

CONFLICT OF INTEREST IN RESEARCH AND SCHOLARLY ACTIVITY POLICY

FOR COMPLIANCE WITH FEDERAL FINANCIAL DISCLOSURE POLICY

Under the Federal financial disclosure regulations, a conflict of interest exists *when it can be reasonably determined that an investigator's personal financial concerns could directly and significantly influence the design, conduct, or reporting of government funded research activities*. Faculty and staff of the University of Massachusetts Amherst (the University) have an obligation to maintain the objectivity of their research, avoiding any conflict of interest. This Conflict of Interest in Research and Scholarly Activity Policy has been developed by the University of Massachusetts Amherst and complies with specific federal agency requirements laid out in Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F, "Responsibilities of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought" which can be found at http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm. Every investigator participating in PHS or NSF funded research must comply with 42 CFR Part 50 Subpart F. When the University carries out PHS-funded research through subgrantees, contractors, or collaborators, the University will take reasonable steps to ensure that Investigators working for such entities comply with 42 CFR Part 50 Subpart F, either by requiring those Investigators to comply with the University's Policy or by requiring the entities to provide assurances to the University that will enable the University to comply with this subpart.

University employees are reminded that, in addition to the provisions of this policy, activities of University employees are subject to the requirements of the University of Massachusetts Policy on Conflicts of Interest Relating to Intellectual Property and Commercial Ventures which can be read at <http://www.umass.edu/research/ora/confl.html>

DEFINITIONS:

As used in this Policy:

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50 Subpart F.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this Policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative research agreement, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- (1) Salary, royalties, or other remuneration from the applicant institution;
- (2) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;
- (3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (4) Income from service on advisory committees or review panels for public or nonprofit entities;
- (5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
- (6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

Small Business Innovation Research (SBIR) Program is the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For the purposes of 42 CFR Part 50 Subpart F the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

PROCEDURES: Each investigator covered by this policy will annually report all "significant financial interests" held by themselves, their spouse and dependent children. Disclosures will be made by completing the **DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST FORM** at the end of this document, and sent to the Department Head/Chair, the Dean and the Vice Chancellor for Research and Engagement on an annual basis and when new significant financial interests are acquired. A disclosure

form must be completed prior to the submission of an application for PHS or NSF grant or cooperative research agreement.

Positive disclosures will be reviewed by the Department Head/Chair and Vice Chancellor for Research and Engagement (or designee). Ad hoc reviewers may be consulted on a case-by-case basis. In those cases where, in consultation with a faculty member involved, the Vice Chancellor for Research and Engagement (or designee) determines that a real or apparent conflict exists, one of the following actions will be taken: 1) Accept the sponsored project; 2) Not accept the sponsored project; 3) Accept the sponsored project subject to certain conditions, e.g.,

- (i) public disclosure of significant financial interests;
- (ii) monitoring of research by independent reviewers;
- (iii) modification of the research plan;
- (iv) disqualification from participation in all or a portion of the research funded by the PHS;
- (v) divestiture of significant financial interests; or
- (vi) severance of relationships that create actual or potential conflicts.

Appeal of the decision may be made to the Provost, who will consult with the Investigator and the review committee before making a final determination, within thirty days of the appeal, as to the action to be taken. In all cases, resolution of the actual or apparent conflict of interest will be achieved before the University implements a sponsored project.

Prior to the University's expenditure of any funds under the award, the University will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced or eliminated in accordance with CFR 42 Part 50, Subpart F. For any interest that the University identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

The Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias.

COMPLIANCE: Failure to comply with the above Policy will subject the Investigator to the University's Scholarly Misconduct Policy which can be read at <http://www.umass.edu/research/ora/misconduct.html> . University employees are reminded that if the failure of an Investigator to comply with the conflict of interest policy of the University has biased the design, conduct, or reporting of the PHS-funded research, the University will promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the University

for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by 42 CFR Part 50 Subpart F the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

RECORDS: The University will maintain the Disclosure Form and other records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations. Records will be maintained in the Office of the Vice Chancellor for Research and Engagement. All disclosures and related documentation are considered confidential, and only those persons involved in the implementation of this policy will have access to such records.

NOTIFICATION TO FEDERAL AGENCIES: As required by PHS, the University will report the existence of a conflict of interest, and its resolution, to the PHS awarding component. As required by NSF, the University will report the existence of a conflict of interest which is unable to be resolved within the University to the NSF Office of the General Counsel.

DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST

FOR INVESTIGATORS SUBMITTING APPLICATIONS TO NATIONAL INSTITUTES OF HEALTH AND NATIONAL SCIENCE FOUNDATION

The following disclosure is made pursuant to the requirements of the PHS rules "Objectivity in Research" (42 CFR Part 50 Subpart F) and NSF rule "The Federal Financial Disclosure Policy". This disclosure must be updated annually, and whenever new reportable significant financial interests are acquired. University employees are reminded that, in addition to the provisions of this policy, they are subject to the requirements of the University of Massachusetts Policy on Conflicts of Interest Relating to Intellectual Property and Commercial Ventures which can be read at <http://www.umass.edu/research/ora/confl.html> As state employees, other activities are subject to the relevant provisions of Chapter 268A of Massachusetts General Laws, including its prohibition against any financial interest (unless such interest is less than one percent of the stock of a corporation), directly or indirectly, in a contract made by a state agency, in which the Commonwealth or the University is an interested party.

DEFINITIONS:

Significant Financial Interest - Anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights), which would reasonably appear to be affected by the research to be funded. This definition specifically excludes financial interests in business enterprises or entities if the value of such interests, when aggregated for the investigator and the investigator's spouse and dependent children, does not exceed ten thousand dollars per annum in salary, fees or other continuing payments; or ten thousand dollars fair market value equity interests (and no more than five percent ownership interest).

Investigator - The Principal Investigator and any other person at the University who is responsible for the design, conduct, or reporting of research educational or service activities funded, or proposed for funding, by the PHS or NSF. Typically this will include the Principal Investigator and co-investigators. For the purposes of this disclosure requirement, the term "investigator" includes the investigator's spouse and dependent children.

***Disclosure: Investigator Name:** _____ **Dept.:** _____

Remuneration: _____ **Source:** _____

Type of Organization (e.g., pharmaceutical firm; biotech firm; engineering company; software company, etc.) _____

Nature of Remuneration that is greater than \$10,000:

Salary _____ **Royalties** _____

Licensing _____ **Consulting** _____

Honoraria _____ **Other** _____

Types of holdings whose fair market value is greater than \$10,000 (and no more than a five percent ownership interest):

Stocks/Stock Options \$ _____ % ownership

Patents/Copyrights _____

Other _____

Investigator's Signature: _____

Date: _____

*Please note that a separate form is required for each enterprise or entity in which a significant financial interest is identified.

Updated 8/20/2009