UC Davis Research Compliance (RCI) Standard Operating Procedure (SOP)

Date: July 30, 2021
Supersedes: Exhibit A to Section 230-05
Author: Christine Lan Higgs, Research Compliance and Integrity Analyst, UC Davis
Approver: Craig Allison, Executive Director of Research Integrity Compliance and Ethics (RICE), UC Davis
Responsible Department: Research Compliance and Integrity (RCI), Office of Research

---

1 PURPOSE

1.1 This procedure describes the process for reporting, reviewing and managing potential outside financial conflicts of interest in non-governmental sponsored research and educational activities, including the process for disclosing financial interests, the referral of positive disclosures to the Conflict of Interest Committee (COIC), the process for reviewing positive disclosures, and the establishment of management plans for managing, reducing or eliminating outside financial conflicts of interest in sponsored research and educational programs, including human subject research (HSR).

2 REVISIONS FROM PREVIOUS VERSION

2.1 New procedure that replaces Exhibit A of Section 230-05.

3 PROCEDURE REQUIREMENTS

3.1 All investigators must submit to UC Davis all required disclosures via the Electronic Conflict of Interest (eCOI) System. Paper disclosures will not be accepted.

3.2 All Principal Investigator(s) (PI) and other Investigators must disclose their outside financial interests and the financial interests of their spouses/domestic partners and dependent children on the appropriate disclosure form(s) (as indicated in section 4 below).

3.3 For non-PHS funded human subject research (HSR) (including Departmentally-funded HSR) and FDA-regulated HSR, the Institution applies UC Davis Policy and Procedure Manual: Chapter 230, Sponsored Programs: Section 05," Individual Conflicts of Interest Involving Research."

3.4 Investigators are defined as any individual who is responsible for the design, conduct, or reporting of the research. This includes the PI and others responsible for the scientific development or execution of the project and those with direct control over subject selection, data collection or data analysis, regardless of salaries or compensation. This does not include individuals whose duties are limited to execution the approved protocol under the oversight of the PI, technical support or purely advisory involvement in the project.

4 REQUIRED DISCLOSURES

4.1 California State Form 700-U must be electronically filed by the PI when:

4.1.1 The research is funded by non-governmental entities (e.g. private entities) or supported (e.g. provision of drugs, medical devices, or other products or services). The disclosure must be made no later than time of award, and anytime, new, incremental, or supplemental funding is received (as defined in PPM Section 230-05).

4.1.2 Change of PI.

4.1.3 Transfer of award/contract to UC Davis from another institution.

4.1.4 There is a request to receive material (MAT) from a non-exempt non-governmental sponsor in support of UC Davis research pursuant to a Material Transfer Agreement (MTA).

4.1.5 A gift is received from a private sponsor, which is earmarked for research or educational activities for which the PI is responsible.

4.1.6 No disclosure is required if the non-governmental funding entity is listed on the exempt list. In addition, all no-profit tax-exempt United States educational institutions are exempt from the disclosure requirement.

4.2 Form 800 must be electronically filed by the PI and all other Investigators when:

4.2.1 At time of proposal submission to the following sponsors:

4.2.1.1 National Science Foundation (NSF).

4.2.1.2 California Institute for Regenerative Medicine (CIRM).

4.2.1.3 University of California (UC) Discovery Grants.

4.2.1.4 University of California, Office of the President (UCOP) Special Programs (e.g. University AIDS, California Breast Cancer, Tobacco Related Disease).

4.2.2 When the PI or other Investigator seeks or receives funds from a non-governmental sponsor for HSR.

4.2.3 Prior to commencement of the project for departmentally funded HSR (includes not FDA regulated).

4.2.4 At IRB continuing review for PI and investigators who previously submitted a positive Form 800.

4.2.5 Within 30 days of any newly acquired/discovered outside Significant Financial Interest (SFI).

4.2.6 A new SFI is any one of the following:

4.2.6.1 A financial interest which previously did not meet the reporting threshold but has increased in value to meet or exceed the reporting threshold; or

4.2.6.2 A different type or nature of SFI than what had previously been disclosed from the same source that meets or exceeds the threshold (e.g. royalty payment from Company A versus Company B).

4.3 Supplemental Form

4.3.1 PI and other Investigators who make a positive disclosure on one of the forms described above must also electronically file a Supplemental Form to describe the nature of the outside financial interest related to the sponsored project. A positive disclosure is made when the PI or another Investigator reports an outside financial interest.

4.3.2 When completing the Supplemental Form for a project sponsored by the federal government or other agency for which Form 800 is required, the PI and other Investigators shall consider all SFIs to determine if any are related to the sponsored project. Examples include but are not limited to the following:

4.3.3 Financial interest in a business entity that develops, manufactures, or improves a product or offers services related to the research project.

4.3.4 Financial interest in a business entity that might manufacture or market a drug, device, procedure, or any other product used in the project or that will predictably result from the research project.

4.3.5 Consulting income from a business entity where the consulting activity could reasonably appear to be related to the research project.

4.3.6 Financial interest in a business entity that will act as a vendor, subcontractor, lessor, or other participant on the research project.

4.3.7 Financial interest in a business entity that is related to intellectual property in which the investigator is named as an inventor if the research project could reasonably appear to be affected by the interest.

4.3.8 PI or other Investigators may, at their option, include a proposed management plan. A proposed management plan shall include the elements set for in section V below.

5 REVIEW BY THE CONFLICT OF INTEREST COMMMITTEE (COIC)

5.1 The COIC will review each positive disclosure to determine whether an actual or potential conflict of interest exists. The COIC may consider the following in determining whether a conflict of interest exists: the amount of the financial interest, the role of the reporting individual with respect to the relevant entity, how closely the financial interest is related to the subject of the research, whether the research involves human subjects, whether and to what extent students are involved in the research, and any other factors that may be relevant. The factors and documents relied upon by the COIC will be addressed in the meeting minutes.

5.2 If the Committee determines that a potential or actual conflict of interest exists, the Committee will consider.

5.2.1 Whether the nature of the conflict could potentially influence or bias the outcome of the research,

5.2.2 Whether any harm could come to research subjects if a conflict biased the design, conduct or results of the research,

5.2.3 Whether the potential conflict should be managed, reduced, or eliminated. If none of these options is viable, the Committee will consider whether the research should proceed.

5.3 If the Committee determines there is a potential or actual conflict, the Committee will transmit its recommendation as follows:

5.3.1 When the case involves research with human subjects, the Committee will transmit its recommendation to the Institutional Review Board (IRB). The IRB will review the recommendation to ensure that the recommended course of action will adequately protect study participants and the credibility of the human research protection program. After receiving input from the IRB, the Committee will transmit its recommendation to the Vice Chancellor—Research (VCR), who will issue a decision regarding the Committee's recommendation.

5.3.2 In all other cases, the Committee will transmit its recommendations directly to the VCR for decision.

5.4 If the VCR decides that a potential or actual conflict of interest exists, the reporting individual will be notified and may be asked to submit a proposed management plan (see section 6, below).

5.5 If the VCR determines that a conflict of interest exists, the VCR will determine (upon review of recommendations by the COIC and/or IRB) what actions should be taken by the campus to manage, reduce, or eliminate the conflict.

6 MANAGEMENT PLAN

6.1 The proposed management plan should include:

6.1.1 Name and role of the PI and other Investigators on the project;

6.1.2 Title of the research and a short abstract of the project;

6.1.3 Name of the business entity with which the PI or any other Investigator has a conflict;

6.1.4 Nature of the conflict;

6.1.5 Names of potential person(s) who could serve as a monitor or as part of a management sub-committee;

6.1.6 Declaration of how research will be conducted to reduce the potential for bias in the research;

6.1.7 Plan for reporting the financial status of the project and on-going compensation from the business entity;

6.1.8 Appropriate level and timing of reporting to the monitor or management sub-committee;

6.1.9 Documents that would be appropriate for the monitor or management sub-committee to review.

6.2 Management and Oversight

6.2.1 Some actions that may be taken to manage a conflict of interest include:

6.2.1.1 Disclosure of the conflict to the public, human subjects, publishers and/or conference organizers,

6.2.1.2 In the case of human subjects research, requiring an independent investigator to obtain informed consent or conduct all or part of the research,

6.2.1.3 In the case of human subjects research, requiring independent safety monitoring,

6.2.1.4 Requiring that the financial interest be divested, restructured or placed in a blind trust,

6.2.1.5 Modification or severance of the financial relationship,

6.2.1.6 Requiring additional disclosures to relevant University committees,

6.2.1.7 Non-participation of the PI or the other Investigators in any business transactions between the PI/other Investigators and the business entity/entities,

6.2.1.8 Disclosure and/or review of relevant publications prior to submission,

6.2.1.9 Review of financial report on a regular basis by a monitor or management sub-committee,

6.2.1.9.1 Submission of reports on a pre-determined basis to a monitor or management sub-committee,

6.2.1.9.2 Annual (or other pre-determined timeline) meeting with a monitor or members of a sub-committee.

6.2.2 If the VCR deems it necessary, he will appoint a monitor or management sub-committee to oversee implementation of the management plan and management of the conflict of interest. The members of the management sub-committee may include individuals from outside of the University where the VCR determines that outside expertise is required to manage the conflict.

6.2.3 In these cases, the monitor or sub-committee will meet with the PI/other Investigators and review and approve the management plan. The plan will be signed by the monitor or chair of the management sub-committee and the PI/other Investigators. Any dispute between the PI/other Investigators and the monitor or sub-committee will be referred to the COIC for a recommended resolution and the VCR for decision.

6.2.4 The monitor/sub-committee and the PI/other Investigators will agree upon a timeline for reporting and reviewing documentation relevant to the oversight responsibility of the monitor/sub-committee. Documentation will vary depending upon the nature of the research and the conflict.

6.2.5 The monitor/sub-committee will review the report and relay the report and any additional relevant information to the COIC. Any revision of the plan or apparent deviation from or non-compliance with the plan will be relayed to the COIC. If the issues cannot be resolved within a reasonable time frame, the Committee will subsequently refer the matter to the Director--Research Compliance and VCR for action consistent with Section 230-05.