1 PURPOSE
1.1 This procedure establishes how Related Financial Interests in Human Research are reported to and evaluated by the IRB.
1.2 The process begins when an individual engaged in Human Research identifies a financial interest that is related to the Human Research.
1.3 The process ends when the IRB makes the final decision as to whether the related financial interest and its management plan, if any, allows the research to be approved.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Added section 3.1.1, additional procedural language.
2.2 Revised policy to concentrate and define UC Davis reporting requirements.
2.3 Revised to clarify IRB reporting procedures. Removed section 3.1.1

3 DEFINITIONS
3.1 Financial Interest: See SOP: Definitions (HRP-001)
3.2 Management Plan: See SOP: Definitions (HRP-001)
3.3 Minimal Risk: See SOP: Definitions (HRP-001)
3.4 Related: See SOP: Definitions (HRP-001)
3.5 Related Financial Interest: A Financial Interest that is Related to the Human Research

4 POLICY
4.1 All personnel engaged in Human Research must report all RFIs to the IRB.
4.2 RFIs must be reported if;
   4.2.1 The RFI existed in the 12 months prior to the application for initial or continuing review, or;
   4.2.2 The RFI is anticipated to exist in the 12 months following initial or continuing review, or;
   4.2.3 A new RFI is acquired during the current approval period.
4.3 It is the responsibility of the Principal Investigators to ensure proper reporting of RFIs for all personnel engaged in the Human Research.
4.4 Reports must be submitted;
   4.4.1 At initial and continuing review;
   4.4.2 Within 30 days of acquiring a new, previously unreported RFI, and
   4.4.3 Within 30 days of acquiring income that exceeds the anticipated RFI previously reported to the IRB for the current 12 month period.
4.5 The IRB reviews RFIs to determine whether the financial relationship to the research creates a bias that might affect the rights and welfare of the human subjects or the reliability of the research data.
4.6 When applicable, the IRB will consider the Conflict of Interest Committee (COIC) determination during review of RFIs; however, the IRB’s determinations and management plan will replace the COIC’s determinations if the IRB’s requirements are more stringent.
4.7 This procedure does not alter replace this institution’s conflict of interest reporting policies.

RESPONSIBILITIES
4.8 Principal Investigators, personnel engaged in Human Research, Designated Reviewers, IRB staff and IRB members carry out these responsibilities.

5 PROCEDURES
5.1 The Principal Investigator reports any existing or expected RFIs for all personnel engaged in the Human Research as part of the application for initial or continuing review.
5.2 The Principal Investigator reports of any new RFI or increase in anticipated amount of an RFI as a modification to research.
5.3 Reports must include;
   5.3.1 The name of the person who has the RFI;
   5.3.2 The name of the entity with which the RFI exists;
   5.3.3 The relationship of the RFI to the study;
   5.3.4 The cumulative amount of income received for the previous 12 months, if any
5.3.5 The cumulative amount of income expected to be received in the coming 12 month period; if any
5.3.6 A description of the services performed; if any
5.3.7 The value of any equity interest in the sponsor or sponsor competitor;
5.3.8 The position title, if the RFI involves employment.

5.4 The IRB will review the RFIs;
5.4.1 RFIs that are less than $35,000 in value or are related to Human Research involving no greater than Minimal Risk may be reviewed by a Designated Reviewer;
5.4.2 RFIs that exceed $35,000 for research involving greater than minimal risk must be reviewed by a convened board.
5.4.3 When applicable, the IRB will consider the COIC determination

5.5 The IRB will determine if the related financial interest requires a management plan.
5.6 The IRB will make a decision as to whether the financial interest and its management, if any, allows the research to be approved.
5.7 IRB Staff will review reports from the COIC Committee, compare the determinations of the IRB to the COIC and notify the COIC staff of any discrepancies in determinations and management plans.

6 MATERIALS
6.1 None

7 REFERENCES
7.1 21 CFR §54
7.2 42 CFR §50
7.3 45 CFR § 94
7.4 SOP: Definitions (HRP -001)
7.5 UC Davis Policy and Procedure Manual: Chapter 230, Sponsored Programs: Section 05, “Individual Conflicts of Interest Involving Research”
7.6 UC Davis Policy and Procedure Manual: Chapter 230, Sponsored Programs: Section 07, “Public Health Service Regulations on Objectivity in Research”