Chapter 5:

Conflicts of Interest

Chapter Contents

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This chapter describes conflicts of interest disclosures and management in relation to research. The focus is on conflict of interest specific to investigators, research team, IRB members, consultants and USC as an Institution.

USC Conflict of Interest policies reflect the U.S. Department of Health and Human Services (DHHS) and Public Health Service (PHS) regulations effective 8/24/12 and the USC Office of Compliance policies.

5.1 Conflicts of Interest

An individual conflict of interest can arise when financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising, or reporting research. Conflicts can exist at the individual or institutional levels and involve financial and non-financial interests.

Conflicts of Interest may include but are not limited to the following:

- Equity (stocks or options, do not include mutual funds)
- Recruitment incentives (bonus payments) *(these are prohibited)*
- Consulting Fees
- Speaking Fees
- Travel Reimbursement
- Gifts
- Corporate Officer or Board of Directors
- Other Employment Relationship

- Trademarks/Copyrights
- Licensing Agreements
- Royalty Payments
- Patent Holdings

An Institutional Conflict of Interest (ICOI) may occur when a financial interest of the University (investments held by the University in a company) has the potential to bias or coerce results of research conducted by its employees or students, or creates an unacceptable risk to human subjects. A Significant Institutional Conflict of Interest is deemed "significant" when a research project includes human subjects and any of the following condition applies:

- The University holds any private equity in the outside entity, or
- The University has the potential to receive cash payments from existing licensing arrangements with the outside entity, or
- The University maintains an ownership interest or an entitlement to equity in a publicly-traded sponsor of human subjects research as a result of technology licensing activities.

To address these conflicts (either individual or institutional), the university established the USC Conflict of Interest in Research Committee (CIRC) to fairly examine and manage conflicts of interest.

5.2 USC Conflict of Interest in Research Committee (CIRC)

The Conflict Of Interest in Research Committees (CIRC) are charged with reviewing conflict of interest disclosures and formulating recommendations to manage, reduce, or eliminate conflicts of interest. The Health Sciences Campus and University Park Campus each have their own committees. When investigators report an actual or apparent conflict of interest for a research activity, the research cannot begin until a conflict management plan has been obtained from the CIRC. Additionally, investigators are not permitted to

begin an external activity that would create a conflict of interest relative to an ongoing research activity before they receive a conflict management plan. Investigators and research team members must comply with all the elements of the Conflict of Interest in Research Committee (CIRC) management plan. Once the CIRC determination is made and/or management plan is issued it is uploaded to the IRB application. CIRC management plans are reviewed and acknowledged by IRB members.

For full board studies, the convened IRB will document member receipt and acknowledgment or edits of the COI management plan and acknowledge. Any IRB-required changes will be noted and may be returned to the PI for action, or referred back to the CIRC for further consideration. The IRB may not limit or reduce the conditions imposed by the management plan but may impose a higher standard, if necessary, to establish that the regulatory criteria for approval of the research has been satisfied. For studies that qualify for exempt or expedited review, the COI management plan will be evaluated and acknowledged by the exempt or expedited reviewer respectively.

For COIs disclosed after full board approval of a study, subsequent CIRC review of COI and development of management plan are provided to the PI. The PI must submit an amendment in iStar and upload the management plan with any applicable changes to the study (e.g., COI disclosure in consent document). The convened IRB will document the review of the COI management plan and note any IRB-required changes, as appropriate.

At any time during the execution of a study, the disclosure of a possible COI to the CIRC results in the creation of an alert notice in iStar that identifies the study noting "A possible conflict of interest has been indicated" and or, "Possible COI has not been cleared". For full board studies this alert creates an IRB agenda item for review of the subsequent management plan, and resolution by the original convened IRB. In the case of exempt and expedited studies, the IRB reviewer will acknowledge that the resulting management plan is acceptable.

5.3 Investigator and / or Research Team Conflict of Interest Disclosures

Disclosures in the IRB application (iStar)

Potential or actual conflicts of interest must be disclosed at the time of submission of the initial and continuing review application to the IRB and at any time when the investigator and/or research team member establish a new outside relationship or change an existing relationship that creates a potential conflict of interest. Also, informed consent documents must disclose conflicts of interest, as applicable.

Conflicts of interest must be declared when the participating study investigators or other research personnel (or their immediate family/domestic partner) have an aggregated financial interest, and/or intellectual property interest in the sponsor or products used with the project, **equal to or exceeding $5,000 per year**. Additionally, investigators must inform the IRB of monies received below $5,000 for specific conditions defined in the iStar application. When these conditions are met, the potential conflict of interest is reviewed by the Office of Compliance.

Disclosures in USC's diSClose system

All disclosure of potential or actual conflict of interests must be made online using the diSClose system. Additionally, the IRB application includes conflict of interest questions for initial and continuing review applications. Investigators must also report conflict of interests if these arise during a study by submitting an amendment. Informed consent documents must disclose conflicts of interest, as applicable.

Disclosures for Research Funded by the Health and Human Services

Researchers who are proposing or have received HHS (including NIH, CDC, HRSA, and AHRQ) support must also make an annual disclosure of all financial interests related to their institutional responsibilities to USC, regardless of whether any of these interests give rise to a conflict of interest related to their research. The annual disclosure must be completed before a proposal can be submitted to HHS, and any identified conflicts must

be managed before an account can be established. In addition, all HHS investigators must complete training on conflicts of interest once every four years.

Disclosures to Sponsors

Investigators must adhere to sponsor-specific disclosure requirements, as applicable.

5.4 Institutional Conflict of Interest (ICOI)

An institutional conflict of interest may occur when a financial interest of the University (investments held by the University in a company) has the potential to bias research conducted by its employees or students, or creates an unacceptable risk to human subjects.

All Institutional Conflict of Interests that do not present a Significant Institutional Conflict of Interest shall be managed by disclosing the University's relationship with the outside entity in all relevant publications, proposals, consent documents and presentations.

An Institutional Conflict of Interest is deemed "significant" when a research project includes human subjects and any of the following condition applies:

- The University holds any private equity in the outside entity, or
- The University has the potential to receive cash payments from existing licensing arrangements with the outside entity, or
- The University maintains an ownership interest or an entitlement to equity in a publicly-traded sponsor of human subjects research as a result of technology licensing activities.

Significant Institutional Conflicts of Interest are presumed to be unacceptable, unless compelling circumstances are present that justify allowing the research to proceed at the University despite the presence of a significant conflict. The University conducts a fact-specific inquiry to determine whether the specific circumstances of a relationship are compelling or not. For more information, refer to the USC Institutional Conflict of Interest in Research: Policy and Procedure.

The Vice President of Research (VPR) will determine on a case by case basis the need for an independent IRB review of studies involving ICOI. Independent review by an outside bioethicist will provide evaluation to determine whether the ICOI meets the threshold necessary to seek review by an independent IRB.

If the VPR determines that the ICOI does not meet such criteria – the study will be reviewed by the USC IRB.

5.5 IRB Members and IRB Consultants Conflict of Interest

Conflict of Interest policy considerations apply to IRB members. The IRB prohibits the participation in IRB initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

An IRB member is considered to have a Conflict of Interest if:

- The IRB member or a Close Relation of the IRB member (spouse, mutual financial dependent, significant other, or person in an intimate relationship, child, parent, or sibling (including in-laws and step-relations), grandparent, grandchild, niece or nephew, aunt or uncle, or cousin) is involved in the conduct of the research

- When the IRB member or Close Relation of the IRB member has a supervisory, managerial or ownership interest in the research sponsor, or licensee, or a company having an economic interest in the research

- Equity interest held by an IRB member or Close Relation of an IRB member in a research sponsor, or licensee, or in any company having an economic interest in the research

- Incentive payments, bonus payments or finder's fees relating to the proposal paid to the IRB member or Close Relation

- Consultation arrangements between the IRB member or Close Relation of an IRB member and an organization or individual having an economic interest in the

research, which, when aggregated for the IRB member and the Close Relations of the IRB member, is equal to or exceeds $5,000

- Gifts, gratuities, or special favors from the sponsor, which, when aggregated for the IRB member and the Close Relations of the IRB member, is equal to or exceeds $5,000

- Honoraria, travel expenses reimbursement, or other reimbursements from the sponsor, which, when aggregated for the IRB member and the Close Relations of the IRB member, is equal to or exceeds $5,000

- Intellectual property rights related to the research IRB member and the Close Relations of the IRB member

- An arrangement has been entered into where the amount of compensation/ value of ownership interests will be affected by the outcome of the research

The IRB member Conflict of Interest policy also applies to consultants. The IRB Chair or Vice Chair will be responsible for providing the consultant with a copy of the IRB member Conflict of Interest policy prior to their review of the study. Once the consultant has read the policy, the IRB Chair or Vice Chair will ask the consultant if a conflict exists. If answered in the affirmative, the consultant may not review the study. All consultants are required to maintain confidentiality and are notified of this prior to reviewing proposed research for the IRB.