

Investigators' Conflicts of Interest (COI)

SOP 107

Approved: December 18, 2015

Purpose and Scope

The SOP describes the management of Conflicts of Interest related of those involved in any conduct of human subjects research.

This SOP applies to all Investigators and key research personnel who are involved in the conduct of human subjects research at the University of Hawai'i (UH).

Definitions

- **IMMEDIATE FAMILY:** spouse or domestic partner and dependent children.
- **INDIVIDUAL CONFLICTS OF INTEREST** or **INDIVIDUAL FINANCIAL CONFLICT OF INTEREST (FCOI):** situations in which personal interests, particularly Significant Financial Interests (SFI), cause competing loyalties that compromise, or have the appearance of compromising, an Investigator's (or Research Staff's) objectivity in meeting University duties or responsibilities. If an Investigator's (or Research Staff's) objectivity in designing, conducting, or reporting Research, or other scholarly work is directly or substantially biased by Significant Financial Interests or other interests (see AP 12.504), the Investigator's judgment in the collection, analysis, review and interpretation of data may be compromised, along with the decisions, for example, on the hiring of staff, procurement of materials or equipment, sharing of results, writing of protocols, safety of Human Research Participants, use of statistical methods, and mentoring of students.
- **ORGANIZATIONAL CONFLICTS OF INTEREST (OCOI):** a situation in which the University, or any of its senior management or trustees, has an external relationship or financial investments or holdings (including licenses, royalties, intellectual property rights, patents, and certain gifts) with an entity that it itself has a financial interest with the University that might affect or possibly appear to affect organizational processes for the design, conduct, reporting, review, or oversight of human participant research.
- **SCHOLARLY OR SCIENTIFIC CONFLICTS OF INTEREST:** conflicts that arise when a scholar or researcher's impartiality is biased by the potential for professional or personal gain, as in the review and commenting on manuscripts, funding applications, tenure or promotion records, or other publications.

- **SIGNIFICANT FINANCIAL INTEREST (SFI)¹**: anything of monetary value or potential monetary value, to an Employee and the Employee’s Immediate Family, which is, or appears to be, reasonably related to the individual’s Institutional Responsibilities with certain exclusions. SFI refers to that received in the past 12 months and includes but is not limited to the following:
 - (1) “With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity...and the value of any equity interest in the entity..., when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel reimbursement); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.”²
 - (2) “With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity..., when aggregated, exceeds \$5,000, or [in which] the investigator...holds any equity interest.”³
 - (3) “Intellectual property rights and interests (e.g., patents and copyrights) upon receipt of income related to such rights and interests.”⁴
 - (4) Compensation or payments for service on boards or provision of executive advisory services to non-University of Hawai`i Entities, excluded are Federal, State, local government agencies, or Institutions of higher education.

Procedures

Disclosure of Financial Interests

1. Before a protocol application can be submitted to the IRB, the Principal Investigator (PI), faculty, key personnel and study staff directly responsible for the design, conduct or reporting of the research is required to complete the COI questionnaire.

On an annual basis the following must be completed:

- All investigators and research personnel must disclose on an annual basis all financial relationships that reasonably appear to be related to their institutional responsibilities. This is reported through eProtocol application (APP 04: New Research Protocol/ Proposal for Initial Approval – Non-Exempt) “Potential Conflict of Interest” section of their active protocols.
- As faculty enter into changed or new financial relationships related to their institutional responsibilities, they can update their University of Hawaii Conflict of Interest Disclosure Form (See Materials below) to update previously reported activities or financial relationships, or to enter new activities.

2. At any other time, potential conflicts of interest relate to human subject research protocols require:

¹ 42 CFR §50.603(1); 45 CFR §94.3(1)

² 42 CFR §50.603(1.i) & 45 CFR, §94.3(1.i)

³ 42 CFR §50.603(1.ii) & 45 CFR, §94.3 (1.ii)

⁴ (42 CFR §50.603(1.III) & 45 CFR §94.3 (1.iii))

- Any potentially perceived or actual conflict of interest should be disclosed in the “Potential Conflict of Interest” section of the eProtocol application form.
- Disclosure by each investigator for him or herself and his or her immediate family.

Management of Investigator Conflict of Interest Disclosures

1. If an Investigator’s SFI is identified as a potential or actual FCOI a COI management plan shall be implemented before any research activity or award expenditure can begin.
2. All investigators’ conflicts of interest (for all schools, including the John A. Burns School of Medicine) are managed via the Conflict of Interest Committee (COIC).
3. Conflict disclosure in the informed consent process is an important part of the management strategy, but will not necessarily be the only strategy used. The COIC, in collaboration with the UH IRB, shall determine what strategy or strategies are appropriate to eliminate, mitigate, or manage conflict that has the potential to harm subjects or compromise the objectivity of the research, or are likely to be perceived as having that potential.

Role of the IRB

1. Review of potential conflicts of interest with initial approval
 - a. When a COI is disclosed or identified, the COIC will establish a plan to eliminate, mitigate, or manage the conflict. The IRB has final authority to accept the COI plan or impose additional conditions in deciding whether to approve the research.
 - b. When there are substantive outstanding COI matters, a protocol will either be tabled or precluded from possible approval until matters are resolved.
 - c. Only when COI matters are completely resolved is the protocol Approval Letter generated.
2. Review of conflicts of interest disclosed after IRB approval of research
 - a. When a potential conflict of interest arises and the investigator discloses it after the IRB has reviewed and approved a protocol, the investigator should:
 - i. Immediately notify the IRB of the potential conflict,
 - ii. Immediately notify the IRB that enrollment and protocol procedures will stop until the conflict of interest has been reviewed and resolved by the COIC as described above.
 - b. The plan established by the COIC is forwarded to the IRB. When a known conflict of interest is discovered after the IRB review and approval, the IRB will ask the PI to file a conflict of interest disclosure in eProtocol Potential Conflict of Interest section as described

above, and may, among other possible actions, ask the investigator to disclose the relationship to research participants.

Materials

- APP 04: New Research Protocol/ Proposal for Initial Approval – Non-Exempt
- [EP 12.214 Conflicts of Interest and Commitment](#) (October 2014)
- [AP 12.504 Procedures for Disclosing and Addressing Conflicts of Interest and Commitment](#) (August 11, 2014)
- [APM A8.956 Financial Conflicts of Interest \(FCOI\) for Public Health Services \(PHS\) Grants, Cooperative Agreements and Contracts](#) (March 13, 2013)
- GUIDE 609 Conflict of Interest Disclosure in the Informed Consent Form
- GUIDE 610 UH Guidelines – Conflict of Interest Management Plan
- DOC 720: [University of Hawaii Annual Conflict of Interest Disclosure Form](#)
- DOC 721: [non-UH Financial Conflict of Interest Disclosure Form](#)
- DOC 722: [UH Financial Conflict of Interest Disclosure Form](#)
- DOC 723: [UH Conflict of Interest Management Plan Template](#)

References

- The University of Hawaii has and follows written policies and procedures to identify, manage, and minimize or eliminate individual financial conflicts of interest of Researchers and Research Staff that could influence the conduct of the research or the integrity of the Human Research Protection Program. The Organization works with the Institutional Review Board in ensuring that financial conflicts of interest are managed and minimized or eliminated, when appropriate. (**AAHRPP Element I.6.B.**)