

AZUSA PACIFIC UNIVERSITY

POLICIES AND PROCEDURES

Title: Policy For Conflicts Of Interest In Research
Policy Number: **PO2012032**
Replacing Policy Number: No prior policy
Effective Date: June 26, 2012
Issuing Authority: Office of the President
Responsible Office: Office of the Vice Provost for Graduate Programs and Research
Date of Amendment(s): October 14, 2014

Policy Statement

This policy is intended to be consistent with federal requirements for grantee institutions, including regulations adopted by the Public Health Service at the Department of Health and Human Services and the National Science Foundation. Faculty or staff applying for federal grants for research should review the applicable federal regulations.

Decisions concerning the nature and direction of scholarly research at the University should 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 should not bias judgment concerning the member's own scholarly research or that of other faculty or students.

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

Reason For Policy

The success of Azusa Pacific University's (the "University") research program depends upon the integrity of the research and the researchers as well as the public's confidence in them. Conflicts of interest in research strike 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 apparent risks that economic 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.

Faculty 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.

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 in research, whether apparent or real, and provide mechanisms for their management, reduction or elimination in compliance with federal and state law as well as any relevant policies of entities funding research at the University.

ORGANIZATIONAL RESPONSIBILITIES

Deans: Each dean shall ensure that all *covered individuals* within their school or college are accurately identified – either as defined by this policy or as individually determined to be *involved in research* by principal investigators. Further, the dean will ensure that all such *covered individuals* complete and sign a *Potential Conflict of Interest Disclosure Form (PCOI)* in a timely manner.

Institutional Officials: University officials, other than chairs or unit heads and deans, under whose general supervision there are *covered individuals* with obligations under this policy, shall resolve ambiguities, if any, as to the identification of such *covered individuals* under their general supervision, and shall be responsible for ensuring that *PCOI* forms are completed, submitted and forwarded as required by this policy. The Research Integrity Officer shall be responsible for all reporting to federal, state and private funding agencies where required, maintaining a publicly available current edition of this policy on the University's website, and maintaining all records of disclosures of financial 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 four years or longer if required by applicable federal or state regulations or agreements with funding agencies. In addition, wherever the university determines that there is a significant financial interest by senior/key a personnel, which is related to federally funded research, and that the significant financial interest is a financial conflict of interest, institutional officials agree to provide the information required by the federal regulations to any requestor within 5 business days.

Covered Individuals: No later than the time of application for funded research or application for approval by a university research panel (e.g., University's Institutional Review Board or Institutional Animal Care and Use Committee) for research that is not funded by entities outside of the University, each *covered individual* must complete a *Potential Conflict of Interest Disclosure Form* under the provisions of this policy and submit it to the *Committee on Conflicts of Interest (CCOI)* or sanctions may be imposed. In the event of changes, the covered individual must complete a *Potential Conflict of Interest Disclosure Form* within 30 days after any significant change in the individual's (and/or his/her spouse and dependent children) *significant financial interests*; or to reflect the emergence of other circumstances that might cause the research the individual is conducting to be affected by significant financial interests. In the case of federally-funded research, covered individuals must verify potential conflicts of interest at least annually.

Subcontractors or Subgrantees: University subcontractors or subgrantees, funded from contract or grant awards to the University, must provide appropriate assurances 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, before funds are released.

Administrative Offices: The Office of the Vice Provost for Graduate Programs and Research (Research Integrity Officer) shall be responsible for administering all University conflicts of interest in research policies, including this policy. The Research Integrity Officer (RIO) or his or her designee shall be responsible for notifying the Institutional Review Board and the responsible institutional official(s), wherever a *covered individual* with a potential conflict of interest proposes to conduct research with human subjects. In addition, the RIO is responsible for informing all Investigators regarding such individuals' responsibilities regarding 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 years; and (iii) immediately when any of the following circumstances apply: (a) the University revises its conflict of interest policies or procedures; (b) the individual is new to the University; (c) if the University finds that the individual is not in compliance with the University's conflict of interest policy or management plan.

Committee on Conflicts of Interest

Membership: The Committee for Conflicts of Interest (CCOI) is a standing Committee of the University, consisting of at least 3 members appointed for three-year terms, renewable, by the Research Integrity Officer. The membership of the CCOI includes, a Chair designated by the Research Integrity Officer, and one or more individuals broadly representative of the membership of the research community at the University, 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 Research Integrity Officer or designee.

Responsibilities: The CCOI is charged with developing and issuing guidelines consistent with this Policy and federal and state law to determine whether an Investigator's significant financial interest is related to research conducted by such Investigator and, if so related, whether such significant financial interest constitutes a financial conflict of interest; making such determinations upon receipt of disclosures from Investigators; and reviewing and/or making recommendations concerning appropriate measures for the reduction or elimination or management (including *management plans, retrospective reviews, and mitigation reports*) of any potential *financial conflict of interest* relating to research. The CCOI also similarly manages other types of conflicts of interest in research. With specific respect to *human subjects research*, the CCOI will determine if an individual with a significant financial interest has overcome the *rebuttable presumption against financial interests in human subjects research* and establish the conditions under which the human studies research may proceed with their involvement. The CCOI shall also follow a similar process in determining whether other research may proceed despite non-financial conflicts of interest.

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.

II PROCEDURE FOR OVERSIGHT OF CONFLICTS OF INTEREST IN RESEARCH

Individuals involved in research for which the University is responsible have an obligation to disclose potential conflicts to the Committee for Conflicts of Interest (CCOI) as described in the Policy for Conflicts of Interest in Research.

The Office of the Vice Provost for Graduate Programs and Research will provide staff support for the CCOI. *Covered individuals* are required by the policy to notify the CCOI of any potential conflicts of interest through the *Potential Conflict of Interest Disclosure Form*.

The Office of the Vice Provost for Graduate Programs and Research has the following procedural obligations:

- 1) To maintain an up to date list of covered individuals conducting current and proposed research, and current disclosures.
- 2) To assist the CCOI in developing standard operating procedures.

The CCOI will determine what level of inquiry, if any, is necessary due to the content of the *Potential Conflict of Interest Disclosure Form*. University employees will provide the CCOI with information and expertise necessary to support the review. The *covered individual* must provide the CCOI with a clear explanation of all significant financial interests so that an appropriate management plan may be adopted. Within 30 days of obtaining all necessary information, the Committee will recommend the appropriate management conditions, if necessary. Recommendations will be forwarded to the Research Integrity Officer for a final determination. Approved management conditions will be communicated to the covered individual and their respective department chair and dean. The Research Integrity Officer will maintain a complete archive of the final approved management plan, including any subsequent revisions.

Appeals Process Any *covered individual* shall have the right to appeal any final decision involving that individual under this Policy and Procedure to the Provost. In the event the Provost has a conflict of interest related to the appeal, the final decision on the appeal will be ceded to the President, or designee.

The appropriate dean or designee is responsible for assuring that the conflict is managed as recommended by the Research Integrity Officer and will report at least annually to the CCOI on the operation of each management process.

DEFINITIONS FOR OVERSIGHT OF CONFLICTS OF INTEREST IN RESEARCH

(1) **“Compelling circumstances in research”** are those facts that convince the University, through the Committee on Conflicts of Interest (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 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.

(2) **“Conflict of interest”** refers to a divergence between the individual’s personal financial, relational, or other interests and his/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.

(3) **“Committee on Conflicts of Interest” (CCOI)** refers to the standing Committee that reviews the Potential Conflict of Interest Disclosure Form, and other documentation and information, of a covered individual, for the purpose of recommending whether a conflict of interest in research exists. The Committee consists of three members appointed for three-year terms, renewable, by the Vice Provost for Graduate Programs and Research.

(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) **“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.

(6) **“Fiduciary interest”** refers to the interest of a covered individual that derives from a legal and/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.

(7) **“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.

(8) **“Financially interested entity”** means a commercial or non-profit entity with financial interests that to an independent observer would reasonably be affected, or appear individual to be affected, by the design, conduct, reporting or management of research in which the covered 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).

(9) **“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.

(10) **“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. Section 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.

(11) **“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.

(12) **“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.

(13) **“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).

(14) **“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. These provisions may include one or more of the following requirements:

- disclosure of significant financial interests – in writing or verbally as appropriate to the public, or human subjects, to sponsors, to IRBs, to researchers and other participants, to publishers, and to conference organizers and attendees;
- monitoring and/or auditing the conduct of the research activity by independent, qualified overseers or reviewers or panel thereof (e.g. a data safety monitoring board), who have no professional ties to the research or direct reporting relationships to the researchers, and who are empowered to obtain whatever information they need from the researchers in order to conduct their oversight activities;
- safeguarding data or the placement of copies of research data in custody of impartial party;
- modification of the research plan, methodology, or conduct;
- disqualification from participation or restrictions on a researcher’s role in all or a portion of the research (e.g. data analysis);
- divestiture or restructuring of the significant financial interest;
- placement of the significant financial interest in a blind trust;
- modification of the significant financial interest or severance of relationships that create actual or perceived potential conflicts of financial interest;
- oversight of covered individual’s research activities and significant financial interests creating the possible conflict, and the management plan, by disinterested individuals or committees;
- change in terms and conditions of agreement relating to the research;

- requiring specific compliance with other University policies, such as those relating to adoption of educational materials, conflict of commitment, outside employment or consulting, use of human subjects in research;
- prohibiting or restricting involvement of covered individual in recruitment of human subjects and/or in the informed consent process;
- requiring that a patient or human subject representative or ombudsperson be present during recruitment and/or the informed consent process;
- requiring that the significant financial interest be held in escrow until the investigational product has been approved and on the market for a specified time period;
- requiring additional disclosures or actions with respect to the significant financial interest to an IRB for its consideration and possible disclosure to human subjects as part of informed consent;
- requiring non-participation in any business transactions between the University and parties to sponsored research agreements; and
- in the case of human subjects research conducted by a covered individual with significant financial interests and justified by compelling circumstances, rigorous, effective, and disinterested monitoring undertaken by individuals with no financial or professional ties to the research or direct reporting relationships to the researchers, which might include the following monitoring mechanisms:
 - regular audits of the informed consent and enrollment process;
 - the involvement of a patient representative or ombudsman when subjects are recruited and informed consent is obtained;
 - a requirement to escrow the financial interest until the investigational product has been approved and on the market for a specified time period; and
 - the use of data and safety monitoring boards.

(15) “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 and 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.

(16) “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 product development.

(17) **“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 Vice Provost for Graduate Programs and Research who is the Research Integrity Officer, or designee.

(18) **“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 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.

(19) **“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 either i) by a covered individual (or his or her spouse or dependent children), or ii) by 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 12 months exceeded \$5,000, or are expected to exceed that amount in the next 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% 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 their 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 (and/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% 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 (and/or his or her spouse or dependent children), over the next 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.

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

(21) “***Sponsored research agreement***” means a contract or formal agreement between an outside sponsor and the University.

(22) “***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/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 Form (PCOI) must identify and describe, and state the nature and amount of the significant financial or other interest. The Potential Conflict of Interest Disclosure 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/her spouse or dependent children) financial and other interests. The Potential Conflict of Interest Disclosure 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.