
A5.000 ACADEMIC AFFAIRS

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A5.504 PROCEDURES FOR DISCLOSING AND ADDRESSING CONFLICTS OF INTEREST AND COMMITMENT

I. PURPOSE.

As expressed in Executive Policy E5.214 entitled "Conflicts of Interest and Commitment," the University of Hawai'i (University) is committed to promoting identification, disclosure, and elimination or management of conflicts of interest in operations of the University and activities of its employees. This includes institutional and individual financial, scholarly, and organizational conflicts of interest, as well as conflicts of commitment. These procedures are intended to delineate the process for addressing conflicts of interest and commitment.

II. DEFINITIONS.

- A. **APM** refers to the University's system-wide Administrative Procedures, numbered with the prefix letter "A." Referred to are this document, APM A5.504, and APM A8.956 "Financial Conflict of Interest (FCOI) for Public Health Services (PHS) Grants, Cooperative Agreements and Contracts."
- B. **AWARDING COMPONENT** refers to the organizational unit of the agency that funds the *Research*.
- C. **COMPELLING CIRCUMSTANCES** are facts that convince the *Institution* that an individual with a *Significant Financial* or other *Conflict of Interest* should be permitted to conduct the activity (e.g., *Research*) in spite of a conflict. Circumstances that may be evaluated (when applicable) include:
1. Nature of the *Research/activity*,
 2. Unique *Investigator* expertise, or unique institutional resources (e.g., equipment, facilities, personnel),

3. Magnitude of financial or other interest and the extent to which such interest is related to the *Research/activity*,
 4. Extent to which the interest could directly and substantially affect the *Research/activity*,
 5. The degree of risk to human subjects that is inherent in the *Research* protocol,
 6. Unique access to particular patient populations, and
 7. Extent to which the interest is amenable to effective oversight and management.
- D. **CONFLICTS OF COMMITMENT** arise when non-University activities of an *Employee* are substantial and overly demanding of the *Employee's* time and attention, and interfere with the *Employee's* obligations and responsibilities to the University.
- E. **CONFLICTS OF INTEREST** refers to situations in which an employee's financial, professional, or other personal interests may influence, or appear to influence, the employee's judgment in fulfilling his or her responsibility to the University. Conflicts of interest may also include institutional or individual financial, scholarly, and organizational conflicts of interest, as well as conflicts of commitment.
- F. **CONFLICTS OF INTEREST COMMITTEE (COIC)** consists of faculty, staff and administrators appointed to review and provide advice on management or elimination in cases concerning potential or real *Conflicts of Interest* or *Commitment*. Committee members are appointed by the *Deciding Official*. The *Deciding Official* will consider all nominations from the Manoa Faculty Senate and will make the final selection of committee members in accordance with institutional policy and these procedures.
- G. **CONTRACTOR** means "an entity that provides property or service under contract for the direct benefit or use" of the University. CFR 45 Part 94 Section 94.3.
- H. **DEANS and DIRECTORS** refers to lead administrators of Schools, Colleges, and Organized Research Units within the University system.

- I. **DECIDING OFFICIAL** refers to the administrator of Executive Policy E5.214. Unless otherwise designated by the University's President, the Vice President for Research (VPR) will serve in this capacity.
- J. **DISCLOSURE** refers to:
 - 1. Notifying the appropriate *Senior Administrator* of any personal potential or actual *Significant Financial* or *other Conflict of Interest* or *Commitment*.
 - 2. Providing a public statement as to the existence of any personal *Significant Financial* or *other Conflict of Interest* that may exist.
 - 3. Notifying funding agencies of any personal potential or actual *Financial* or *other Conflict of Interest*.
- K. **EMPLOYEE** means any person possessing either a full-time or part-time appointment at the University, whether compensated or not, including positions of the Research Corporation of the University of Hawai'i (RCUH), postdoctoral fellows, and some students or trainees.
- L. **ENTITY** means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business, real estate trust, or any other legal body organized for profit or nonprofit purposes.
- M. **EQUITY** is a financial interest in a business representing an ownership interest, and may include stock, stock options, stock warrants, or any other security.
- N. **HUMAN SUBJECTS RESEARCH** means a systematic investigation through experimentation, testing, evaluation, or observation performed on a living individual or group of individuals, about whom an *Investigator* obtains 1) data through intervention or interaction with the individual(s), or 2) identifiable private information (45 CFR 46.102).
- O. **IMMEDIATE FAMILY** means the *Employee's* spouse, domestic partner, or reciprocal beneficiary and dependent children.
- P. **INDIVIDUAL CONFLICTS OF INTEREST or INDIVIDUAL FINANCIAL CONFLICT OF INTEREST (FCOI)** refers to situations in which personal interests, particularly *Significant Financial Interests (SFI)*, cause competing loyalties that compromise, or have the appearance of compromising, an *Employee's*

objectivity in meeting University duties or responsibilities. If an *Employee's* objectivity in designing, conducting, or reporting *Research*, or other scholarly work is directly or substantially biased by *Significant Financial Interests* or other interests, his/her 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 Subjects* in *Research*, use of statistical methods, and mentoring of students.

1. Examples of potential *Financial Conflicts of Interest* situations may include the acceptance of income from non-University of Hawai'i sources, *Equity*, consulting fees, or royalty interest from an outside *Entity* which relates to the *Employee's Institutional Responsibilities*; income from seminars, lectures, or teaching engagements; income from service on advisory committees or review panels; legal partnerships; gifts to the *Employee's* unit/department; and other forms of payment to the *Investigator, Key Personnel*, or members of their *Immediate Family*.
2. Other *Conflicts of Interest* situations may arise when an *Employee*, or a member of his/her *Immediate Family*, has loyalties to another *Entity*:
 - a. that may affect decision-making with respect to University teaching, *Research*, or administration; or
 - b. that may result in a material, financial or other personal benefit from the use or release of non-public information pertaining to the University.

Q. **INSTITUTION** means "any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that received, research funding" (CFR 42 Part 50.603).

R. **INSTITUTIONAL FINANCIAL CONFLICTS OF INTEREST** may occur when the *Institution*; any of its senior management or trustees; a department, school, or other subunit; or an affiliated foundation or organization has a *Significant Financial Interest* in an outside *Entity* that itself has a *Financial Interest* in University *Research* or *Scholarly Activity*. *Senior Administrators* or trustees may also have conflicts when they serve on the boards of, or otherwise have an official relationship with, organizations that have

significant commercial transactions with the University. The existence or appearance of such conflict can lead to actual bias, or perception of bias, in the review, administration, or conduct of *Research* at the University.

- S. **INSTITUTIONAL RESPONSIBILITIES** (modified from CFR 42 Part 50.603) are defined as an *Employee's* professional responsibilities on behalf of the Institution, which may include activities such as research, teaching, consulting, professional practice, institutional committee memberships, or service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- T. **INVESTIGATOR** may be an *Employee*, project director (PD), principal investigator (PI), co-PD, co-PI, and any other person who shares responsibility for the design, conduct, or reporting of *Research* or other *Scholarly Activity*. Included are clinical investigators who are directly involved in *Human Subjects Research* and share responsibility for obtaining the informed consent of human subjects. "**INVESTIGATOR**" can also include non-employees such as *Contractors*, sub-grantees, sub-recipients, sub-contractors, or investigators' collaborators, who are expected to adhere to the provisions of this policy if such agreement is established (see ORS APM A8.956).
- U. **MANAGE** means taking action to address *Conflicts of Interest (COI)*, and may include reducing or eliminating the *COI*, to ensure, to the extent possible, that the design, conduct, and reporting of *Research* or other *Scholarly Activity* will be free from bias (modified from the definition in the CFR 42 Part 50.603).
- V. **OFFICE OF RESEARCH COMPLIANCE** is the administrative office under the Vice Chancellor for Research and Graduate Education that manages compliance-related issues; namely, *Research* and scholarly misconduct, *Conflicts of Interest*, responsible conduct of *Research*, *Human Subjects Research*, laboratory animal welfare and biosafety, and animal and veterinary services.
- W. **ORGANIZATIONAL CONFLICTS OF INTEREST** means conflicts that arise when the University cannot provide an *Entity* with impartial advice. This arises when technical advice that is given is biased and/or gives the University an unfair advantage.
- X. **RESEARCH** means "a systematic investigation, study or experiment designed to develop or contribute to

generalizable knowledge..." "The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development." (CFR 42, Part 50.603)

- Y. **SCHOLARLY ACTIVITY** means "creative work" that is used in teaching, the creation or sharing of knowledge, the *Research* or "discovery" of new knowledge, or the development of new technologies, methods, materials, or uses. (Modified from: <http://www.cals.vt.edu/facultystaff/evaluation/documents/scholarlyactivitydefinition.pdf>).
- Z. **SCHOLARLY OR SCIENTIFIC CONFLICTS OF INTEREST** means 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.
- AA. **SENIOR ADMINISTRATOR** is a member of the University administration above the organizational level of Department Chairperson or the equivalent in non-academic units of the University.
- BB. **SENIOR/KEY PERSONNEL** means the PD/PI, and any other persons identified as primary and/or essential personnel by the University in a grant application, progress report, or any other report submitted to a funding agency. (CFR 42 Part 50.603).
- CC. **SIGNIFICANT FINANCIAL INTEREST**
1. **SIGNIFICANT FINANCIAL INTEREST** [reference 42 CFR §50.603(1); 45 CFR §94.3(1)] refers to anything of monetary value or potential monetary value, to an *Employee* and his/her *Immediate Family*, which is, or appears to be, reasonably related to the individual's *Institutional Responsibilities* with certain exclusions listed below in section CC.2. *Significant Financial Interest* refers to that **received in the past 12 months** and includes but is not limited to the following:
 - a. "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." (42 CFR §50.603(1.i) & 45 CFR, §94.3(1.i)).

- b. "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" (42 CFR §50.603(1.ii) & 45 CFR, §94.3 (1.ii)),
- c. "Intellectual property rights and interests (e.g., patents and copyrights) upon receipt of income related to such rights and interests." (42 CFR §50.603(1.III) & 45 CFR §94.3 (1.iii)).
- d. 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.

2. **SIGNIFICANT FINANCIAL INTEREST** does not include:

- a. Salary, royalties, or other remuneration paid by the University to its *Employee*. If paid by another *Entity*, total remuneration is less than \$5,000 when aggregated for the *Employee* and the *Employee's Immediate Family*.
- b. *Equity* interests arising solely by reason of investment in a business by a mutual, pension, or other institutional investment fund over which the *Employee* does not exercise control.
- c. Income from seminars, lectures, or teaching engagements sponsored by Federal, State, local government *agencies*, or *Institutions* of higher education.
- d. Royalties or related remuneration paid by the University including intellectual property rights assigned to the University and agreements to share royalties related to those rights.

- e. Income from service on advisory committees or review panels for Federal, State, or local governmental *Entities* or *Institutions* of higher education.
 - f. Any ownership interests in the University, related to serving as a recipient under the Phase I Small Business Innovation Research (SBIR) (SBIR is "the extramural research program for small businesses established by the awarding components of the Public Health Service and certain other Federal agencies under Public Law 97-219", CFR 42 Part 50.603), or Small Business Technology Transfer Programs (STTR).
3. Compensation or sponsorship of travel related to *Institutional Responsibilities* which are not reimbursed by a Federal, State, or local government agency, or *Institution* of higher education may be considered to be a *Significant Financial Interest*. *Employees* must disclose such benefits including the following details: purpose of the trip, identity of the sponsor/organizer, cost of travel, destination, and duration. In the determination as to whether there is a *FCOI*, the *Senior Administrator* to whom the *Employee* reports will determine whether additional information is needed.

III. POLICY IMPLEMENTATION AND ADMINISTRATIVE GUIDELINES

A. Disclosure Responsibilities Relating to Conflicts.

1. Dissemination of Policy.

Senior Administrators are responsible for ensuring that all *Employees* within their respective units are fully informed about Executive Policy E5.214 and these procedures, upon initial appointment and reminded annually of the obligation to submit *Conflicts of Interest Disclosure* forms, unless exempt.
2. Conflicts of Interest Disclosure Forms.

Forms must be submitted electronically to the appropriate administrative office. *Disclosure* forms will be considered confidential to the extent possible. An individual may be exempt from *Disclosure* depending upon the position to which the individual is assigned. An *Employee* may be exempt only if he or she is not responsible, directly or indirectly, for the design, conduct, or reporting of *Research* or other *Scholarly Activity*. Individuals should consult their immediate supervisors, departmental chairperson, *Dean*, or *Director*

regarding exemptions; however, directives are listed below.

a. Individuals required to submit a *Disclosure* form:

1. Persons holding the faculty ranks of professor, associate professor, assistant professor (and all of the foregoing whose appointments contain such terms as "researcher," "adjunct," "associate," "assistant", "visiting," or "clinical"), instructor, lecturer, as well as specialists.
2. Any staff member, student, trainee, postdoctoral research fellow, associate or assistant, and other individuals identified as *Investigators* or *Senior/Key Personnel* by the University. These individuals may be compensated or not and, on behalf of the University, are responsible for or in a position to influence the design, conduct, or reporting of *Research* or other *Scholarly Activity*.
3. All administrators, including Executive and Managerial positions, such as President, Vice Presidents, Chancellors, Vice Chancellors, *Deans* and *Directors*.
4. Any individual who acts or appears to act as an agent of the University in using, controlling, or assigning to others the use of University facilities and resources as well as procurement of facilities and resources. Examples are individuals involved in auxiliary services and financial management.

b. *Disclosure* forms are to be submitted:

1. Within 30 days of initial appointment to a University or RCUH position.
2. At least once annually thereafter with submission by April 15 each year.
3. At any time when an actual or potential *Conflict of Interest* or *Commitment* arises or when there are changes to, or elimination of a prior conflict.

The *Disclosure* statement (Attachment A) is the primary vehicle through which actual and potential

Individual Financial and other *Conflicts of Interest* can be identified and resolved through early, open review and discussion. New *Conflicts of Interest* situations, relationships and/or activities that give rise to them should be disclosed promptly if not already part of the annual *Disclosure* statement. The *Disclosure* statement serves as a written acknowledgement that the *Employee* has reviewed and is complying with this document, Executive Policy E5.214, and, if applicable, APM A8.956. Accordingly, each *Employee* shall be required to declare explicitly whether he/she does or does not have such personal *Financial* and/or other *Conflicts of Interest*. The failure to report is an unacceptable violation of Executive Policy E5.214.

4. *Senior Administrators* are responsible for the review of *Disclosure* forms for each of their *Employees*. They are also responsible for providing a ***Conflicts of Interest Disclosure summary (Attachment B)*** for their units annually to their respective Vice Chancellor's or Chancellor's Office. The deadline for submissions is June 30 of each year.

5. All forms are archived in the offices of the appropriate *Dean, Director, Senior Administrator, Vice Chancellor* or *Chancellor*. Updated forms must be submitted throughout the year if changes arise that may create a potential *Conflict of Interest*, alter the details of, or eliminate a previously disclosed conflict.

3. Nature of Disclosures.

a. All personal *Significant Financial Interests* of an *Employee*, and their *Immediate Family*, and other *Conflicts of Interest* that are related to the *Employee's Institutional Responsibilities* must be disclosed.

b. *Significant Financial Interests* required to be disclosed include:

1. Those which would reasonably appear to affect *Research* (funded or proposed for funding), scholarly, professional, administrative, or educational activities of the *Employees*.

2. In *Entities* where financial interests would reasonably appear to be affected by activities of the *Employee*.
- c. Investigators applying for funding, regardless of the funding *Entity*, must disclose any personal *Significant Financial Interests* or other potential *Conflicts of Interest* to the appropriate *Senior Administrator* prior to submission of a grant or contract application to the University's Office of Research Services (ORS). The *Disclosure* can take the form of Attachment A as required annually, or as required by ORS for all proposals submitted to the National Science Foundation or Public Health Service. The following *Disclosure* requirements shall be met:
1. Before an application or proposal is submitted to the sponsor when *Significant Financial Interests* could potentially affect the *Research* for which funding is sought, and when involving *Entities* whose financial interests could appear to affect the *Research*.
 2. At the time of the application or proposal submission. The University must certify to the sponsor that it has a written and enforced administrative process in place to identify and *Manage*, reduce, or eliminate *Conflicts of Interest* with respect to all *Research* for which funding is sought.
 3. Prior to spending any funds under an award. The University must report to the *Awarding Component* the existence of any *Conflicts of Interest* and ensure that it has been *Managed*, reduced, or eliminated. Upon request the *Institution* will make available to the *Awarding Component* detailed *Conflicts of Interest* information and how those interests have been *Managed*, reduced, or eliminated to protect the *Research* from bias.

Included in the initial report to the *Awarding Component* shall be the following:

- a. Project, Award or Grant/contract number, PD/PI name or contact PD/PI name.
- b. Name of *Investigator* with a *COI*.

- c. Name of the *Entity* with which the *Investigator* has a *COI*.
- d. Nature of the *COI* (e.g., *Equity*, consulting fees, travel reimbursements, honoraria).
- e. Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amounts between \$20K-100K by increments of \$20K; amounts above \$100K by increments of \$50K or a statement that a value cannot be readily determined and why.
- f. A description as to how the *Conflict of Interest* relates to the sponsor's *Research* interests and the basis for the University's determination that the interest conflicts with such *Research*.
- g. A statement as to whether the *COI* was *Managed*, reduced, or eliminated.
- h. If *Managed*, details of the *Institution's* management plan.

Included in the Annual Report to the *Awarding Component* shall be the following:

- i. Status of the *COI*.
 - j. Changes in the management plan.
 - k. Other records of the University regarding *COI* will be provided to the *Awarding Component* upon request.
4. For any *Conflict of Interest* that the University identifies subsequent to an initial report under an award, a follow up report will be made and the conflicting interest *Managed*, reduced, or eliminated—at least on an interim basis—within sixty days of that identification.
 5. When *COI* are identified actions taken by the University to eliminate, reduce or *Manage* the *COI* will be publically disclosed by display of information on the web site of the University's Office of Research Services.

d. *Investigators* who receive Federal funding and who assume the role of marketing consultants as defined in 48 CFR, Part 9, Subpart 9.501 are subject to additional *Conflict of Interest* regulations as set forth in Subpart 9.5.

B. Review of Disclosure Statements.

1. *Senior Administrators* shall be responsible for the initial review of all *COI Disclosures* filed by the *Employees* assigned to their respective units, determination of whether a *Conflict of Interest* exists, and identification of any conditions or restrictions that may be necessary to reduce or eliminate such *Conflict of Interest*. **All Disclosures containing potential FCOI, and other Conflicts of Interest should be forwarded to the Office of Research Compliance for further review and possible referral to the COIC or Deciding Official.** Approval of a *Research* proposal for *Investigators* that have a *FCOI* or other *COI* shall not be granted until an appropriate management plan has been developed. In reviewing *Disclosure* statements the following assessment criteria should be used:
 - a. A potential for a *Conflict of Interest* exists when it is determined that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the *Research* or *Scholarly Activity*.
 - b. *Conflicts of Interest* should be considered in relation to the impact of the *Scholarly Activity* on:
 1. Integrity of *Research* data or teaching activity.
 2. Risks to the rights and welfare of *Human Research Subjects*.
 3. Risks to the rights and obligations of students and trainees participating in the activity.
 4. Availability of *Research* results to the scientific community and public interest.
 5. Public perception of a *Conflict of Interest*.
 - c. *Investigators* conducting, or proposing to conduct, *Human Subjects Research* must disclose all *Conflicts of Interest* and *FCOI* in accordance with the

applicable Institutional Review Board (IRB) policies and procedures of the University. The IRB may consult with the *COI Committee* and develop a management plan when necessary.

d. All *Conflicts of Interest* related to *Research* shall be reviewed and *Managed* by the same *Conflicts of Interest* standards and procedures described here, regardless of funding status or funding source (Federal, State or other) and in accordance with APM A8.956 when PHS funding is involved.

2. *Senior Administrators* may request that the *COI Committee* review *Disclosure* statements and make recommendations on the determination of and/or management of any *Conflicts of Interest*.

C. Subrecipient Responsibilities

Subrecipients (e.g., subcontractor, subawardee, consortia) shall agree to terms of compliance and may be required to comply with the policy of the University of Hawaii as the awardee institution. The Office of Research Services (ORS) shall obtain a certification from the subrecipient as to whether the University of Hawaii's *COI* policy (E5.214) or the subrecipient's institutional *COI* policy will be utilized for compliance (see ORS APM A8.956).

IV. UNIVERSITY CONFLICTS OF INTEREST COMMITTEE

A. Purpose. The *University Conflicts of Interest Committee (COIC)* is established to review cases of potential or real *Conflicts of Interest or Commitment*. As appropriate, the COIC will prepare written recommendations for management or elimination of *Conflicts of Interest*.

B. Appointment and Membership. The Deciding Official will consider nominations from the Manoa Faculty Senate and will appoint 16 members, including a Chair. The *Conflicts of Interest Committee*:

1. May invite individuals with expertise in special areas to assist in the review process.
2. May include qualified members not employed at the University, should community membership be considered appropriate or necessary.

3. May confidentially consult with administrators, faculty, and others involved in the *Research* or administrative matter, the academic discipline in question, or the nature of administrative decision-making in question in order to make a fully informed recommendation.
 4. When University faculty *Conflicts of Interest* issues are referred to the *COIC*, committee members assigned will hail predominantly from the University faculty and staff, with the intention of conducting a peer-review evaluation.
- C. Responsibility. The *COIC* transmits a report to the *Deciding Official* to make recommendations regarding the following: the disposition of cases involving potential *Conflicts of Interest*, determination as to whether real or potential conflicts exist; how such conflicts should be eliminated, reduced, or *Managed*, and the progress of cases being *Managed*. In some instances, the Committee may decide that a case would be more appropriately referred to the Hawaii State Ethics Commission or the University's Research Integrity Officer.
- The *COIC* shall provide the *Employee* with an opportunity to respond to the issues raised in the course of such review. Any such responses will be appended to the Committee's report for review by the *Deciding Official*.
- D. Confidentiality. The proceedings of the *COIC* including all documents, drafts, and discussions will be kept confidential to the extent possible.

V. CONFLICT RESOLUTION - INDIVIDUAL CONFLICTS OF INTEREST.

- A. The *COIC* will review cases referred by *Senior Administrators* and determine the appropriate action for conflict resolution. The *COIC* may require a management plan that includes the following:
1. Description of the potential conflict.
 2. Delineation of criteria that may lead to risk.
 3. Justification for proceeding with management (vs. eliminating the conflict).
 4. Management strategies addressing each of these criteria and the requirements for plan modifications.

- B. Conditions or restrictions that may be imposed to *Manage, reduce, or eliminate Conflicts of Interest* include, but are not limited to the following:
1. Public *Disclosure* of the *COI* on the ORS web site (see Section IIIA above entitled "Disclosure Responsibilities Relating to Conflicts"), and additionally may include *Disclosures*:
 - a. In all relevant publications and presentations.
 - b. To the appropriate *co-Investigators*, members of the laboratory or *Research* group, students or trainees.
 - c. On *Human Subjects Research* consent forms. In addition, the appropriate Institutional Review Board (IRB) for *Human Subjects Research* may consult the *COIC* to review *Investigator Financial Interest Disclosures* and determine an appropriate management plan when necessary.
 2. Monitoring of *Research* by the *COIC* and the *Office of Research Compliance*, which may include measures such as:
 - a. Reviewing of notebooks, publications and presentations for accurate *Disclosure* and/or data integrity.
 - b. Meeting regularly with the PD/PI of the *Research* project and the scientific collaborators as well as the responsible department chair.
 - c. Reporting to the *Deciding Official*, at least annually with respect to the management of conflicts.
 - d. Reporting any significant concerns to the *Deciding Official*, immediately, including recommendations for revisions to the management plan or any mitigation concerns.
 3. Modification of the *Research* plan of a *Research* project as originally conceived.
 4. Prohibition from contributing to any *Research* activity that could be influenced because of *Significant Financial Interests*. For example, the *Investigator* may be prohibited from serving as the *PD/PI*, analyzing data, determining whether potential subjects are eligible for enrollment, or soliciting consent.

5. Divestiture of *Significant Financial Interests*; i.e., allow work to progress contingent upon the sale or disposal of specified financial interests.
6. Severance of relationships that create conflicts; e.g., relinquishing a seat on a board of an outside *Entity*.
7. Exception—*Compelling Circumstances*; i.e., facts that convince the *Conflicts of Interest Committee* that an *Investigator*/individual is uniquely positioned, and should be permitted to participate in a specific project, activity, or clinical trial under appropriate management despite a *Significant Financial Interest*.

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 over *Significant Financial Interests*. In such a case, the *Deciding Official* will make a final determination.

- C. Approval and Execution of Conflict Management Plan. When the *COIC* recommends a *Conflict of Interest* management plan, it is to be reviewed and approved by the *Deciding Official* before implementation.
- D. Sanctions. Allegations of violations of Executive Policy E5.214 may be forwarded to the Office of Research Compliance, which will investigate the circumstances and take appropriate action. If the violation or failure to comply is not remedied, formal proceedings pursuant to the relevant University policy (e.g., Executive Policy E5.211) may be initiated.
 1. The failure of an *Employee* to disclose a personal *COI*; failure or refusal to respond to requests for additional information; providing incomplete, misleading, or knowingly inaccurate information; failure to comply with directives from the *Deciding Official*; failure to cooperate with appointed project monitoring persons; or failure to eliminate a conflict when so directed may be grounds for disciplinary action up to and including termination for cause.
 2. Agreements may be terminated with sub-grantees, sub-recipients, contractors, or collaborators (e.g., consortia) who either fail to file a complete *Disclosure* or fail to comply with directives of Executive Policy E5.214.

3. In addition, the University is required to report to Federal sponsors any violation of Federal *Conflicts of Interest* regulations.

E. COI Inquiries. Questions or concerns related to potential COI should be brought to the Office of Research Compliance, preferably in writing. Questions or concerns may be raised anonymously. Confidentiality will be maintained to the greatest extent possible.

F. Conflicts for Committee Members. A Committee member shall not participate in the evaluation of a case when the following conditions apply:

1. The *COIC* member has a personal interest because of personal or professional relationships, such as collaboration with the individual whose case is under consideration.
2. The *COIC* member has a financial interest in the case under discussion.
3. The *COIC* may make exceptions to the above by majority vote.

VI. CONFLICT RESOLUTION - INSTITUTIONAL CONFLICTS OF INTEREST.

With respect to *Senior Administrators* and their roles as representatives of the University in initiation and management of interactions with *Entities* outside of the University community, the University will honor the guiding principles and objectives as stated in Executive Policy E5.214, APM A8.956, and herein. The procedures to be followed in addressing possible *Institutional Conflicts of Interest* are the same as when considering the activities of individual faculty, *Investigators*, and staff, but some differences may apply.

Like all other *Employees*, *Senior Administrators* must file yearly *Conflicts of Interest Disclosures* of personal/individual activity. If *Senior Administrators* disclose an activity or interest as a representative, or on behalf, of the University, then these *Disclosures* must be reviewed by the Administrator's supervisor and/or referred to the *Deciding Official*. If determined that the activity or interest could potentially give rise to an *Institutional Conflict* and require management or elimination, the *Conflicts of Interest Committee* may be asked to evaluate the *Disclosure* and make recommendations to the *Deciding Official*. In such cases the procedures described in section V. above will apply. By involving the *Conflicts of Interest Committee*, representatives of the faculty and the central

administration will evaluate the institutional activity and the appropriate University response.

VII. CONFLICT RESOLUTION - ORGANIZATIONAL CONFLICT OF INTEREST

A conflict may arise when the University cannot provide a government agency or private sector *Entity* impartial advice, such as when an agency contracts with the University to design and write specifications and goals for future solicitation of proposals with the intent of accomplishing a particular task for the agency. The University may then have an unfair advantage in competition for award of contracts or grants arising from the advice provided to the agency or *Entity*. To avoid such real or perceived *Conflicts of Interest*, full *Disclosure* to the offering agency or *Entity* must be made, and, if desired, a waiver obtained to allow open competition for the resources offered.

In the management of an *Organizational Conflict of Interest* involving interactions with Federal agencies, the University is governed by 48 CFR, Part 9, subpart 9.5 entitled "Organizational and Consultant Conflicts of Interest." The same principles and procedures are utilized in management of such interactions with government agencies and private sector *Entities*.

As noted by Dr. Dean O. Smith in his book dated 2011 and entitled "Managing the Research University," *Organizational Conflict of Interest* may take other forms. For example, one University faculty member in the Department of Chemistry may successfully compete for funding of a grant from a chemical manufacturing company to improve upon the toxicity of a pesticide used in the control of frog populations. Another faculty member at the University may successfully compete for a Federal grant to fund studies of the deleterious environmental effects of the pesticide. The perception may thus arise that the design and conduct of such studies are fundamentally competing and in conflict with each other, even though the researchers are impartially pursuing truth. The procedures to be used in addressing cases such as these are the same used in management of *Individual Financial Conflicts of Interest* (Section V. above).

VIII. CONFLICT RESOLUTION - SCHOLARLY AND SCIENTIFIC CONFLICTS OF INTEREST.

A scholar should not allow the potential for personal, financial, or professional gain to influence his or her judgments in reviewing, evaluating, and commenting on the writings of other individuals. Knowledgeable scholars are routinely called upon to conduct peer review of documents and manuscripts that are under consideration for publication or that may be used in facilitating

effective decision-making by governmental agencies or businesses, that may be used in deciding whether there will be an award of a contract or grant, or that may be used in arriving at decisions regarding promotion and/or tenure. If a reviewer is in competition with the author(s) of a document under review or has an undisclosed personal bias, then a *Conflict of Interest* exists and must be disclosed to the person or organization requesting the review, or the reviewer must excuse him or herself. Likewise, *Disclosure* must be made by a scholar to the editors of periodicals or other publications who are asked by the scholar to publish his or her unsolicited editorial comments regarding a publication. After *Disclosure*, the decision as to whether to proceed with a review or commentary would be made by the requestor of the review.

If an individual observes what appear to be violations of these expectations in scholarship on the part of a University *Employee*, allegations should be filed with the Research Integrity Officer, following the procedures stated in Executive Policy E5.211.

IX. CONFLICT RESOLUTION - CONFLICTS OF COMMITMENT.

For the benefit of the University, *Employees* are expected to commit their work efforts to the tasks specified in their job descriptions.

Faculty are hired to perform teaching, *Research*, and service; however, in that context they have a special agreement with the University in that they are allowed to devote one work day per week at their discretion to the pursuit of outside activities that are relevant to the University's and their own professional interests. *Conflicts of Commitment* most often arise when the time commitment of a faculty member to outside interests quantitatively exceeds what is expected as a direct commitment to the University and/or qualitatively differs from the interests and functions of the University.

Commitment issues are to be initially addressed by the immediate *Senior Administrator*, communicating directly with the faculty member. This is to be regarded as an administrative matter not requiring involvement of the *COIC* unless there are substantive issues that cannot be resolved.

X. RETROSPECTIVE REVIEWS

When the University discovers a *Conflict of Interest* not disclosed according to this APM or APM A8.956, it will be reported to the appropriate *Senior Administrator* for evaluation. If determined that there is a need to *Manage*, reduce, or eliminate the conflict,

then the matter shall be addressed by the *Senior Administrator* or referred to the *COIC*. The *Deciding Official* will make final decisions if the *COI* cannot be resolved. The retrospective review and resulting action may be reportable to *Awarding Components*. Retrospective reviews should be completed within 120 days from discovery of the conflict.

XI. RECORDS RETENTION

All records relevant to issues of *Conflicts of Interest*, including personal *Disclosure* forms, whether or not a conflict exists, will be retained in the office of the appropriate *Senior Administrator*. Records shall be retained for a minimum of three years. For *Disclosure* records related to a funded award, these shall be retained for a minimum of three years after acceptance of the final grant or contract report by the funding *Entity*. If a *Conflict of Interest* matter was addressed, and all requirements were adequately satisfied upon acceptance of the final report, these records will be retained for three years after all conflicts are resolved.

XII. TRAINING

It is important that *Senior Administrators* be adequately trained in identifying *Conflicts of Interest*, how to resolve conflicts that are identified, or when to refer a case for evaluation to his or her supervisor. This training may be provided in the form of the Collaborative Institutional Training Initiative's (CITI) online *Conflicts of Interest* educational training modules, or a tutorial provided by the National Institutes of Health. In addition, interactive sessions in a classroom setting will be provided by the *Office of Research Compliance*. The session is to be designed for *Senior Administrators* to help them meet their obligations as described in this Administrative Procedures document. For the rest of the University's *Employees*, the same training will be provided using an interactive session designed to assist *Employees* in understanding and identifying *Conflicts of Interest* and University policy and procedures.

ATTACHMENT A to APM A5.504**University of Hawai'i Conflicts of Interest Disclosure Form**

This form must be completed by all employees (defined in Section II.K. of APM A5.504) as required by UH Executive Policy E5.214. Disclosures must be provided:

1. Annually by April 15;
2. Immediately when a new relationship or financial interest arises;
3. When a previous disclosure or conflict status is modified;
4. Within 30 days of new hire or appointment;
5. That exist at the time of filing; or
6. That existed during the previous 12 months;
7. For interests of the employee **and** employee's immediate family¹.

Part I and Part II (if applicable) must be completed, signed, dated, and given to your supervisor for their review and signature. If assistance is needed, Supervisors will forward disclosure forms to the Office of Research Services, Compliance Section. Contact ORS if you have any questions at compliance@ors.hawaii.edu.

Name: _____ Title: _____ Date: _____

Campus: _____ School/College/Unit: _____

Department: _____

PART I

1. Ownership Interests

Do you or any member(s) of your immediate family own or control any equity interest (e.g., stock, stock options) in an entity² that could appear to be related to your institutional responsibilities?

YES ÁNO

2. Offices and Positions

Are you or any member(s) of your immediate family a director, board member, officer, trustee, partner, employee, agent, or hold any other position for an entity outside the University of Hawai'i that could appear to be related to your institutional responsibilities?

YES NO

3. Remunerative Activities

Do you or any member(s) of your immediate family receive income or compensation for services (e.g., fees, honoraria, loans, gifts, royalties, cash or in-kind compensation) that could appear to be related to your institutional responsibilities from any entity outside the University that when aggregated exceeds \$5,000.00 per year?

YES NO

¹"Immediate family" signifies the employee's spouse, domestic partner, or reciprocal beneficiary and dependent children.

²"Entity" signifies any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business, real estate trust, or any other legal body organized for profit or nonprofit purposes.

4. Outside Employment of Students or Staff

a) Do you employ or plan to employ any of your students or staff member(s) in an entity outside the University? **OR** b) do any students or staff member(s) participate in your non-University activities?

a) YES NO b) YES NO

5. Sponsored Travel

Have you or any members of your immediate family, received reimbursement or sponsorship for travel related to your institutional responsibilities? If so, was the total travel cost greater than \$5,000 when aggregated for each entity, or was travel sponsored or reimbursed by an outside entity (excluding federal, state, or local government agencies, institutions of higher education [as defined by 20 U.S.C 1001(a)], academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education?

YES NO

6. Other Transactions or Facts

Do you or any member(s) of your immediate family have an interest in any contract, sale, or other transaction to which the University of Hawai'i or one of its affiliates is a party, or are there other situations, not listed above, that you believe may create a conflict of interest or commitment?

YES NO

PART I: SIGNATURE AND CERTIFICATION

If you answered "Yes" to any of the Part I questions you MUST complete Part II of this disclosure form.

By signing this form, I certify the following: 1) I have read and understand the University of Hawai'i Policy on Conflicts of Interest and Commitment; 2) the information in this disclosure form is an accurate and complete statement of my outside interests and activities; and, 3) I understand my continuing obligation to disclose any change(s) to my significant financial interests and other conflicts of interests that may arise after submission of this form.

Signature: _____ Date: _____

Supervisor's Certification

I certify that the person named above reports to me and I have reviewed this disclosure form. To the best of my knowledge:

No conflicts of interest or commitment exist and no further action is required; or
Potential existing conflicts have been reported and further review may be required.

Print Name: _____ Date: _____

Signature: _____

Conflicts of Interest Disclosure Form **PART II**
Detailed statement of Outside Interests and Activities

COMPLETE PART II IF YOU ANSWERED "YES" TO ANY OF THE PART I QUESTIONS.

1. Equity/Ownership Interests

Provide details of ownership or equity interest for yourself and any member(s) of your immediate family (including stock, stock options, or other securities) in an entity that appears to be related to your institutional responsibilities.

Entity name	Description of entity	Individual holding the interest	Amount of annual income/compensation (if when aggregated exceeds \$5,000) <u>or</u> ownership percentage

Do you use University resources to conduct business for any of these entities (e.g., University office or laboratory, phone, computer, stationery, or other supplies)? If so, please indicate resource(s) used and for which entity.

2. Associations, Memberships, Positions

Please provide details for any position(s) you or any member of your immediate family hold as director, board member, officer, trustee, partner, employee, agent, or any other position in an entity outside of the University that appears to be related to your institutional responsibilities.

Entity name	Amount of annual income/ compensation received (if over \$5,000)	Position, individual holding the interest & description of activity (in detail)	Time dedicated to activity (days/month, days/year)

Do you use University resources to conduct business for any of these entities (e.g., University office or laboratory, phone, computer, stationery, or other supplies)? If so, please indicate resource(s) used and for which entity.

3. Remunerative Activities

Provide details of income or compensation you or any member of your immediate family receives (e.g., consulting fees, honoraria, lecture fees, salary, loans, gifts, royalty payments, cash or in kind) from any entity outside the University that appears to be related to your institutional responsibilities and that when aggregated exceeds \$5,000 per year.

Entity name	Amount of annual income/ compensation received (if over \$5,000)	Individual holding the interest & description of activity (in detail)	Time dedicated to activity (day/month, days/year)

Do you use University resources to conduct business for any of these entities (e.g., University office or laboratory, phone, computer, stationery, or other supplies)? If so, please indicate resource(s) used and for which entity.

4. Outside Employment of Students or Staff

Do you or any member of your immediate family employ or plan to employ any of your students or staff member(s) in an entity outside of the University? **OR** do any students or staff participate in your non-University activities? If so, please describe below:

Entity name	Name of student(s) or staff	Describe activity performed (in detail)	Time dedicated to activity (hrs/day, days/mo.)

5. Sponsored Travel

Please provide details about travel (for yourself or members of your immediate family) reimbursed or sponsored by an entity **NOT** considered to be a federal, state, or local government agency, an institution of higher education or affiliated with an institution of higher education [as defined by 20 U.S.C 1001(a)], which appears to be related to your institutional responsibilities.

Entity/Sponsor/ Organizer name	Individual traveling/ Purpose of trip	Travel destination and duration of trip	Total travel costs(if when aggregated exceeds \$5,000)

6. Goods and Services

Please provide details of your or any member of your immediate family's interest(s) in any contract, sale, or other transaction to which the University of Hawai'i or one of its affiliates is a party.

Entity name	Relationship to entity	Individual holding the interest and role in transaction (in detail)	Amount of transaction

7. Other Situations or Facts

Are there other situations, not listed above, that you believe may create a conflict of interest or commitment? Please describe such situations, including nature, parties, subject matter, income or compensation received.

PART II: SIGNATURE AND CERTIFICATION

By signing this form, I certify the following: 1) I have read and understand the University of Hawai'i Policy and Procedures on Conflicts of Interest and Commitment; 2) the information in this disclosure form is an accurate and complete statement of my outside interests and activities; and 3) I understand my continuing obligation to disclose any change(s) to my significant financial interests and other conflicts of interests that may arise after submission of this form.

Signature: _____

Date: _____

Supervisor's Certification

I certify that the person named above reports to me and I have reviewed this disclosure form. To the best of my knowledge, full disclosure of significant financial and other interests have been reported. I understand that further review may be conducted by other Senior Administrators, ORS, and/or the Conflicts of Interest Committee (COIC) may be called upon to assist in the development of an appropriate management plan.

Based on my review of the completed disclosure(s):

Potential conflict(s) of interest exist?	Yes	No
Potential conflict(s) of commitment exist?	Yes	No

If yes, select one:

- Conflict(s) have been eliminated.
- No management plan is necessary/no further action required.
- An appropriate management plan is/will be in place.
- A management plan will be developed and submitted for review.
- Additional assistance is requested.

Print Name: _____

Date: _____

Signature: _____

ATTACHMENT B to APM A5.504**ANNUAL SUMMARY REPORT OF DISCLOSURES OF CONFLICTS OF INTEREST**

Each Dean or Director of an academic unit or department, or other Senior Administrator, shall compile an annual report to submit to their respective Vice Chancellor or Chancellor by June 30 of each year. The report shall include the following:

1. A list of individuals, if any, who did NOT submit the required disclosure form.
2. The number of department/unit faculty, staff, or administrators who were required to submit disclosure forms, **AND** the number and percentage of those who actually submitted disclosure forms.
3. The number of department/unit faculty, staff, or administrators who completed Part II disclosures.
4. The number and percentage of department/unit faculty, staff, or administrators whose outside interests and activities were found to conflict with their University and/or professional commitments, but for whom conflicts were resolved by the Dean/Director or the Conflicts of Interest Committee.
5. Pertaining to question #4 (above), list the details regarding corrective actions recommended and taken to resolve conflicts.
6. The number and percentage of department/unit faculty, staff, or administrators whose conflicts of interest were not resolved and summarize the recommendations or plan for each unresolved case.