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Administrative Procedure Chapter 12, Research  
Administrative Procedure Section AP 12.304, Procedures for Disclosing and Addressing  
Conflicts of Interest Related with Extramural Funds

Effective Date: XXXX

Dates Amended: XXXX (previously AP 8.956), August 2014, July 2012

Responsible Office: Office of the Vice President for Research and Innovation

Governing Board and/or Executive Policy: XXXX

Review Date: XXXX

**I. PURPOSE:**

To establish clear guidelines and procedures consistent with applicable university executive policy(ies) and to ensure that the design, conduct, and reporting of all Extramurally-Funded Activities will be free from bias resulting from Investigator or Institutional Conflicts of Interest.

**II. DEFINITIONS**

- A. COI – Stands for Conflicts of Interest, and refers to a financial, professional, or other personal interest which may influence, or appear to influence, an Investigator's objectivity or judgment in fulfilling his or her Institutional Responsibilities.
- B. COIC – Stands for Conflict of Interest Committee, and refers to a group of individuals appointed by the Deciding Official to review and consult on FCOI/COI matters.
- C. Management Plan – A written plan describing the oversight and monitoring activities that will be undertaken to manage and mitigate the FCOI/COI. The Management Plan must be acknowledged and agreed to by Investigators with identified FCOI/COI and those with responsibilities for oversight of the Management Plan.
- D. Deciding Official – Unless otherwise designated by the University of Hawai'i (UH) President, the Vice President for Research and Innovation (VPRI) will serve in this capacity.
- E. Disclosure - Refers to:
  - 1. Making known to UH the existence of any Significant Financial Interest;

2. Making known to UH the existence of any potential or actual FCOI/COI;
  3. Providing a statement as to the existence of any FCOI/COI, such as in public presentations or publications;
  4. Notifying funding agencies of any potential or actual FCOI/COI; and/or
  5. Notifying other individuals involved in Extramurally-Funded Activities of any potential or actual FCOI/COI.
- F. Extramurally-Funded Activity – An activity that is funded by an external, non-UH entity and may include research, instruction, training, public service, or any other scholarly or administrative activity.
- G. FCOI – Stands for Financial Conflicts of Interest, and refers to COI that are specifically financial in nature.
- H. Immediate Family – Includes the Investigator’s spouse, domestic partner/reciprocal beneficiary and/or dependent children.
- I. Investigator – May include a Project Director (PD), Principal Investigator (PI), Co-Investigator, Co-PD, Co-PI, key person or any other person who shares responsibility for the design, conduct, or reporting of the Extramurally-Funded Activity. May also include clinical investigators, subrecipients, and students.
- J. Institutional Responsibilities – Refers to an Investigator’s professional responsibilities on behalf of UH, which may include activities such as research, teaching, training, consulting, professional practice and committee memberships or service.
- K. ORS – Refers to the UH Office of Research Services.
- L. PHS – Stands for Public Health Service, and refers to the Public Health Service of the United States Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including but not limited to, the National Institutes of Health (NIH). PHS has authority for the administration of 42 CFR § 50 and 45 CFR § 94, as may be amended from time to time. Other funding entities such as private non-profits have adopted PHS FCOI regulations, and this Administrative Procedure shall also apply to Extramurally-Funded Activities with such entities.

See [http://sites.nationalacademies.org/PGA/fdp/PGA\\_070596](http://sites.nationalacademies.org/PGA/fdp/PGA_070596) for a listing of funding entities utilizing the PHS FCOI regulations in their award terms.

- M. SFI – Stands for Significant Financial Interest, and refers to anything of monetary value or potential monetary value, to Investigators and/or their Immediate Family, received from non-UH entities, which is, or appears to be, reasonably related to the Investigator’s Institutional Responsibilities. SFI refers to anything of monetary value received in the past 12 months and includes, but is not necessarily limited to, the following:
1. From publicly traded entities:
    - a) Remuneration in excess of \$5,000, aggregated per entity; or
    - b) Any equity interest (e.g., ownership, stocks) in excess of \$5,000, aggregated per entity
  2. From non-publicly traded entities:
    - a) Remuneration in excess of \$5,000, aggregated per entity; or
    - b) Any equity interest of any value
  3. Intellectual Property: royalties/income from intellectual property (e.g., patents, copyrights and trademarks) not partially licensed to and/or owned by UH.
  4. Sponsored Travel: reimbursement or sponsorship for travel made by a non-UH entity, related to Investigator’s Institutional Responsibilities. Applies ONLY to PHS-funded Investigators.

SFI does not include:

- Salary, royalties, or other remuneration paid by UH to its Investigators;
- Equity interests arising solely by reason of investment in a business by a mutual fund, pension, or other institutional investment fund over which the investor does not exercise control;
- Income from seminars, lectures, or teaching engagements sponsored by federal, state, local government agencies, or U.S. institutions of higher education;

- Royalties or related compensation paid by UH, such as intellectual property rights assigned to UH and agreements to share royalties related to those rights; or
  - Income from service on advisory committees or review panels for federal, state, or local governmental agencies or U.S. institutions of higher education.
- N. Supervisor -- Refers to the immediate supervisor of an Investigator (e.g., Department Chair) who must review and approve Disclosures, as well as the next level in an Investigator's organization with no less responsibility such as a Dean, Director, Campus Chancellor, or Vice President, as appropriate, who must provide a second level of approval.

### III. **ADMINISTRATIVE PROCEDURE:**

#### A. Responsibilities

1. Investigators involved in Extramurally-Funded Activities shall be responsible for:
  - a) Complying with applicable governmental regulations and funding agency policies pertaining to FCOI/COI;
  - b) Disclosing to ORS the existence of any SFI (see III.B.1 Disclosure);
  - c) Disclosing to ORS the existence of any potential or actual FCOI/COI;
  - d) Disclosing the existence of any FCOI/COI, in public presentations or publications;
  - e) Disclosing to other individuals involved in Extramurally-Funded Activities any potential or actual FCOI/COI;
  - f) Establishing a Management Plan prior to engaging in Extramurally-Funded Activities, if one is required, and complying with the measures described therein (see III.B.2 Management Plan);
  - g) Disclosing to ORS any changes to previously made Disclosures within 30 days of such a change;
  - h) Completing FCOI training, if such training is required by a funding agency, such as PHS (see III.B.6 Training); and

- i) When conducting human subjects research, informing human participants of the presence of an FCOI/COI in compliance with 45 CFR § 46, regardless of the source of funding, and informing the UH Human Studies Program or other Institutional Review Board, as appropriate.

2. ORS shall be responsible for:

- a) Certifying that UH has an established FCOI/COI policy and procedure, when required to do so by funding agencies;
- b) Notifying an Investigator's Supervisor of the Disclosure of any SFI, or any actual or potential FCOI/COI.
- c) Reviewing Disclosures submitted by Investigators and approved by Supervisors for concurrence that the SFI are reasonably related to their Institutional Responsibilities and/or whether or not an actual or potential FCOI/COI exists;
- d) Referring cases to the COIC, through the Deciding Official, when an Investigator and a Supervisor cannot agree whether a SFI does or does not constitute an FCOI/COI;
- e) When SFI constitutes an FCOI/COI, assisting an Investigator with establishment of a Management Plan for the ORS Director and Deciding Official's review;
- f) Consulting with the UH Office of Technology Transfer and Economic Development on conditions of Management Plans concerning ownership, royalties, and licenses, when necessary;
- g) Referring cases of actual or potential FCOI/COI to the COIC through the Deciding Official if a Management Plan cannot be agreed to by an Investigator and/or those with responsibility for the Management Plan's oversight;
- h) Monitoring an Investigator's compliance with an established Management Plan;
- i) Referring cases to the Deciding Official where the Investigator has failed to comply with a Management Plan;
- j) Referring cases to the Deciding Official where there may have been a violation of UH FCOI/COI policy or procedure, federal regulation, or funding agency policy;

- k) Notifying federal funding agencies of any potential or actual FCOI/COI (see III.B.3 Reporting) and notifying non-federal funding agencies of any potential FCOI/COI, if required by the agencies;
  - l) Notifying the UH Human Studies Program or other Institutional Review Board, as appropriate, of identified FCOI/COI pertaining to human subjects research;
  - m) Providing FCOI/COI training; and
  - n) Keeping records pertaining to Disclosures, Management Plans, Reports, Retrospective Reviews, and Training for a minimum of three (3) years following the date that the final expenditure report or final invoice is submitted to the funding agency.
3. Supervisors shall be responsible for:
- a) Reviewing Investigators' Disclosures for concurrence that the SFI are reasonably related to their Institutional Responsibilities and/or whether or not an actual or potential FCOI/COI exists, and approving such Disclosures;
  - b) Assisting with the establishment of a Management Plan, if one is required.
4. The Deciding Official shall be responsible for:
- a) Upon referral by ORS, making recommendations for conditions of Management Plans and, reviewing and approving of finalized Management Plans;
  - b) Upon referral by ORS, determining whether or not an Investigator's SFI does or does not constitute an FCOI/COI, and when such a determination cannot be made, delegating the COIC to make such a determination;
  - c) Reviewing determinations made by the COIC as to whether or not a violation of UH FCOI/COI policy or procedure, federal regulations, or funding agency policy has occurred, and initiating an additional review and/or consultation with the UH Professional Assembly and/or UH Manoa Faculty Senate, as appropriate;

- d) Notifying ORS when a determination has been made that an FCOI/COI does exist, so that ORS may initiate reporting to the funding agency;
  - e) Initiating a retrospective review by the COIC when necessary (see III.B.4. Retrospective Review);
  - f) Imposing corrective action requirements or sanctions upon an Investigator for violations of UH policy or procedure, federal regulation, or funding agency policy (see III.B.5. Sanctions); and
  - g) Appointing of COIC members.
5. When delegated by the Deciding Official, the COIC shall be responsible for:
- a) Determining whether an Investigator's SFI does or does not constitute an FCOI/COI;
  - b) Recommending measures for a Management Plan;
  - c) Conducting a retrospective review when necessary; and
  - d) Determining whether or not a violation of UH COI policy or procedure, federal regulation, or funding agency policy has occurred.

B. Procedures

1. Disclosures

Investigators involved in Extramurally-Funded Activities, including those applying for extramural funds, shall disclose to ORS any SFI, FCOI/COI. Investigators who have disclosed SFI and/or have received extramurally-funded award(s) shall submit or update their Disclosure no less frequently than annually. Additionally, all Investigators shall review and update their Disclosure, as appropriate, when any of the following actions occur:

Prior to applying for extramural funding,

- a) Within 30 days of receiving an extramurally-funded award,
- b) Within 30 days of changes occurring to an Investigator's SFI, FCOI/COI, or

- c) When a new Investigator will participate in an existing Extramurally-Funded Activity.

If an extramural award is received without an application, Investigators must update their Disclosures, as appropriate, at the time the award is received.

Supervisors and ORS will review the Disclosures for concurrence and determination as to whether or not the Investigator's SFI could directly and significantly affect the design, conduct, or reporting of the Extramurally-Funded Activity. Prior to allowing any award expenditures, ORS may require the Investigator implement a Management Plan for any identified actual or potential FCOI/COI. ORS may also be responsible for reporting identified FCOI/COI, as required by regulation or funding agency policy. (See III.B.3. Reporting.)

## 2. Management Plans

Management Plans are intended to mitigate or eliminate the potential for bias in an Extramurally-Funded Activity. Management Plans are normally agreed to by Investigators and their Supervisors, with assistance and input from ORS. If a Management Plan cannot be agreed to by the above listed parties, ORS may refer the matter to the Deciding Official. All completed Management Plans will be furnished to ORS for transmittal to the Deciding Official, for approval.

Management Plans, at minimum, will include a description of the potential conflict and criteria that may lead to risk, a justification for proceeding with management (versus eliminating the conflict), and management strategies, including conditions or restrictions that may be imposed to ensure integrity and objectivity, eliminate bias, and protect human subjects in all Extramurally-Funded Activities. Additionally, Management Plans may include, but not necessarily be limited to, the following measures:

- a) Public disclosure of the FCOI:
- (1) upon request;
  - (2) in all relevant publications and presentations;



- (3) to appropriate co-Investigators, members of the laboratory or research group, students or trainees; and/or
  - (4) to the UH Human Studies Program (or other Institutional Review Board).
- b) Monitoring of the Extramurally-Funded Activities by Senior Administrators.
  - c) Review of notebooks, publications and presentations for accurate disclosure and/or data integrity.
  - d) Meeting regularly with Senior Administrators, a PD/PI, and/or scientific collaborators who will oversee compliance with the Management Plan.
  - e) Annual reporting to ORS of the activities undertaken with respect to compliance with the Management Plan.
  - f) Reporting any significant concerns to the COIC, ORS or Deciding Official, including recommendations for revisions to the Management Plan or any mitigation concerns.
  - g) Modification of the research or extramural activity plan to mitigate or eliminate the FCOI/COI.
  - h) Prohibition from contributing to any activity that could be influenced because of SFI (e.g., the Investigator may be prohibited from serving as the PD/PI, analyzing data, determining whether potential subjects are eligible for enrollment, or soliciting consent).
  - i) Divestiture of SFI (i.e., allowing work to proceed contingent upon the sale or disposal of specified financial interests).
  - j) Severance of relationships that create conflicts (e.g., relinquishing a seat on a board of an outside entity).
  - k) Documentation of any exception (i.e., facts that support that an Investigator is uniquely positioned, and should be permitted to participate in a specific Extramurally-Funded Activity under appropriate management, despite a SFI).

In rare cases, the COIC may also advise that the potential for significant scientific progress, important technology transfer, and

benefits to society or public health and welfare outweigh concerns about FCOI/COI. In such cases, the COIC and/or the Deciding Official shall establish an appropriate Management Plan.

3. Reporting

a) ORS shall submit initial and annually updated FCOI reports to funding agencies, as necessary. Included in the FCOI reports shall be the following:

- (1) Project/award/grant/contract number, PI/PD name or contact PI/PD name,
- (2) Name of Investigator with the FCOI,
- (3) Name of the entity with which the Investigator has a FCOI,
- (4) Nature of the FCOI (e.g., equity, consulting fees, travel reimbursements, honoraria, etc.),
- (5) Value of the financial interest by range of value as follows:
  - i. \$0 to \$4,999;
  - ii. \$5,000 to \$9,999;
  - iii. \$10,000 to \$19,999;
  - iv. Amounts between \$20,000 and \$100,000 by \$20,000 increments; and
  - v. Amounts above \$100,000 by \$50,000 increments;

or, a statement that a value cannot be determined, and why,

- (6) A description of how the FCOI relates to the Extramurally-Funded Activity and the basis for determining that the interest conflicts with such activity, and

- (7) A statement as to whether the FCOI was managed, reduced, or eliminated, and if managed, details of the Management Plan.
  - b) ORS shall submit annual update reports to funding agencies, which shall include all of the above, in addition to all of the following:
    - (1) Status of the FCOI,
    - (2) Changes, if any, in the Management Plan, and
    - (3) Other records regarding the FCOI upon request by funding agencies.
  - c) ORS shall report FCOI information required by funding agencies prior to expenditure of extramural funds. The FCOI information shall be reported within 60 days of the date the new SFI was identified and shall be updated annually. Additionally, ORS shall make available FCOI information to the public, upon request, for three years following the date that the final expenditure report or final invoice is submitted to the funding agency.
4. Retrospective Review
- a) If an Investigator with an active extramurally-funded project fails to disclose timely an SFI that is potentially an FCOI/COI, or if an Investigator fails to comply with a Management Plan, the Deciding Official shall initiate a retrospective review through the COIC to determine whether bias in the Extramurally-Funded Activity exists. Retrospective reviews shall be completed within 120 days of identification of noncompliance, and shall include, at minimum, documentation of the following:
    - (1) Project/award/grant/contract number, PI/PD name or contact PI/PD name,
    - (2) Name of Investigator with the FCOI,
    - (3) Name of the entity with which the Investigator has a FCOI,
    - (4) Nature of the FCOI (e.g., equity, consulting fees, travel reimbursements, honoraria, etc.),

- (5) Value of the financial interest by range of value as follows:
    - i. \$0 to \$4,999;
    - ii. \$5,000 to \$9,999;
    - iii. \$10,000 to \$19,999;
    - iv. Amounts between \$20,000 and \$100,000 by \$20,000 increments; and
    - v. Amounts above \$100,000 by \$50,000 increments;

or, a statement that a value cannot be determined, and why,
  - (6) Reason(s) for the retrospective review,
  - (7) Details of the retrospective review (e.g., methodology of review process, composition of review panel, documents reviewed, etc.), and
  - (8) Findings and conclusions of the review.
- b) If the retrospective review concludes that bias in the Extramurally-Funded Activity occurred:
- (1) Interim measures shall be implemented immediately and may include suspension of the Extramurally-Funded Activity until an appropriate Management Plan is decided upon;
  - (2) As necessary, ORS shall submit a mitigation report, and/or update any previously submitted FCOI report to the funding agency, specifying actions that eliminate/mitigate the effect of the bias and any interim measures necessary to remove the conflicted investigator from the Extramurally-Funded Activity; and
  - (3) After the initial mitigation report, ORS shall submit updated reports annually to funding agencies, as necessary. (See III.B.3. Reporting.)

5. Sanctions

If an Investigator fails to report SFI, FCOI/COI, comply with this Administrative Procedure, or an established Management Plan, it shall be considered to be a violation of UH policy and may result in suspension or termination of Extramurally-Funded Activities. Funding agencies may also impose restrictions or penalties upon Investigators for non-compliance with their FCOI/COI policies and or regulations. UH may take further disciplinary action up to and including termination of employment, if appropriate.

6. Training

Some funding agencies, such as PHS, require FCOI training for funded Investigators. FCOI training is available through ORS and PHS-funded Investigators must complete training:

- a) Prior to engaging in any Extramurally-Funded Activity or expending any extramural funds;
- b) Once at least every four years; or
- c) Immediately, whenever UH revises its policy(ies), an Investigator is new to UH or new to the Extramurally-Funded Activity; or if UH finds that an Investigator is not in compliance with UH policy(ies) or an approved Management Plan.

**IV. DELEGATIONS OF AUTHORITY:**

There is no administrative procedure specific delegation of authority.

**V. CONTACT INFORMATION:**

The Office of the Vice President for Research and Innovation, telephone number: (808) 956-5006; and email [uhovpri@hawaii.edu](mailto:uhovpri@hawaii.edu) may be contacted for information relating to this Administrative Procedure.

**VI. REFERENCES:**

- Link to superseded procedures: <https://www.hawaii.edu/policy/archives/ap/>
- 42 CFR §§ 50.601-607, Promoting Objectivity in Research
- 45 CFR §§ 94.1-6, Responsible Prospective Contractors

- 45 CFR § 46, Protection of Human Subjects
- See the UH Office of Research Services Website -- <http://www.ors.hawaii.edu/> - for more information.

**VII. EXHIBITS AND APPENDIXES:**

None

**Approved:**

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Vassilis Syrmos  
Vice President for Research and Innovation

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Date