

Responsible Office: Office of the Vice Provost for Research

Effective Date: April 1, 2013 Revision Date: June 1, 2018

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Collaborations: Guidance on Conflict Management Considerations

Reason for Guidance

Harvard University collaborates extensively as a subcontractor with small businesses receiving funding under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) federal programs. The SBIR/STTR program's stated purpose is to strengthen the role of innovative small business concerns in federally-funded research and development. SBIR/STTR awards are limited to U.S.-based, for-profit small businesses. Small businesses receiving STTR funding are required to subcontract a minimum of 30% of funding to a non-profit research institution. Small businesses receiving SBIR funding are not required, but often choose, to collaborate with universities and other non-profit research institutions.

Participation in these programs involving University faculty and small businesses can create a conflict of interest on the part of the faculty member, particularly if that faculty member, spouse, or dependent children is a cofounder and/or has an equity interest with the small business. The following guidelines may assist faculty in their consideration of entering into such relationships in order to ensure compliance with all federal regulations and University policies concerning conflicts of interest.

Who Must Comply

This guidance is applicable to faculty and *investigators* at the University who participate in an SBIR or STTR collaboration in which they have a *significant financial interest*, such as serving as a co-founder or having an equity interest in the small business collaborator. Each of the <u>School's Conflict of Interest Officer</u> shall manage conflict in accordance with the School's policies and procedures.

Roles and Responsibilities

Principal Investigators (PIs) are responsible for submitting their annual financial interest report in accordance with their School's policies and procedures. In addition, faculty and *investigators* should seek advice from their School's Conflict of Interest Officer to discuss any potential conflict of interest concern. Faculty and *investigators* should consult with the Office of Technology Development regarding any potential licensing or intellectual property concerns.

Designated Institutional Official – The appropriate <u>School's Conflict of Interest Officer</u> will manage the conflict of interest in accordance with the respective School policy and procedure.

Procedures

SBIR / STTR Proposal Process

When Harvard is anticipating serving as a subrecipient to a small business receiving SBIR or STTR funding, the Principal Investigator or the department/local level managing unit should provide the sponsored office (Office for Sponsored Programs/Sponsored Projects Administration/Office of Research Administration): (1) a copy of the solicitation, (2) the complete proposal and budget for the Harvard scope of work, and (3) the full proposal submitted by the small business to the prime sponsor. These documents should, to the extent possible, be submitted along with documentation from the small business that it has a primary operating space outside of Harvard University.

Financial Interest Reporting Requirement

In accordance with the <u>University Policy on Individual Financial Conflicts of Interest for Persons Holding a Faculty and Teaching Appointments</u>, all holders of faculty or teaching appointments and any *investigator* applying for or receiving funding from the U.S. Public Health Service (PHS) (including the National Institutes of Health and the Centers for Disease Control and Prevention), sponsors adopting the PHS regulations, or the National Science Foundation (NSF) must submit an internal, confidential report of their and their family members' *significant financial interests* in the preceding twelve months in any related outside entity.¹

Management of Identified Conflicts of Interest

A *financial conflict of interest* may result when the report includes a financial interest in a small business which receives SBIR or STTR funding, and the small business would like to issue a subcontract to the University. The conflict of interest must be managed by the <u>School's Conflict of Interest Officer</u> in accordance with the School's policies and procedures prior to the award initiation. Conflict management plans may include, but is not limited to, the following requirements:

- <u>Elimination of conflicting role:</u> The *investigator* may be requested to forgo any fiduciary role with the small business while the proposed research is active. Alternatively, the *investigator* may be requested to assign an alternate faculty member to serve as the principal investigator for the University research.
- <u>Clear delineation of roles:</u> The proposal must clearly delineate the roles of each scientist under the grant. No
 individual shall have a scientific role simultaneously in both the small business research and the University
 research. In addition, small business research must occur using the small business facilities and personnel
 rather than University facilities and personnel. University research may utilize University facilities and
 personnel.
- Outside oversight of science: A University faculty member who does not have a *significant financial interest* in the small business should be appointed to act as a scientific arbitrator of conflict of interest related concerns for the project. The arbitrator should serve as a contact for the University personnel and a reviewer of draft manuscripts, presentations, and completed data for possible bias.
- <u>Increased reporting:</u> In addition to clearly delineating roles in the proposal, more frequent reporting or meetings at the School level may be required.
- <u>Public disclosure:</u> Written disclosure of a financial interest in the small business shall be required to collaborators and mentees and in publications or other public presentations of research results.

¹ School policies and implementation plans may require the disclosure of certain significant non-financial outside interests.

Definitions

Financial conflict of interest (FCOI) - a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research

Investigator - the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research

Significant Financial Interest - includes, but is not limited to, (1) financial compensation, including travel, from consulting, employment, managerial, and fiduciary relationships that, when aggregated over the preceding twelve months, exceed \$5,000; (2) equity and other financial interests above \$5,000; (3) equity interests of any amount, or entitlement to the same, in a non-publicly traded, for-profit, entity; and (4) intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests. "Financial compensation" does not include, for example, interests of any amount in diversified financial holdings, or royalties or other remuneration paid by the University.²

Related Policies and Guidance

Harvard University Policy on Individual Financial Conflicts of Interest for Persons Holding Faculty and Teaching Appointments

SBIR/STTR General Program Information

SBIR/STTR Program Solicitations

Revision History

April 2013

New guidance released

June 2018

- Moved responsibility from Office for Sponsored Programs to Office of the Vice Provost for Research
- Added new procedure "SBIR/STTR Proposal Process"
- Transferred into new guidance template format

² School policies may use a different definition of "significant financial interest".