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**1 PURPOSE**

- 1.1 This procedure outlines when Investigators engaged in Human Subjects Research (HSR) must disclose individual outside financial interests and how such interests are evaluated by the Institution.
- 1.2 The process begins when an Investigator submits 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.
- 2.6 Revised to define “Investigator”, require Form 800 for unfunded research when there is an SFI, require Form 800 at Cont. Review only when there are changes.
- 2.7 Revised to require annual updates to ongoing FCOIs.

**3 POLICY**

- 3.1 All Investigators 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 (including Departmentally-funded HSR) and FDA-regulated HSR, the Institution applies UC Davis Policy and Procedure Manual: [Chapter 230, Sponsored Programs: Section 05](#), “Individual Conflicts of Interest Involving Research.”
- 3.4 For purposes of this Procedure, Investigators are defined as any individual who is responsible for the design, conduct, or reporting of the research. This includes the PI and others responsible for the scientific development or execution of the project and those with direct control over subject selection, data collection or data analysis, regardless of salaries or compensation. This does not include individuals whose duties are limited to execution the approved protocol under the oversight of the PI, technical support or purely advisory involvement in the project.

**4 REQUIRED DISCLOSURES**

- 4.1 Form 700-U: This form must be electronically filed by the Principal Investigator (PI) when the HSR is funded by a non-governmental entity (e.g. private entity) or supported (e.g. provision of drugs, medical devices, or other products or services). The disclosure must be made no later than the time of award, and anytime new, incremental, or supplemental funding is received (as defined in PPM [Section 230-05](#)).
- 4.2 Form 800: This form must be electronically filed by:
  - 4.2.1 The PI and all other Investigators when the HSR is non-PHS funded and/or FDA-regulated HSR.
  - 4.2.2 Any Investigator (including the PI) who has one or more Significant Financial Interests (SFI) when the research is unfunded (i.e. Departmentally-funded) and not FDA-regulated.
- 4.3 A Form 800 must be submitted at the following times:
  - 4.3.1 No later than initial IRB submission.
  - 4.3.2 At continuing review, but only when there is an existing FCOI and management plan in effect.
  - 4.3.3 Within 30 days of any newly acquired/discovered outside financial interest.
    - 4.3.3.1 A **new** SFI is any one of the following:

**SOP: Financial Conflicts of Interest**

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- 4.3.3.1.1 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
- 4.3.3.1.2 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
- 4.3.3.1.3 The same type or nature of SFI from a different source (e.g., royalty payment from company A versus company B).

4.4 PHS-COI disclosure: When HSR is PHS-funded, all Investigators (including the PI) must electronically submit this form at the time of proposal in compliance with [PPM Section 230-07](#).

**5 RESPONSIBILITIES**

5.1 Investigators, IRB Administration and Committees, Research Compliance and Integrity Administration, and the COIC carry out these procedures.

**6 PROCEDURE**

- 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