

Research Institute Financial Conflict of Interest Policy

This policy is predicated on the expectation that investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs investigators about situations that generate conflicts of interest related to research, provides mechanisms for investigators and Bastyr University to manage those conflicts of interest that arise, and describes situations that are prohibited. Every investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raises questions of conflict of interest, the investigator should discuss the situation with the Director of the Office of Research Integrity.

This policy applies to all faculty or research staff, including scientists, postdoctoral fellows, predoctoral fellows or student researchers who are responsible for the design, conduct or reporting of funded research activities at the university.

1) DEFINITIONS

Clinical Trial means any research study that involves interaction with human subjects and the concurrent investigative use of botanicals, homeopathic remedies, drugs, biologics, devices or medical or other clinical procedures.

Conflict of Interest Committee (COI Committee) is led by the Director of the Office of Research Integrity and advises the Director of Research on conflict of interest matters.

Family means any member of the investigator's immediate family, specifically, any children, spouse or significant partner.

Financial Interest means anything of monetary value received or held by an investigator or an investigator's family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers;
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
- e) is reimbursed or sponsored travel related to their institutional responsibilities.

Financial Conflict of Interest means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of sponsored research.

Institutional responsibilities means the investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, research investigators, or students. The definition may also include collaborators or consultants as appropriate.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

2) DISCLOSURE OF FINANCIAL INTERESTS

All investigators are required to disclose their outside financial interests to Bastyr University on an annual and on an ad hoc basis, as described below. The Director of the Office of Research Integrity is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a) Annual Disclosures

All investigators must disclose their Significant Financial Interests that are related to the

investigator's institutional responsibilities on an annual basis. Disclosures must include that of the investigator and of the investigator's spouse, domestic partner and children. The disclosure must include all known financial interests in entities whose financial interest could or would reasonably appear to affect or be affected by the research. Additionally, if a financial interest exists, the disclosure must provide information relevant to the separation of university and private interests, appropriateness to the university's mission, openness of teaching and research environment, use of university resources and facilities, and any disclosure forms in place that convey intellectual property rights. The FCOI Annual Certification form, plus any supporting documentation, should be submitted to the Director of the Office of Research Integrity, or designee, by March 1 for the previous calendar year.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. Investigators must disclose their Significant Financial Interests to the Institution within 30 days of their initial appointment or employment.

Prior to entering into sponsored projects or applications for sponsored projects, where the investigator has a Significant Financial Interest, the investigator must submit to the Director of the Office of Research Integrity an FCOI Project-Grant Certification form, plus any supporting documentation. Bastyr University will not submit a research proposal unless the Investigator(s) has submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Director of the Office of Research Integrity an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

c) Subaward Disclosures

If it is determined a subaward does not have a Financial Conflict of Interest Policy at least as rigorous as that mandated by the NIH at 42 CFR Part 50, Subpart F or 45 CFR Part 94 [that will apply to the budgeted activities], BURI requires that each individual listed as key personnel complete Bastyr University's FCOI Project-Grant Certification form as part of the subcontract.

d) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Director of the Office of Research Integrity will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

3) REVIEW AND DECISIONS

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Conflict of Interest Committee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the committee will make a recommendation to the

Director of Research as to how to manage the financial conflict of interest, including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Conflict of Interest Committee determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of sponsored research. If a financial conflict of interest has been determined, the committee will notify the Director of Research, who will develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related sponsored research goes forward.

The Director of Research will periodically review the ongoing activity, monitor the conduct of the activity to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

4) CLINICAL TRIALS

Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial. In the event of non-compliance with reporting and/or management of a financial conflict of interest involving a sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, device or treatment as required by this policy, the investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected sponsored research and request an addendum to previously published presentations.

5) REPORTING TO AGENCY

The Director of Research will report financial conflicts of interest or non-compliance to the awarding agency according to PHS regulations for all awards, whether private or PHS-funded. Such reports shall be made to the agency or prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest.

6) INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Director of Research may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate is implemented.

A decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of Director of Research, will be described in a written explanation of the decision to the investigator, the Conflict of Interest Committee and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The institution will promptly notify the awarding agency of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

b) Retrospective Review

In addition, if the Director of the Office of Research Integrity determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Conflict of Interest Committee will complete a retrospective review of the Investigator's activities and the sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Director of Research will update any previously submitted report to the awarding agency or the prime awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the institution will promptly notify the Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

7) TRAINING

Each Investigator must complete training on this policy, the investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training in the event that this policy is substantively amended in a manner that affects the requirements of investigators, if the investigator is new to the institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

8) RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the awarding agency or to the prime awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

9) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the awarding agency, to HHS or to a requestor of information concerning financial conflict of interest related to funding or to the primary entity who made the funding available to the institution, if requested or required. If the institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the investigator will be informed of this disclosure.

10) PUBLIC ACCESSIBILITY

The Director of Research, or designee, will respond to any requestor within five business days of the written request, and provide information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior or key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation.

11) REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

For more information on the DHHS Conflict of Interest Policy:

NIH Policy: <http://grants.nih.gov/grants/policy/coi/index.htm>

Federal Registry: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

This policy was adapted from Federal Demonstration Project materials.