UC San Diego Senior Associate Vice Chancellor for Health Sciences Office of Clinical Research	SOP Number	OCR:007 Page 1 of 2
	Date:	04/02/2025
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SOP TITLE: CONFLICT OF INTEREST MANAGEMENT		

1 PURPOSE

1.1 This procedure establishes the process for Principal Investigators (PIs) and study personnel under the PI's supervision to follow for identifying, disclosing, and managing financial conflicts of interest (FCOI) when conducting human subjects research at UC San Diego Health Sciences.

1.2 The process begins when an investigator- or sponsor-initiated clinical study is being developed or is under review by the PI.

1.3 The process ends when an investigator- or sponsor-initiated clinical research study is no longer under consideration or has been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 N/A

3 REQUIREMENTS

3.1 Conflicts of interest (COI) may be actual, perceived, or potential conflicts that could affect research objectivity or participant safety.

3.1.1 COI disclosure should cover any relevant professional or financial interests within **the past 12 months** leading up to the research submission, or while the study is being performed, including data analysis. Investigators are required to update their COI disclosures at least **annually** or whenever there are new financial interests related to the study. At study completion, investigators should submit any final COI disclosures as part of the study's closing documents, which may include the final report or any ongoing commitments that arise from the research.

3.2 Financial interests are defined by institutional policy for federal and non-federal sponsors.

3.3 The Research Compliance and Integrity Office (RCI) monitors compliance with COI policies.

3.4 UC San Diego policy and state and federal law provide sanctions to be imposed for non-compliance with COI requirements, including disciplinary action, civil liabilities, termination of an award, and/or barring of an investigator from receipt of future awards.

3.5 COI disclosures are submitted via the Kuali COI system.

3.6 Disclosures must be completed as soon as the PI is aware of the COI or potential COI, and must be updated if a change occurs in the financial interests of the investigators or study personnel.

3.7 The Independent Review Committee (IRC) reviews financial disclosure statements and relevant features of a research project to determine if a potential, perceived, or real conflict of interest exists by virtue of the investigator's financial interests.

3.8 COI management plans stipulate the conditions under which an investigator may participate in human subjects research in which they have a COI.

4 RESPONSIBILITIES

4.1 The PI is responsible for ensuring that all required disclosure reports are submitted for each protocol via the Kuali COI system, including disclosure reports for all other personnel who have responsibility for the design, conduct, or reporting of the research.

4.2 The PI is responsible for following, and for ensuring that other personnel under their supervision follow, all COI management plan stipulations from the IRC and/or the IRB.

5 PROCEDURE

5.1 The PI will submit the required disclosure forms via the Kuali COI system as soon as they become aware of an outside financial interest or potential interest associated with the research.

5.1.1 Co-investigators must disclose all COIs to the PI and IRC, as applicable.

5.2 The PI or designee will indicate all personnel who have a COI in the initial IRB submission, or will submit a modification to the research if a new COI becomes known or if there is a change in an existing COI.

5.3 When the PI receives a concurrence letter from the IRC with a written management plan or documentation stating that no management plan is necessary, the PI must ensure that the IRB protocol documentation in the electronic submission system is accurate and that associated study documents, including the informed consent form, align with the requirements of the management plan, if any.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 OIA-001 SOP: Definitions

7.2 42 CFR Part 50, Subpart F: Promoting Objectivity in Research

7.3 45 CFR Part 94: Responsible Prospective Contractors

7.4 UC San Diego Kuali Conflict of Interest

7.5 UC San Diego COI Tutorials