

AZUSA PACIFIC UNIVERSITY
POLICIES AND PROCEDURES

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Procedures for Disclosure and Management of Conflicts of Interest in Research

Policy Statement

This policy is intended to be consistent with federal requirements for grantee institutions, including regulations adopted by the *Public Health Service (PHS)* of the Department of Health and Human Services and the *National Science Foundation (NSF)*. Faculty or staff *investigators* applying for federal grants for *research* should review the *entity* specific federal regulations that apply.

Decisions concerning the nature and direction of scholarly research at Azusa Pacific University (“APU” or “University”) are to be governed by judgments of scholarly merit and intellectual importance. A faculty or staff member’s involvement with, or interest in, outside commercial or professional applications of research that are related to the member’s own scholarly research or that of other faculty or students raises issues of potential conflict of interest that must be addressed in accordance with the policy below.

Students rely on faculty advice and guidance concerning educational matters within the University (including the nature and direction of research). Such advice and guidance are to be governed by a student’s best interest and may not be made to serve a faculty member’s interest in research or outside commercial and professional activities.

Reason for the Policy

The success of APU’s research program depends upon the integrity of the investigators and their research teams, as well as the public’s confidence in them. A *conflict of interest* in research, as defined in section IV of this policy, strikes at the heart of a university’s integrity. In pursuit of its mission as a private institution of higher education, the University seeks excellence in the quality of its research, in the teaching and education it provides to its students, and in the service it provides to the broader community. This knowledge transfer inevitably leads to increasingly close relationships between universities and those with financial capital in the private sector. The benefits that potentially accrue from this proximity are accompanied by real or perceived risks that personal, financial, relational, or other interests might compromise academic research by influencing an investigator’s judgment about the design, conduct, reporting, or management of research, and, in the case of research involving human subjects, imperil the safety of participants. Investigators *involved in research* through assuming the responsibility for the design, conduct, or

reporting of research have a special obligation to avoid bias or the appearance of bias in the conduct of these studies. Any possible conflict of interest must be formally disclosed to the institution.

I. POLICY

The University, its faculty, and other members of the University research community commit themselves to the pursuit of research at the University in accordance with the highest standards of integrity and in compliance with legal, professional, ethical, and other requirements that promote objectivity and protect against financial conflicts of interest in research. The University will identify possible conflicts of interest associated with research, whether apparent or real, and provide mechanisms for their management, reduction, or elimination in compliance with federal and state law and relevant policies of entities providing funds for research at the University.

II. ORGANIZATIONAL RESPONSIBILITIES

Institutional Officials: University officials, other than chairs, unit heads, and deans, under whose general supervision there are *covered individuals* with obligations under this policy, shall:

- a. Designate a responsible institutional official, the Research Integrity Officer (RIO), to carry out the University responsibilities related to this policy. [The current RIO is identified on the University's website: <https://www.apu.edu/researchandgrants/ethics/research-misconduct/>.]
- b. In collaboration with the RIO, maintain an up-to-date, written, enforced policy on *financial conflicts of interest in research* and make such policy available via a publicly accessible website.

The following tasks/responsibilities shall be carried out by the RIO:

- a. Oversee the solicitation and review of *disclosures on potential conflict of interest* through the *Potential Conflict of Interest (PCOI) disclosure form*.
- b. Certify in applications for federal funding that: (i) the University has an up-to-date written and enforced process in effect; (ii) the University promotes and enforces investigators' compliance; (iii) the University manages conflicts of interest and provides initial and on-going reports to federal agencies; (iv) the University agrees to make information available promptly upon request; and (v) the University fully complies with the applicable federal regulations.
- c. Provide reports to federal, state, and private funding agencies where required.
- d. Provide information required by federal regulations to requestors within five (5) business days, wherever the University determines there is a *significant financial interest* by investigator(s) related to federally funded research, and that the significant financial interest is a financial conflict of interest in research.
- e. Resolve ambiguities, if any, as to the identification of covered individuals under their general supervision, and shall, in coordination with the appropriate administrative offices, be responsible for ensuring that PCOI forms are completed, submitted, and forwarded as required by this policy.
- f. Notify the administrative offices and the responsible institutional officials, wherever a covered individual with a determined conflict of interest (including fiduciary interest) proposes to conduct research. In addition, the RIO is responsible to ensure all investigators

are informed regarding such individuals' responsibilities related to disclosure of significant financial or other interests, and of any relevant federal or state regulations, and to require each such person to complete training regarding the same: (i) prior to engaging in research; (ii) at least every four (4) years; and (iii) immediately when any of the following circumstances apply: the University revises its conflicts of interest policies or procedures; the individual is a new investigator to the University; if the University finds that the individual is not in compliance with the University's conflicts of interest policy or management plan.

- g. Provide guidance consistent with the relevant federal conflict of interest policies and oversight to the *Committee on Conflict of Interest (CCOI)* and the Administrative Offices in aspects related to this policy and relevant federal regulations.

Administrative Offices: The following subdivisions of the Office of Research and Grants (ORG) are involved in the University processes on conflicts of interest in research: Sponsored Research (pre-award), Grants Management (post-award), Institutional Review Board (IRB), and Institutional Animal Care and Use Committee (IACUC). Additionally, the Office of the General Counsel and other University administrators might be involved in matters related to this policy. The following tasks/responsibilities shall be carried through by the Administrative Offices:

- a. Inform investigators (including new investigators) of this policy and accompanying guidance, and the investigator's responsibilities regarding disclosure of potential conflict of interest and participation in relevant training;
- b. Solicit and review disclosures on potential conflict of interest as outlined in the Procedures for Disclosure and Management of Conflicts of Interest in Research;
- c. Maintain records of disclosures of potential financial conflicts of interests and the University's review of and response to, such disclosures, and all actions under the University's policy or retrospective review, if applicable, for a minimum of three (3) years, or longer, if required by applicable federal or state regulations or agreements with funding agencies;
- d. Maintain records of management plans implementation (monitoring, frequency, training);
- e. Organize and host Conflicts of Interest training for covered individuals as need be.

Deans: Each dean shall ensure that covered individuals within their school or college are accurately identified. This identification is accomplished through dean review and approval of faculty and staff online applications, that is, during grant applications routing and protocol submissions through the IRB and IACUC. The Administrative offices will then prompt all such covered individuals to complete and sign a PCOI disclosure form with the expectation this will be done in a timely manner.

Covered Individuals: No later than the time of application for research funding, or application for approval by a University research panel (e.g., IRB, IACUC), each covered individual must complete a PCOI under the provisions of this policy and submit it as part of the application process. In the event of changes, the covered individual must complete a PCOI within thirty (30) days after any significant change in the individual's (or his or her spouse and dependent children) personal, financial, relational, or other interests to reflect the emergence of other circumstances that might cause the project the covered individual is involved with to be affected by a conflict of interests. In the case of federally funded research, covered individuals must verify

potential conflicts of interest at least annually.

Subrecipients: University subrecipients, funded from contract or grant awards to the University, must provide appropriate assurances/certifications that they are in compliance with University policies relating to financial conflicts of interest in research or that they have the equivalent of these policies and procedures in place, in pre-award stage or before funds are released.

Committee on Conflicts of Interest (CCOI)

Membership: The CCOI is a standing committee of the University, consisting of at least three (3) members appointed for three (3) year terms, renewable, by the RIO. The membership of the CCOI is composed of individuals broadly representative of the membership of the University research community, including those who conduct human subjects research, and other faculty and University staff members familiar with ethical, legal, and regulatory issues involved in the oversight of conflicts of interest in research. The CCOI reports to the RIO or designee.

Responsibilities:

- a. The CCOI collaborates with ROI in developing and issuing guidelines consistent with this policy and federal and state laws.
- b. The CCOI reviews and makes recommendations to determine whether an investigator's significant financial interest is related to research conducted by such an investigator and, if so related, whether such significant financial interest constitutes a financial conflict of interest. The CCOI makes such recommendations upon receipt of disclosures from investigators. The CCOI evaluates the *compelling circumstances in research*. The CCOI also makes recommendations concerning appropriate measures for the reduction, elimination, or management. This includes *management plans, retrospective reviews*, and mitigation reports (such as engagement with the *financially interested entity or financially interested individuals*) of any potential *financial conflicts of interest* relating to research.
- c. The CCOI also similarly manages other types of conflicts of interest such as those arising from relational or professional associations in research. With specific respect to *human subject research*, the CCOI will determine if an individual with a significant financial interest has overcome the *rebuttable presumption against financial interests in research* and establish the conditions under which the research studies may proceed with investigator's involvement. The CCOI shall also follow a similar process in determining whether other research may proceed in situations where non-financial conflicts of interest are present.

Procedural details around the **ORGANIZATIONAL RESPONSIBILITIES** outlined in section II are provided in the [Procedures for Disclosure and Management of Conflicts of Interest in Research](#) document that accompany this policy.

III. VIOLATIONS OF THIS POLICY

A violation of this policy may be the basis for discipline of any individual committing it. Violations of this policy include but are not limited to failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure form; failure to provide additional information as requested by the reviewing or approving authority; and intentionally tardy responses or a pattern of non-cooperation in responding to requests for additional information by the reviewing or approving authority. It can also include not cooperating with the CCOI and not complying with management

plans and other directives. If sanctions are necessary, they will be imposed in accordance with University policies and procedures and may include but are not limited to:

- (a) Letter of reprimand or admonition
- (b) Suspension of the processing of any grant applications made by the individual, or a declaration of ineligibility of the individual for future such applications
- (c) Suspension of research contract negotiations involving the individual as investigator, or a declaration of ineligibility of the individual for future research contracts
- (d) Suspension or ineligibility of the individual for Institutional Review Board (“IRB”) approval or for supervision of graduate students
- (e) Removal as principal or co-principal investigator in respect to any current research activity
- (f) Suspension
- (g) Non-renewal of appointment
- (h) Dismissal

IV. DEFINITIONS FOR OVERSIGHT OF CONFLICTS OF INTEREST IN RESEARCH

1. “*Committee on Conflicts of Interest*” (“CCOI”) refers to the standing committee that reviews the PCOI disclosure forms, and other documentation and information, of a covered individual, for the purpose of recommending whether a conflict of interest in research exists, and if so, to recommend to the Research Integrity Officer a management plan that mitigates any conflict of interest. The committee consists of three (3) members appointed for three (3) year terms, renewable, by the Research Integrity Officer.

2. “*Compelling circumstance in research*” are those facts that convince the University, through the CCOI and its responsible institutional official, that an individual with financial or other interests that might affect or compromise, or appear to affect or compromise, the design, conduct, reporting, or management of research, should nonetheless be permitted to conduct the research. A *covered individual* must present a written statement to the CCOI for its consideration, explaining why compelling circumstances exist to permit such research to go forward. This process of showing such circumstances is the process necessary to overcome a *rebuttable presumption against conflicts of interest in research*. When considering such a statement by an interested *covered individual*, the circumstances that the CCOI and the responsible institutional official should consider are the nature of the research; the magnitude and nature of the interest, and the degree to which it is related to the research; the extent to which the interest could be directly and significantly affected by the research; the risk (measured in terms of its nature, probability, severity, duration, and frequency) to the subjects involved that is inherent in the research protocol; and, where future royalty interests might be involved, the anticipated time interval between the research activity and marketing approval of the investigational product. The designated official and the CCOI should also consider the extent to which the interest is amenable to effective oversight and management.

3. “*Conflict of interest*” refers to a divergence between the individual’s personal financial, relational, or other interests and his or her professional obligations to the University –

whether through teaching, involvement in research, contracting, purchasing, or performing other administrative duties – such that an independent observer might reasonably determine that the individual’s professional actions or decisions are, or potentially could be, adversely affected, distorted, or otherwise compromised by the individual’s personal interest. The term conflict of interest is broader and encompasses more professional activities than the term financial conflict of interest in research, defined below.

4. “*Covered individual*” includes any faculty member (whether full-, partially-, or non-salaried), staff member, administrator, or other employee who, under the aegis of the University, is involved in research, or conducts research pursuant to the review and approval of a University research panel, or is otherwise identified as involved in research by a principal investigator, chair, or unit head, or other University administrative officer responsible for research activities. It also includes any student, fellow, or trainee who works (whether paid or unpaid) on a federally funded research project, as well as any student who is a primary investigator or co-investigator.

5. “*Disclosure of potential conflict of interest*” means an investigator’s indicating to the institution through the Potential Conflict of Interest Disclosure form that there could be a significant conflict of interest associated with the research.

6. “*Entity*” means any public or private organization, corporation, partnership, proprietorship, or firm, regardless of whether organized for profit or as a non-profit entity. The term does not include the University.

7. “*Fiduciary interest*” refers to the interest of a covered individual that derives from a legal or ethical role the individual has to act in the best interests (e.g., the financial success) of another. Examples of fiduciary interests include but are not limited to membership on a board of directors, a management role in a company, or partnership.

8. “*Financial conflict of interest in research*” is the existence of a significant financial interest that an independent observer might reasonably determine affects or compromises, or appears to affect or compromise, the design, conduct, reporting, or management of research.

9. “*Financially interested entity*” means a commercial or non-profit entity with financial interests that to an independent observer would reasonably be affected, or appear to be affected, by the design, conduct, reporting, or management of research in which the covered individual is involved. The term includes entities that compete with the sponsor of the research or the manufacturer of the investigational product, if the covered individual actually knows, or could reasonably be expected to know, that the financial interests of such an entity would reasonably appear to be affected by the research. The term also includes any entity acting as the agent of a financially interested company (e.g., a contract research organization).

10. “*Financially interested individual*” means a covered individual who holds a significant financial interest that to an independent observer could reasonably appear to be affected by the individual’s research.

11. “*Human subjects research*” includes all research meeting the definition of “research” involving a “human subject” as these terms are defined or used in the federal Common Rule 45 C.F.R. § 46.102(d) and (f) and 21 C.F.R. Part 56, regardless of the source of research

funding or whether the research is otherwise subject to federal regulation, and includes but is not limited to clinical trials.

12. “*Institutional responsibilities*” means an investigator’s professional responsibilities on behalf of the University, which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.

13. “*Investigator*” means an individual responsible for the design, conduct, reporting or management of research, and includes but is not limited to a principal investigator and a co-principal investigator.

14. “*Involved in research*” means having responsibilities that include the design, conduct, reporting or management of research, that include enrolling research subjects (including obtaining subjects’ informed consent or making decisions related to eligibility to participate in research), or that include direct and significant access to research data with control over its collection, analysis, or reporting (including submission for publication).

15. “*Management plan*” means a written plan for the management, reduction, or elimination of a known or likely financial conflict of interest relating to research. It relies upon, and is therefore limited by, good faith disclosures about significant financial interests made in the financial disclosure statement, as well as other information provided, by the covered individual to the University. In general, the management plan shall contain provisions appropriate for the purposes intended (e.g., management, reduction, or elimination of the research-related financial conflict), for the identity, nature, and amount of the financial conflict, and for the other circumstances in question.

16. “*National Science Foundation*” or “*NSF*” is an independent agency of the United States government that supports fundamental research and education in all the non-medical fields of science and engineering. NSF Conflict of Interest policies in PAPP Guide Chapter IX.

17. “*Potential Conflict of Interest Disclosure form*” means a written statement made, signed, and attested to by a covered individual that discloses all significant financial and other interests (and those of his or her spouse and dependent children) that to an independent observer would reasonably appear to be affected by research in which the individual is involved or that exist in entities whose financial interests to an independent observer would reasonably appear to be affected by the research (e.g., stock values, etc.). The Potential Conflict of Interest Disclosure (“PCOI”) form must identify and describe, and state the nature and amount of the significant financial or other interest. The PCOI form must be completed at the time of a grant application, or at the time of negotiation of a sponsored research agreement, or to disclose a significant change in a covered individual’s (and those of his or her spouse or dependent children) financial and other interests. The PCOI form is treated as confidential by the University and is considered part of the personnel file of the covered individual; however, the CCOI shall provide copies of such forms to University research panels or other institutional officials as appropriate. For covered individuals with federally funded research, the contents PCOI form must be verified at least annually.

18. “*Public Health Service*” or “*PHS*” is a division of the U.S. Department of Health and Human Services concerned with public health. It contains eight out of the department’s eleven

operating divisions and the PHS agencies are:

- National Institutes of Health (NIH)
- Food and Drug Administration (FDA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Agency for Healthcare Research & Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)

Standards for promoting objectivity in PHS-funded research are outlined in 42 CFR Part 50 Subpart F

19. “*Rebuttable presumption against financial interests in human subjects research*” is a presumption that a financially interested individual may not be involved in research that uses human subjects. This rule is not intended to be absolute; a financially interested individual may rebut the presumption by demonstrating facts that, in the opinion of the reviewing bodies (including an IRB, and the CCOI) and administrative officers, constitute compelling circumstances. If compelling circumstances were found, the individual would then be allowed to design, conduct, report, or manage the research under conditions specified in an approved management plan and any other conditions specified by the reviewing bodies and administrative offices, in accordance with regulatory and ethical requirements.

20. “*Research*” means a systematic investigation designed to develop or contribute to knowledge, and includes both sponsored research and non-sponsored research, that involves use of University personnel, patients, students, facilities, or resources, or the expenditure of University funds. The term includes clinical and health-related research, and behavioral and social science research, and encompasses basic and applied research and experimental development as defined below:

- Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view.
- Applied research is an original investigation undertaken in order to acquire new knowledge. It is directed primarily towards a specific, practical aim or objective.
- Experimental development is systematic work, drawing on knowledge gained from research and practical experience and producing additional knowledge, which is directed to producing new products or processes or to improving existing products or processes.

21. “*Responsible institutional official*” or “*designated official*” for purposes of any reporting requirements or final decision-making required by or pursuant to this policy shall mean the Research Integrity Officer, or designee.

22. “*Retrospective review*” refers to the process that the University must follow whenever, in the course of an ongoing research project, an investigator who is new to participating in the research project discloses a significant financial or other interest, or an existing investigator discloses a new significant financial or other interest. In such circumstances the University must, within sixty (60) days, review the disclosure of the interest, determine whether it is related to

research, determine whether a conflict of interest exists, and, if so, implement a management plan to manage such conflicts of interest and update any required reporting to any funding agencies.

23. “*Subrecipient*” means an entity, usually but not limited to non-Federal entities, that receives a subaward from a pass-through entity to carry out part of an award; but does not include an individual that is a beneficiary of such award. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency.

24. “*Significant financial interest*” means anything of economic or monetary value that to an independent observer would be or reasonably appear to be affected by research, with inclusions and exclusions as set forth below:

(1) Inclusions. Significant financial interest includes but is not limited to any economic or monetary interest of the following types or categories that is held by either (i) a covered individual (or his or her spouse or dependent children); or (ii) any entity in which a covered individual (or his or her spouse or dependent children) has a financial or fiduciary interest:

(a) “*Compensation interest*,” meaning non-university salary, consulting fees, wages, retainers, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts, “in kind” compensation from a financially interested company (or entitlement to the same), or any other thing of economic or monetary value whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the past twelve (12) months exceeded \$5,000, or are expected to exceed that amount in the next twelve (12) months.

(b) “*Equity interest*,” meaning (i) any equity interest (or entitlement to the same), in a publicly traded financially interested entity that exceeds \$5,000 in value or represents more than 5 percent ownership interest in any single entity (see exclusions below); or (ii) equity interests, including stock options, warrants, or other convertible securities, of any amount in a non-publicly traded financially interested entity (or entitlement to the same).

(c) “*Intellectual property interest*,” meaning (i) royalty income or the right to receive future royalties under a patent license or copyright, whether the research is directly related to the licensed technology or work; or (ii) any other direct or indirect interest in a patent, trademark, copyright, trade secret, know-how, or other intellectual property right where the research is directly related to the interest.

(d) “*Extraneous research payments*,” meaning any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution), including any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested *entity* or from the institution.

(e) “*Fiduciary relationship*,” meaning service as an officer, director, or in any other fiduciary role for a financially interested entity, regardless of whether remuneration is received for such service.

(f) “*Travel expense*,” meaning any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to his or her institutional responsibilities; provided, however, that disclosure is not required for travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

(2) Exclusions. Significant financial interest excludes, and therefore is not meant to refer to, the following types of categories of economic or monetary interest:

(a) “*Mutual fund interests and retirement accounts*,” meaning interests of any amount in publicly traded, diversified mutual funds or retirement funds as long as the investigator does not directly control the investment decisions made by these vehicles.

(b) “*De minimis equity interests*,” meaning stock or stock options in a publicly traded company that when aggregated for the covered individual (or his or her spouse or dependent children) meets both the following tests: it does not exceed \$5,000 in value (as measured in reference to public prices or other reasonable measure of fair market value) and does not represent more than a 5 percent ownership interest in any single entity.

(c) “*Outside payments*,” meaning salary, royalties, and other payments from entities other than the University, or via the University to the individual, that when aggregated for the covered individual (or his or her spouse or dependent children), over the next twelve (12) months, are not expected to exceed \$5,000.

(d) “*Regular research payments*,” meaning payments to the University, or via the University to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement between the sponsor and the University.

(e) “*University compensation*,” meaning salary, royalties, and other remuneration for services from the University.

(f) “*Income from service*,” meaning income for service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

(g) “*Income from lectures*,” meaning income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

25. “*Sponsored research*” means research funded or otherwise supported by anything of economic or monetary value, in whole or in part, by an entity.

[end]