

Guidelines and Procedures for Evaluation and Management of Conflicts of Interest in Human Subjects Research

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Abbreviations

Co-I	Co-investigators
COI	Conflict of Interest
COI Office	Conflict of Interest Officer
CMP	Conflict management plan
HSR	Human Subjects Research
ICF	Informed consent forms
IRB	Institutional Review Board
IRB COI Subcommittee Interest Procedure	Institutional Review Board (IRB) Subcommittee on Conflict of
PI	Principal
UC COI Committee	University Standing Committee on COI

1. Conflict of Interest Guidelines Related to Financial Relationships with a Company Sponsoring Research

Conflicts of Interest in Human Subjects Research (HSR)

Financial Interest (in the previous 12 months)	What's Required
\$0 - \$10,000 in cash compensation	Disclosure in the informed consent form (ICF).
\$10,000-\$25,000 in cash compensation;	Disclosure in the informed consent form (ICF). Conflict management plan developed and approved by the IRB COI Subcommittee.
>\$25,000 in cash compensation	Not permitted to be PI, Co-I, or subinvestigator on the HSR protocol.*
A fiduciary role	Not permitted to be PI, Co-I, or subinvestigator on the HSR protocol.*
Any ownership interest: Equity, stocks (options)	Not permitted to be PI, Co-I, or subinvestigator on the HSR protocol.*
Any royalties, license agreement, rights to royalties, "future distribution of UC interest"	Not permitted to be PI, Co-I, or subinvestigator on the HSR protocol.*

* Exceptions could be made when the IRB COI Subcommittee completes a risk/benefit calculation and determines that risks to human subjects and data integrity is minimal or can be mitigated with a conflict management plan.

1. The restrictions on payments include the 12 months prior to UC IRB approval of the study, while the study is approved by the UC IRB, and the 12 months following approval of the final progress report by the UC IRB. The revised Guidelines and Procedures are effective August 1, 2018.
2. This requirement applies to payments for acting as a scientific advisor, consultant, or speaker for the sponsor or having financial interests that compete with devices/therapeutics that are being evaluated in the study, or any other payments not directly related to the study. This requirement does not apply to payments directly related to conducting the study.
3. Disclosure in the informed consent document is required for payments greater than \$0. Minimum management of payments received in the past 12 months related to or directly from the sponsoring entity from \$1 to \$10,000 include disclosure in the informed consent document. The IRB COI Subcommittee could require additional management on payments depending on the circumstances.
4. Protocols in which the principal, co-investigator, or subinvestigators (or their immediate families) have received payments greater than \$10,000 but less than \$25,000 in the past 12 months are reviewed by the IRB COI Subcommittee prior to discussion at the IRB meeting. The IRB COI Subcommittee recommends a COI management plan to the IRB at the meeting when the protocol is discussed.
5. Investigators, co-investigators, subinvestigators, and their immediate family members, cannot receive greater than \$25,000 in the past 12 months from a sponsor and act as a principal investigator, co-investigator, or subinvestigator on a human subjects research study sponsored by that company at the University. This is also true for investigators, co-

investigators, or subinvestigators who have a significant financial relationship with a competing sponsor that directly relates to the proposed protocol. Some exceptions may apply pending IRB COI Subcommittee review and determination.

6. Once a conflict of interest is identified, requiring management (disclosure, conflict management plan, or otherwise), the management strategies remain in effect for the duration of the study.
7. The Conflict of Interest (COI) Officer contacts the investigator disclosing the financial relationship to understand the relationship and services provided to the sponsor. This information is then relayed to the IRB COI Subcommittee for their evaluation.
8. The IRB COI Subcommittee meets monthly or as needed (ad hoc). The conflict, as it relates to the investigator's role and responsibilities on the protocol, is evaluated and a recommended management plan is developed and approved by the Subcommittee prior to discussion at an IRB meeting.
9. Outside Activity Reports (OARs) for UC employees must be current when a research protocol is submitted to the IRB for review and approval. Disclosures in the OAR must be accurate and updated within 30 days of acquisition or discovery of a new outside activity that could reasonably appear to be related to an employee's institutional responsibilities. An employee who has not submitted an OAR or whose OAR has expired will not be allowed to conduct research until a current OAR has been submitted. The Office for Ethics in Industry Engagement will review OARs upon being notified of investigator financial relationships. Please see following policy on Conflict of Interest on Externally Funded Projects: http://researchhow2.uc.edu/docs/default-source/bulkupload/conflict-of-interest-on-externally-funded-projectsf64d0bbf5268494f95ab0096a0f93f75.pdf?sfvrsn=66cde2ef_0

2. Institutional Review Board Subcommittee on Conflict of Interest Procedure

Evaluation and management of conflicts of interest in human subjects research requires knowledge of policies, regulations and guidance on both human subjects protection and conflict of interest. This knowledge is gained by service on the IRB, continuing education opportunities, and COI Officer input and guidance. Therefore, the IRB Subcommittee on COI is composed of IRB members who are knowledgeable in the policies, regulations, and guidelines on management of COI in human subjects research including the COI Officer and/or other employees from the Office for Ethics in Industry Engagement.

The Subcommittee may consult with the University Standing Committee on COI as needed, however, the final authority for evaluation and management of COIs in human subjects research is the IRB.

The Subcommittee will evaluate protocols in which the principal, co-investigators, or subinvestigators (or their immediate family members) have received payments greater than \$10,000, but less than \$25,000 in the past 12 months. Payments of less than \$10,000 may be reviewed by the Subcommittee if an IRB member, HRPP staff, or the COI Officer have concerns about human subject protections and/or data integrity; disclosure in the informed consent document at a minimum is required for payments greater than \$0. Payments of greater than \$10,000 in the past 12 months will be reviewed by the COI Officer and the IRB Subcommittee

on COI to determine if the payments constitute a conflict of interest that may adversely affect the rights or welfare of research participants or impact the integrity of the research. If the Subcommittee determines that a COI exists, the Subcommittee will develop a management plan to protect participants and data integrity. The management plan will be presented to the IRB for approval.

1. The members of the IRB COI Subcommittee will include:
 - a. the IRB Chair
 - b. one of the IRB Vice-Chairs
 - c. three IRB members (at least one of these members will be actively conducting human subjects research at the University)
 - d. an IRB member not affiliated with UC
 - e. the HRPP Director or Assistant Director
 - f. an IRB member acting as a representative of the VA (if the conflict of interest involves a protocol being conducted at the one of the UC IRB VA affiliates)
2. The Subcommittee will be chaired by the COI Officer. The IRB Vice-Chair will chair the meeting when the COI Officer is unavailable.
3. The Subcommittee will meet on the first Monday of the month.
4. Subcommittee members may attend in-person or by phone.
5. The deadline for submission of materials to be discussed by the Subcommittee will be at 5 PM on the Tuesday before the meeting.
6. The agenda and materials will be distributed to all Subcommittee members on the Wednesday before the meeting.
7. To make recommendations on COI evaluation and management, a quorum must be present for the meeting. To establish a quorum at least half plus one of the members must be present.
8. Investigators may attend the subcommittee meeting to describe their proposed COI management plan.
9. Recommendations will be approved by a simple majority. A tie vote will be considered to be a recommendation against approval.
10. Recommendations of the Subcommittee will be presented to the IRB for approval or disapproval.

Information to be submitted for evaluation by the IRB Subcommittee on COI

1. A copy of the contract or other document that describes the services provided to the company including the amount of compensation received in the past 12 months may be requested from the researcher.
2. Amount of time spent on the activity.
3. Responsibilities of the investigator with a financial relationship in the study.
4. A description of how the investigator will ensure that the financial relationship will not negatively impact the rights and welfare of participants in the study.

3. Evaluation of Payments Related to Providing Services to a Sponsoring Company

Procedure

The IRB Subcommittee on COI will evaluate the following criteria to determine if there are compelling circumstances to justify the involvement of a conflicted investigator in a human subjects research study.

1. Is the investigator's participation essential for the conduct of the research? Is involvement of the investigator necessary to ensure the:
 - Safety of participants
 - Reliability of the data
 - Validity of the research
 - OtherDoes the successful completion of the study require the investigator's:
 - Insights,
 - Knowledge
 - Perseverance
 - Laboratory resources
 - Special patient populations of the investigator
 - Other
2. Would the best interests of patients who could benefit from the discovery justify involvement of the investigator?
3. What is the stage of the research?
 - Phase I
 - Phase II
 - Phase III
4. Type of study
 - multi center
 - single center
 - open-label
 - double-blind
5. Risk to participants
 - Minimal risk with no direct potential benefit
 - Minimal potential risk with direct benefit
 - More than minimal risk no direct potential benefit
 - More than minimal risk with potential direct benefit
6. Basis of Investigator Conflict of Interest
 - Payment for consulting
 - Speakers fees
 - Other
7. Evaluation of Services Provided
 - A copy of the contract or other document that describes the services the investigator provided to the company will be reviewed
 - Amount of time that the investigator spent on the activity

8. Responsibilities of the investigator in the study:
 - Principal or Co investigator
 - Conduct informed consent
 - Evaluate adverse events
 - Lead investigator for a multi-site study
9. Amount of payment received in the past 12 months

4. Development of COI Management Plan by IRB Subcommittee on COI Procedure

The following procedure will be used to develop management plans to protect the rights and welfare of participants

1. Management plan should define the stages of the research and the specific activities for which there are compelling reasons for the conflicted discoverer/investigator's involvement. An approved management plan should be structured to restrict the investigator's roles to those stages and activities.
What stage of the research may the investigator be involved?
What specific research activities may or may not the investigator be involved?
2. Is there a timeline proposed for elimination of the conflicted investigator from research participation?
If yes, what is the timeline?
If no, why not?
3. How will participants in the study be protected from risks related to the investigators conflict of interest?
Disclosure
Limits on the conflicted investigator's role in the study
Other
4. How will introduction of bias be prevented?
Data monitoring
Protocol design (e.g. double blind)
Limits on the conflicted investigator's role in the study
Other
5. The Subcommittee may adopt any of the management strategies listed below or may develop any other strategy to protect the rights and welfare of participants in the research:
 - a. The researcher will reduce or eliminate the financial interest;
 - b. The financial interest will be disclosed to research participants;
 - c. Responsibilities for financial and research decisions will be separated;
 - d. There will be additional oversight of the research;
 - e. An independent DSMB or other similar body will provide oversight;
 - f. Modification of roles in the research (e.g. PI change);
 - g. Elimination of the conflict.