

## PHS/NIH & Any Sponsors that have Adopted PHS Regulations Proposal Conflict of Interest Information

This form is required to be filed for every NIH/PHS proposal and should accompany the Proposal Routing Form (PRF). It is required for all Investigators and any other person who is responsible for the design, conduct, or reporting of the research. If an Investigator has a reportable financial interest, it must be disclosed to SPA when the Investigator submits the relevant grant proposal and whenever a reportable financial interest arises during the period of an award. Please complete the applicable section below and return to SPA.

1. **This form is required for proposals to the following sponsors:** Office of Global Affairs (OG); Office of the Assistant Secretary for Health (OASH); Office of the Assistant Secretary for Preparedness and Response (ASPR); Agency for Health Care Research & Quality (AHRQ); Agency for Toxic Substances and Disease Registry (ATSDR); Centers for Disease Control and Prevention (CDC); Food and Drug Administration (FDA); Health Resources and Services Administration (HRSA); Indian Health Service (IHS); National Institutes of Health (NIH); Substance Abuse and Mental Health Services Administration (SAMHSA); Alliance for Lupus Research (ALR); American Asthma Foundation; American Cancer Society (ACS); American Heart Association (AHA); American Lung Association (ALA); Arthritis Foundation (AF); CurePSP; Juvenile Diabetes Research Foundation (JDRF); Lupus Foundation of America (LFA); Patient-Centered Outcomes Research Institute (PCORI); Susan G. Komen for the Cure
2. The Principal Investigator (PI) and each Investigator must sign the Disclosure Summary at the point of each proposal submission & confirm no change in status at the point of each award. Awards will not be processed by the Sponsored Programs office until the Investigators have reaffirmed their disclosure status.
3. Investigators having a Significant Financial Interest that is reasonably related to the Investigators' Institutional Responsibilities must also complete the Disclosure of Financial Interest Form. Allow sufficient time for the Office of Institutional Compliance & Ethics to complete a review, and, if necessary, make a recommendation to the Vice Provost for Research prior to award acceptance.
4. Submission of this form is also required on an annual basis for non-competing continuation awards, when a new Investigator is added to a project, or when an Investigator's financial interests increase, whichever comes first.
5. Any project that involves human subjects research is subject to the requirements of the University of Massachusetts Guidelines for the Oversight of Individual and Institutional Financial Interests in Human Subjects Research ("Human Subjects Guidelines"). Any amount of remuneration or any equity ownership related to a human subjects study requires additional reviews and oversight. See <http://www.massachusetts.edu/policy/academic.html>

**Who Must Disclose?** All individuals responsible for the design, conduct, or reporting of the results of work performed or to be performed under the sponsored project, referred to as "**Investigator.**" Investigator includes, but is not limited to the Principal Investigator, Co-Investigators, and any other individuals (including personnel from other institutions) who are involved in accomplishing project objectives. It may include students, graduate and undergraduate, and other personnel who may be listed as authors on project results, even if they are not paid from the project.

**What is a "Significant Financial Interest"?** Any of the following payments:

1. With regards to **Publicly-Traded Entities**, payments or value exceeding \$5,000 when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children from a single entity, including salary, consultant payments, honoraria, paid authorship, equity interest (stock, stock option or other ownership interest) during the prior 12 months.
2. With regards to **Privately Held Entities**, payments or value exceeding \$5,000 when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children from a single entity during the prior 12 months or when the Investigator and the investigator's spouse/domestic partner and dependent children hold **any** equity interest (stock, stock option, or other ownership interest).
3. With regards to **Intellectual Property**, intellectual property rights and interests (patents, copyrights) **upon receipt of income** related to such rights and interests.
4. With regards to **Travel Reimbursements**, any reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities during the prior 12 months (with the exception of 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).

The term "Significant Financial Interest" **does not include:** salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed, including intellectual property rights assigned to the Institution and agreements to share royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts; 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 affiliated with an institution of higher education; or income from 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 affiliated with an institution of higher education.

**What are “Institutional Responsibilities”?** An Investigator’s Institutional Responsibilities means the Investigator’s professional responsibilities on behalf of the Institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

### **Review Process and Guidelines**

The Director of SPA will review the Investigator’s Summary Disclosure Form to ensure completeness and consistency with prior disclosures. Investigator’s Summary Disclosure Form disclosing Significant Financial Interests that reasonably appear to be related to the Investigator’s Institutional Responsibilities and any supporting documentation (disclosure of financial interest form) shall be forwarded to the Director of the Office of Institutional Compliance & Ethics. The Director will consider whether any of the disclosed Significant Financial Interests of the Investigator is related to the project and whether the financial interest could directly and significantly affect the design, conduct, or reporting of the project.

For example, a direct affect would occur when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the entity in which the Investigator has a Significant Financial Interest, or when the entity is a proposed subcontractor or participant in the project. A significant affect on the financial interest is one that will materially affect the value of the entity, its earnings, or sales of its products. The following are examples of when an Investigator would be deemed to have a financial conflict of interest (FCOI): (i) if the Investigator (together with Investigator’s spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that could be affected by the research results from a proposed PHS-funded contract based on an analysis of the scope and subject matter of the proposed project described in the application, or (ii) the Investigator (together with Investigator’s spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that licenses technology from the University which has resulted in license income and that technology is the subject of a proposed PHS-funded award. In making this determination, the designated institutional official(s) may consult with all appropriate institutional and governmental officials.

The Director will review the information and make a recommendation to the Vice Provost for Research, who is the responsible institutional official for UMass Dartmouth. Disclosures of Significant Financial Interests of amounts in excess of \$10,000 shall be submitted to the University Conflicts Committee, with a recommendation from the Vice Provost for Research for review and approval.

**PHS/NIH & Any Sponsors\* that Have Adopted PHS Regulations Proposal Summary Disclosure Form**

**THIS SECTION IS REQUIRED**

PI Name :	Project Title:
	Project Start and End Dates:
Department:	Award No. (If Continuation Proposal):
	Sponsor:
Contact Phone:	If UMass-D is Subcontractor, Name of Prime Sponsor:
	Is there a Subcontract on Proposal: ( )Yes or ( )No
E-mail:	Name of Subcontractor:

**I. To be Completed by the Principal Investigator:**

The lead Principal Investigator on a proposed PHS application for funding is responsible for obtaining this disclosure form for all participating Investigators. The PI certifies that this form provides (1) a complete disclosure of all the investigators responsible for the design, conduct, or reporting of activities associated with this project, and (2) an accurate report of whether or not there are any Significant Financial Interests related to the Investigators Institutional Responsibilities. The PI agrees to update this form as needed during the project award period.

II. Do you, your spouse/domestic partner or dependent children have any Significant financial interests related to the investigator's institutional responsibilities? **Yes No**

III. Do you, your spouse/domestic partner or dependent children have any Travel related Significant Financial Interests to disclose? **Yes No**

I<sub>5</sub>. Will Non-University Investigators be responsible, with the PI or Additional University Investigators, for the design, conduct, or reporting of the activities associated with the project (e.g., subcontractors, consultants, others with significant responsibilities)? **Yes No**

IF THE ANSWER TO ANY OF THE ABOVE QUESTIONS IS "YES" THEN PLEASE SUBMIT A DISCLOSURE OF FINANCIAL INTERESTS FORM TO SPA.

**II. NON-UNIVERSITY INVESTIGATORS: (to be completed if corresponding question in section I is checked "yes.")**

The University must be assured that the Investigator's home institution has policies that comply with the funding agency's regulations. Such assurance should be provided along with the non-university investigators letter of commitment to the project.

1. Name: \_\_\_\_\_ Affiliation: \_\_\_\_\_
2. Name: \_\_\_\_\_ Affiliation: \_\_\_\_\_
3. Name: \_\_\_\_\_ Affiliation: \_\_\_\_\_
4. Name: \_\_\_\_\_ Affiliation: \_\_\_\_\_

### III. To be Completed by Additional University Investigator(s):

By signing below, each University CO-Investigator on this project certifies (1) that this form provides an accurate report of whether or not there are any Significant Financial Interests related to the their Institutional Responsibilities and (2) acknowledges their responsibility to provide a complete disclosure of all Significant Financial Interests reasonably related to their Institutional Responsibilities prior to award receipt, as those interests change, and on an annual basis during the project award period. Please submit a disclosure for each additional university investigator on this project.

Additional University Investigator #1:

- Do you, your spouse/domestic partner or dependent children have any Significant Financial Interests related to the Investigator's Institutional Responsibilities? **Yes** **No**

\_\_\_\_\_  
SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PRINT NAME

\_\_\_\_\_  
TITLE

IF THE ANSWER TO ABOVE QUESTION IS "YES" THEN PLEASE SUBMIT A DISCLOSURE OF FINANCIAL INTERESTS FORM TO SPA.

Additional University Investigator #2:

- Do you, your spouse/domestic partner or dependent children have any Significant Financial Interests related to the Investigator's Institutional Responsibilities? **Yes** **No**

\_\_\_\_\_  
SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PRINT NAME

\_\_\_\_\_  
TITLE

IF THE ANSWER TO ABOVE QUESTION IS "YES" THEN PLEASE SUBMIT A DISCLOSURE OF FINANCIAL INTERESTS FORM TO SPA.

Additional University Investigator #3:

- Do you, your spouse/domestic partner or dependent children have any Significant Financial Interests related to the Investigator's Institutional Responsibilities? **Yes** **No**

\_\_\_\_\_  
SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PRINT NAME

\_\_\_\_\_  
TITLE

IF THE ANSWER TO ABOVE QUESTION IS "YES" THEN PLEASE SUBMIT A DISCLOSURE OF FINANCIAL INTERESTS FORM TO SPA.

### SECTION IV - PRINCIPAL INVESTIGATOR CERTIFICATION:

*To the best of my knowledge, I certify that the information provided above is accurate. I certify that this form provides (1) a complete and accurate disclosure of all Investigators responsible for the design, conduct, or reporting of activities associated with this project; (2) any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and (3) I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports or updates if a grant is awarded as a result of the application.*

Principal Investigator Signature: \_\_\_\_\_

Date: \_\_\_\_\_