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

3 POLICY
3.1 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 Programs: Section 07, "Public Health Service Regulations on Objectivity in Research" to all sponsored Human Research.
3.1.1 For non-sponsored studies regulated by the FDA as identified on "FORM: APPLICATION FOR INITIAL REVIEW (HRP-211)," the institution applies PPM 230-05 in accordance with 21 CFR Part 54.
3.2 The financial disclosure threshold may not vary by funding source or regulatory oversight. Reporting of financial conflicts of interest will vary by applicable regulations and funding source.
3.3 Individuals subject to this policy are required to disclose their financial interests Related to the Research:
3.3.1 On submission of an initial review.
3.3.2 At least annually on submission of continuing review.
3.3.3 Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
3.3.4 As provided in the Policies identified in 3.1 above.

4 RESPONSIBILITIES
4.1 The Designated Official for Conflicts of Interest carries out these procedures.

5 PROCEDURE
5.1 Apply 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 Programs: Section 07, "Public Health Service Regulations on Objectivity in Research" to evaluate and manage the individual financial interest, as disclosed in the Financial Interest Declaration section of "FORM: APPLICATION FOR INITIAL REVIEW (HRP-211)."
5.2 If the individual financial interest is determined to be a conflict of interest, provide the IRB staff of the reviewing IRB with the written management plan so the IRB can make the final decision as to whether the financial interest and its management, if any, allows the research to be approved.

6 MATERIALS
6.1 None

7 REFERENCES
7.1 21 CFR §54
7.2 42 CFR §50
7.3 45 CFR §94