividends, loans from the entity, or any other payments or consideration with value – including those received for lectures, seminars, and/ or teaching engagements. This *excludes* salary, royalties, or other remuneration paid by Loma Linda University Adventist Health Sciences Center or its affiliated corporations to the investigator if the investigator is currently employed or otherwise appointed by this institution.

Institutional Responsibilities: The investigator's professional responsibilities on behalf of Loma Linda University Adventist Health Sciences Center or its affiliated corporations, including but not limited to activities such as research, teaching, professional practice, institutional committee memberships, and service on panels such as the Institutional Review Board.

Investigator: the principal investigator, co-investigator, significant personnel or any other person who participates in the design, conduct, or reporting of any portion of a research project.

Manage/Managed/Management/Managing [of conflicts]: taking action to address a financial conflict of interest. This may include reducing or eliminating the financial conflict of interest so that the design, conduct, and reporting of the research will be free from bias to the extent possible.

Ownership/ Equity Interest: is a percentage of company valuation or in dollar amount (current market value if publicly traded; internal estimate of value if not publicly traded; otherwise, amount of investment). May be in the form of stock, stock options, real estate, or any other investment or ownership vehicle.

PHS awarding component: an organizational unit of the Public Health Service (e.g. NIH) that funds research.

Research: A systematic investigation or study designed to formulate generalizable knowledge such that the conclusions of the study may be applied to areas beyond that of the original setting. Research may be related to any domain of knowledge, recognizing that at Loma Linda University most research is broadly related to the health, social and behavioral sciences. The term includes basic research (that seeks to uncover fundamental rules or operations of nature), applied studies (that search for information to address practical issues), and product development, but it excludes quality improvement activities.

Small Business Innovation Research (SBIR) Program: an extramural research program for small businesses that was established by the awarding components of the Public Health Service and certain other federal agencies, the Small Business Innovation Development Act as amended. For purposes of this policy, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program.

APPROVED: __LLUAHSC President's Council: August 13, 2013__