1 PURPOSE

1.1 This procedure establishes the conditions under which researchers engaged in Human Subjects Research (HSR) disclose individual outside financial interests and how such interests are evaluated by the Institution.

1.2 The process begins when the researcher submits to the Institution the required disclosure(s).

1.3 The process continues with the IRB and/or the Conflict of Interest Committee (COIC) evaluating whether the outside interest constitutes a Financial Conflict of Interest (FCOI).

1.4 The process ends when the IRB makes the final decision as to whether the FCOI, if present, 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.

2.3 Revised to clarify IRB reporting procedures. Removed section 3.1.1.

2.4 Revised to require reporting to Conflict of Interest Committee and define Required Disclosures.

2.5 Revised to clarify thresholds and reporting responsibilities.

3 POLICY

3.1 All Investigators responsible for the design, conduct or reporting of the HSR must submit to the Institution all required disclosures via the eCOI system.

3.2 For PHS-funded HSR, the Institution applies UC Davis Policy and Procedure Manual: Chapter 230, Sponsored Programs: Section 07, “Public Health Service Regulations on Objectivity in Research.”

3.3 For non-PHS funded HSR and all FDA regulated HSR regardless of funding, the Institution applies UC Davis Policy and Procedure Manual: Chapter 230, Sponsored Programs: Section 05, “Individual Conflicts of Interest Involving Research.”

4 REQUIRED DISCLOSURES

4.1 For all privately funded or supported (e.g. provision of drugs, medical devices, or other products or services) HSR, all Principal Investigators (PIs) must electronically submit a Form 700-U at the time of award, and anytime new, incremental, or supplemental funding is received (as defined in PPM Section 230-05).

4.2 For all non-PHS funded and/or FDA-regulated HSR, all Investigators responsible for the design, conduct or reporting of the research (including the PI) must electronically submit a Form 800 at the following times:
   4.2.1 No later than initial IRB submission
   4.2.2 At continuing review only for investigators who previously submitted a positive Form 800
   4.2.3 Within 30 days of any newly acquired/discovered outside financial interest.

   4.2.3.1 A new SFI is any one of the following:
      4.2.3.1.1 A financial interest which previously did not meet the COIC’s reporting threshold but has increased in value to meet or exceed the COIC’s reporting threshold; or
      4.2.3.1.2 A different type or nature of SFI than what had previously been disclosed from the same source that meets or exceeds the COIC’s threshold (e.g., royalty payment versus consulting fees); or
      4.2.3.1.3 The same type or nature of SFI from a different source (e.g., royalty payment from company A versus company B).

4.3 For PHS-funded HSR, all Investigators responsible for the design, conduct or reporting of the HSR (including the PI) must electronically submit a PHS-COI disclosure in compliance with PPM Section 230-07 at the time of proposal.

5 RESPONSIBILITIES

5.1 Investigators responsible for the design, conduct, or reporting of HSR, IRB Administration and Committees, Research Compliance and Integrity Administration, and the COIC carry out these procedures.
6 PROCEEDURE
6.1 Investigators submit required disclosures via the eCOI system.
6.2 The Institution applies UC Davis PPM Section 230-05 or Section 230-07 to evaluate and manage the individual financial interest as indicated above.
6.3 If the outside financial interest is determined by the COIC to be an FCOI, the COIC will 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.

7 MATERIALS
7.1 None

8 REFERENCES
8.1 42 CFR §50
8.2 45 CFR §94