

**SOP: Institutional Conflicts of Interests**

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-054	08/15/2014	L. Smith	C. Kiel	1 of 2

**1 PURPOSE**

1.1 Establishes procedures to identify and manage institutional conflicts of interest.

**2 REVISIONS FROM PREVIOUS VERSION**

2.1 Updated sections 3.1 and 5.1

2.2 Added sections 3.1.1 thru 3.1.5 and 5.3 thru 5.6, additional reporting and procedural information

**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" and 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 and all non-sponsored Human Research governed by FDA regulations. (See Statement of Economic Interest-Supplemental Form, Questions 35-36, Licensing.) These documents explain the procedures that must be followed with respect to conflicts of interest of senior administrative officials and the University, including:

3.1.1 Licensing (e.g. licensing or technology transfer agreements)

3.1.2 Investments of the Institution

3.1.3 Gifts to the Institution

3.1.4 Financial interests of senior administrative officials

3.1.5 Other financial interests

3.2 Senior administrative officials are required to disclose their financial interests pursuant to California Political Reform Act state law of 1974, Gov. Code, Section 81000 et seq.

3.2.1 Upon joining the Institution

3.2.2 Every year

3.2.3 When there are changes to financial interests

3.3 The University of California and UC Davis have numerous and long standing policies and procedures addressing conflicts of interest. A summary statement of principles and policies on institutional conflict of interest was published on June 1, 2011, RPAC Memo No. 11-05, "Summary Statement of Principles and Policies on Institutional Conflict of Interest in Research." The summary statement articulates principles, explains the relevancy of the California Political Reform Act of 1974, and summarizes policies on licensing, separation between financial decisions and research decisions, training on conflict of interest, and health care vendor relations and health care fraud, waste and abuse.

**4 RESPONSIBILITIES**

4.1 IRB Committee Members and Investigators as appropriate.

**5 PROCEDURE**

5.1 UC Davis complies with the California Political Reform Act of 1974 and the UC Conflict of Interest Code, both of which require all UC employees to disqualify themselves from participating in official decisions or making any recommendations to a decision-maker when they have a personal financial interest. The IRB relies on employees and institutional leaders to comply with the law and the Code.

5.2 When completing Form HRP-226, Department Chairs shall identify whether they are aware that the University has any licensing or equity interest in connection with the study under consideration. If so, the Chair shall advise the investigator of the conflict and the investigator will include language in the consent form regarding the University's financial interest consistent with RPAC Memo No. 11-05, "Summary Statement of Principles and Policies on Institutional Conflict of Interest in Research."

5.3 Investigators shall identify whether they are aware that the University has any licensing or equity interest in connection with the study under consideration. If so, the investigator will include language in the consent form regarding the University's financial interest consistent with RPAC Memo No. 11-05, "Summary Statement of Principles and Policies on Institutional Conflict of Interest in Research" and RPAC Memo No. 11-04, "Financial Interest Disclosure in the Research Consent Form."

**SOP: Institutional Conflicts of Interests**

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-054	08/15/2014	L. Smith	C. Kiel	2 of 2

- 5.4 Per RPAC Memo No. 11-05, each week the IRB Administration will review the current list of institutional conflicts maintained by UC Office of the President and compare the list to submissions included on the next meeting agenda to determine whether there are any institutional conflicts of interest. If a conflict is identified, the IRB Administration will require language to be added to the informed consent document, which will alert IRB members that a conflict exists.
- 5.5 The IRB will determine whether institutional financial interests represent an institutional conflict of interest. If so, the IRB shall institute a management plan that prevents the institutional financial interest from affecting the design, conduct or reporting of research relative to human research protection. The management plan may include:
  - 5.5.1 Inclusion of language in the consent form regarding the University's financial interest consistent with RPAC Memo No. 11-04.
  - 5.5.2 Review by an external IRB
  - 5.5.3 Oversight by an external audit, or
  - 5.5.4 Involvement of external individuals in key portions of the protocol
- 5.6 If the IRB cannot institute a management plan that prevents the institutional financial interest from affecting the design, conduct, or reporting of research as it relates to human research protection, the Committee will not allow the research to be conducted.

**6 MATERIALS**

- 6.1 None

**7 REFERENCES**

- 7.1 UC Davis Policy and Procedure Manual: Chapter 230, Sponsored Programs: Section 05
- 7.2 UC Davis Policy and Procedure Manual: Chapter 230, Sponsored Programs: Section 07
- 7.3 UC Office of the President, RPAC Memo No. 11-04
- 7.4 UC Office of the President, RPAC Memo No. 11-05