1 Purpose
1.1 This policy establishes how the institution evaluates individual financial interests.
1.2 The process begins when the IRB or the Designated Official for Conflicts of Interests identifies a potential individual conflict of interest.
1.3 The process ends when the IRB makes the final decision as to whether the financial interest and its management, 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.

3 DEFINITIONS
3.1 Related Financial Interest (RFI): See SOP: Definitions (HRP – 001)

4 POLICY
4.1 The institution applies UC Davis Policy and Procedure Manual: Chapter 230, Sponsored Programs: Section 05, “Individual Conflicts of Interest Involving Research” or UC Davis Policy and Procedure Manual: Chapter 230, Sponsored RE: Section 07, “Public Health Service Regulations on Objectivity in Research” to all sponsored Human Research. For non-sponsored studies regulated by the FDA as identified on “FORM: INITIAL REVIEW APPLICATION,” the institution applies PPM 230-05 in accordance with 21 CFR Part 54. Contact UC Davis COIC for information about reporting financial relationships under the policies cited above.

4.2 The IRB reviews RFIs to determine whether the investigator’s relationship to the research creates a bias that might affect the rights and welfare of the human subjects or the reliability of the data.

4.3 The IRB will consider the COIC determinations 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.

4.4 Investigators must report related financial interests to the IRB:
4.4.1 At initial review; and
4.4.2 Within 30 days of acquiring the RFI. In instances where the investigator acquires knowledge of the RFI more than 30 days after acquiring the relationship (e.g. inheritance), the information must be reported within 30 days of acquiring knowledge.

5 RESPONSIBILITIES
5.1 IRB staff and Principal Investigators carry out these responsibilities

6 PROCEDURES
6.1 At the time of initial review Investigators must indicate if there are any known RFIs on the electronic Initial Review Application;
6.1.1 Investigators must report the amount and relationship of any known RFI by submitting either a narrative addendum or the COIC Forms 700-U, 800 and/or Supplemental Form.
6.1.2 Investigators may report additional income that is expected from the same entity before IRB approval of the study will expire.

6.2 RFIs that are acquired or newly discovered after the initial review of the research, or changes to any previously reported RFI that result in exceeding the expected income must be submitted as a change in research;
6.2.1 Investigators must report the new RFI or change to a previously reported RFI by submitting FORM: Modification to Research (HRP – 213) within the timeframe described in Section 4.4.2 above.
6.2.2 Investigators may either describe the RFI in a narrative in the description field of FORM: Modification to Research (HRP – 213) or submit the COIC Forms 700-U, 800 and/or Supplemental Form.
6.2.3 Investigators may include on the FORM: Modification to Research (HRP – 213) any income that is expected from the same entity before IRB approval of the study will expire.
6.3 RFIs reported on research involving only minimal risk may be reviewed by a Designated Reviewer;
6.3.1 A Designated Reviewer will consider the COIC determinations during the review of the RFI (See Section 3.2);
6.4 RFIs reported on research involving greater than minimal risk must be reviewed by a convened board.
6.4.1 Committee Analysts will assure that the RFI is scheduled for review on an appropriate agenda;
6.4.2 If the results of the COIC review are available, Committee Analysts will include the results in the submission for the convened board review;
6.4.3 Upon receipt of the COIC Determinations, the Committee Analyst will compare the COIC determinations to the IRB determinations and notify the COIC if the IRB requirements are more stringent.
6.4.4 Committee Analysts will place the project on an appropriate agenda for reconsideration if the COIC’s determination is more stringent than the IRB’s determination.

7 MATERIALS
7.1 None

8 REFERENCES
8.1 21 CFR §54
8.2 42 CFR §50
8.3 45 CFR § 94
8.4 SOP: Definitions (HRP -001)
8.5 UC Davis Policy and Procedure Manual: Chapter 230, Sponsored Programs: Section 05, “Individual Conflicts of Interest Involving Research”
8.6 UC Davis Policy and Procedure Manual: Chapter 230, Sponsored Programs: Section 07, “Public Health Service Regulations on Objectivity in Research”