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Guidelines for Consideration When Determining Whether to Approve Funding or a Gift into an Investigator's Lab from a Private Company in Which the Investigator Owns Equity Interest

Princeton University is a leading academic research institution that welcomes interest in our discoveries from entrepreneurs, industry and potential collaborators. We encourage the creative and innovative process through a number of programs including the provision of incubators, accelerators, start-up support and entrepreneurial education. Funding for such interests, especially during initiation, is often challenging. While encouraging innovation, Princeton must also maintain its status as a premier research and education institution.

During initiation, funding may come from many possible sources, including industry, venture capital, private foundations and even the government. When funding comes from private sources in which owners or investors may have personal or vested interests in the research outcome, potential conflicts of interest exist.

This document establishes guidelines for Dean of the Faculty (DOF) appointees (Faculty, Academic Professionals and Professional Librarians) who would like to receive research funds or gifts into their Princeton University laboratory, office, or department from a privately held company in which they also own equity interest. Any equity ownership interest in a privately-owned company is deemed significant and should be disclosed as a significant financial interest (SFI) either on the annual disclosure form in *Part G: Significant Financial Interests Relating to Your Institutional Responsibilities* if it is related to the investigator's institutional responsibilities of research, teaching and/or service, or on the Conflict of Interest (COI) update form. Requests to receive funding or gifts from such entities must be approved by the Dean for Research (DFR) or the Conflict of Interest in Research Panel (Panel) prior to accepting those funds/gifts.

History:

Historically, Princeton University supported a 5% practice for requests to fund research, either via a sponsored contract or a gift, into a person's University laboratory. Such funding requests would typically be initiated either through the Office of Research and Project Administration (ORPA), in the case of a funded award or contract, or through Corporate Engagement and Foundation Relations (CEFR), in the case of a gift. Under this paradigm, in general, if a person owned greater than 5% equity in a company, they were not allowed to fund research into their lab from that company. The new guidelines will replace the 5% practice funding paradigm. The new guidelines are not intended to be a scoresheet: each case will be considered on its own merits and the decision to allow funding (or not) will be based upon the totality of the circumstances, which will include background information on the company, the research, and the investigator's current source(s) of funding.

Regulatory Background:

Federal COI regulations and Princeton COI policy are designed to ensure research integrity by assuring that outside influences do not affect the design, conduct or reporting of research or interfere with one's institutional responsibilities. To avoid undue influence, federal regulations and University policy require DOF appointees to disclose SFIs and/or potential conflicts of interest. Princeton University must identify and manage any relationship that may affect an appointees' abilities to perform their institutional responsibilities, which include their ability to perform teaching, research, or service. In addition, the research must not be overly influenced by external factors (obligations, financial interests, etc.) that could impact the design, conduct or reporting of funded research or teaching activities.

Princeton University follows the Public Health Service (PHS) Federal Regulation 42 CFR Part 50, Subpart F*, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" to define thresholds used to identify an SFI in cases where such interests relate to an individual's institutional responsibilities.

Princeton University's Rules and Procedures of the Faculty state: *"The risk of conflict of interest, or serious appearance of conflict, can arise when a University investigator (or his/her spouse or* *dependent children) has an SFI in an external enterprise engaged in activities closely related to the investigator's line of University research. It is the policy of the University to require faculty to complete an annual disclosure form designed to identify any potential conflicts of interest arising from SFIs so that they may be appropriately managed.*"**

Although the University supports and helps to manage potential conflicts, the Rules and Procedures (Chapter V, Part I – *Conflicts of Interest in Research*** and the Policy Library (*Conflict of Interest in Sponsored Research****) clearly state the following:

"Outside professional, financial and entrepreneurial activities of individual faculty and staff can contribute to University goals and provide valuable public and personal benefits as well. Primary commitment must however be devoted to the University. External interests and activities have to be ordered so as to minimize any risk of conflict with University objectives and values. "

"Faculty and staff must at all times scrupulously avoid providing research guidance and facilities to students with the dominant aim of serving their own outside professional, financial and/or entrepreneurial activities and objectives."

"An individual should not undertake or orient any research within the University with the purpose of serving the needs or interests of an external individual or organization, except in connection with projects financed by the same individual or organization and approved by the University."

For more in depth background and other policy or regulatory information please see either the COIR Panel Charter or the University COI Policy and Research Integrity and Assurance (RIA) COI Guidelines. Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) are programs that encourage domestic small businesses to engage in Federal Research/Research and Development (R/R&D) that has the potential for commercialization. Through a competitive awards-based programs, SBIR and STTR enable small businesses to explore their technological potential and provides the incentive to profit from its commercialization. By including qualified small businesses in the nation's R&D arena, high-tech innovation is stimulated and the United States gains entrepreneurial spirit as it meets its specific research and development needs. At this time, both Phase I SBIR and STTR awards are not subject to financial conflict of interest regulations.

Basic Principles:

Members of the University who own equity interest in a company and would like to receive research funding or a gift from the same entity must take care that the agreements that define these activities are not in conflict with the provisions of Princeton's Patent Policy****, its obligations under any sponsored grant or contract, or any other policies of the University. Financial gain must be incidental to the research and the prospect of such gain cannot be allowed to govern the selection and conduct of research projects.

When a DOF appointee has equity interest and is being funded by the same entity, they may not use University resources or personnel, including students, academic professionals, facilities and/or equipment for company-related activities, except for the research collaboration that is being funded by the entity. In conducting research funded by an entity for whom the DOF appointee also has equity interest, the same rules concerning the use of University resources apply as they would for any other research activity. In particular, inappropriate use of University resources includes the following:

- A DOF appointee assigning tasks to students, staff, or postdoctoral scholars for purposes of potential or real financial gain to the faculty member and/or his or her spouse or dependent children rather than the advancement of the scholarly field or the students' educational needs.
- Involvement of the DOF appointee's students or staff in his or her outside company or business activities without prior review and approval by the Department Chair and the DOF.
- Granting the external entities with whom the DOF appointee has equity interest and receives funding or gifts access to Princeton University resources, personnel or services for purposes outside the University's missions.

Guidelines Affecting Determination:

The determination as to whether Princeton University will accept research funding or a gift into a researcher's lab from a company in which the researcher has an equity interest will be based upon the following guidance:

1. The justification for the request for research funding from the company in which the DOF appointee has equity interest.
2. The proposed research should satisfy minimum scholarly standards (i.e. be publishable in a peer reviewed journal) and there should be no restrictions on publication. Reasonable restrictions may be imposed by a company to delay publications for 60 to 90 days in order to allow for IP documentation.

3. The proposed funding should not support contract research (i.e. research with strict pre-determined deliverables).
4. The potential for the significant financial interest (SFI, in this case equity interest) to constitute a Financial Conflict of Interest (FCOI). In general, clear separation between any federally-funded research and the company's platform will be a favorable factor when considering whether to approve funds/gifts.
5. The proposed funding should not be a significant fraction of the PI's annual sponsored research expenditures. Although a strict numerical criterion is arbitrary, a reasonable guideline is that if the proposed funding exceeds 30% of the researcher's overall sponsored research funding, this may be viewed as inconsistent with an otherwise active lab that is pursuing and being awarded other extramural funding awards and contracts.
6. The percent equity interest that the investigator owns in the company should be considered in light of the value of the company. In general, investigators that own less than 30% of a company will be considered more favorably than those for whom the equity owned establishes controlling interest of a company.
7. The amount of the requested gift or fund and the likelihood that additional funds or gifts will be requested in the future. An exception to this would be an SBIR or STTR award.
8. The number and degree of competing conflicts of commitment between the outside entity and the PI's institutional responsibilities/commitments.
9. The extent that 3rd parties, who may provide the funding, may also be involved in the entity's leadership, structure or organization, either directly or through relationship or nepotism. This consideration is designed to prevent pass-through or 3rd party funding opportunities in which individuals directly or peripherally involved with the startup company may have additional equity or financial interests in entities associated with the new company, resulting in a financial benefit to the individual (3rd party) if such funding or gifting is allowed.
10. The extent and degree of additional connections between the PI and the company that would provide the funding. Examples of other connections (besides ownership interest) that may exist include, but are not limited to, Material Transfer Agreements, consulting arrangements, service on scientific advisory boards, paid honoraria, visitors from the entity and/or potential use of Princeton University personnel, space or equipment. In general, the fewer interconnections, the more likely the funding may be approved.
11. The extent and degree of additional disclosed SFIs involving other companies that either fund the PI's lab or involve payment for other services, for example through board membership or consulting. In general, these funding requests should be limited to no more than 2 per year at the same time without a written approval from the DFR or DOF. In the case of multiple SFIs there could be a potential conflict of commitment that needs to be addressed.

Special considerations for new start-up companies when determining whether to approve funding or a gift into an investigator's lab:

Special consideration may be granted to PIs with new start-up companies, so called shell companies that are in the very early stages of developing strategies to obtain outside funding through grants, gifts, or other investors. Such consideration will be granted to labs still performing basic, fundamental or proof-of-concept research to support their start-up. Typically, such start-ups have a limited number of partners, are within the first year or two of creation and may not have physical space to perform independent research.

References:

*Public Health Service Federal Regulation 42 CFR Part 50, Subpart F, Page 11, "Promoting Objectivity in Research"

**Rules and Procedures of the Faculty, Chapter 5, Part I – Conflicts of Interest in Research

*** Conflict of Interest in Sponsored Research Policy

**** Princeton University Patent Policy