

**THE JOHNS HOPKINS
BLOOMBERG SCHOOL OF PUBLIC HEALTH**

OFFICE OF THE DEAN

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POLICY AND PROCEDURE MEMORANDUM FACULTY – 4

SUBJECT: Conflicts of Interest and Commitment

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I. Introduction

Appointment to the faculty of The Johns Hopkins Bloomberg School of Public Health signifies recognition of the individual’s achievements and excellence in academic areas of research, teaching and service. To those appointed to its faculty, the School endeavors to provide an environment that will serve to enhance and further academic careers and accomplishments. The acceptance of a full-time faculty appointment connotes the individual’s willingness to commit to the School his or her primary professional efforts in research, teaching and service. In this regard, the individual agrees to give highest priority to meeting the academic and professional objectives of the School over external interests and goals.

Academic and professional activities may be classified into two broad categories: those that are internal and those that are external to the University. Internal professional activities include all those covered by sponsored projects (i.e., grants and contracts) administered by the University and activities supported by University such as teaching, scholarship, professional practice and other service conducted as a University employee. Outside (i.e., external) activities are those not meeting the above criteria and would include, for example, serving as a consultant for remuneration, being a member of a board or advisory committee whether compensated or not, possessing an ownership interest in a private business, or assuming significant academic activities at another institution. Faculty members should be discriminating in the selection of

outside activities in order to avoid impairing the University's reputation and that of its faculty and should avoid activities that could be perceived as compromising their basic scholarly independence.

University policies require that faculty report external activities, including those activities that potentially pose either or both a conflict of interest or a conflict of commitment. **Conflicts of Interest** occur when a faculty member's obligations to the University could be compromised by his or her external activities. For example, a common conflict of interest arises when a faculty member conducts research that is sponsored by, or involves a product of, an entity with which the faculty member has an external relationship. **Conflicts of Commitment** occur when faculty members' time and attention devoted to external activities interferes with their ability to fulfill their obligations to the School, including teaching, research, and administrative duties. The School has a standing committee, the Conflict of Interest Committee, which reviews and manages conflicts.

II. Applicability

This PPM applies to all full-time faculty and salaried part-time faculty. The University's revised Policy on Financial Interests and Financial Conflict of Interest in Research:

http://web.jhu.edu/conflict_of_interest/overview_of_policies was adopted by the Board of Trustees and became effective on August 24, 2012. That policy allows each division to implement an individual policy within the parameters established by the University policy.

III. Conflict of Commitment

Outside activities that provide for development and maintenance of professional skills, facilitate the transfer of basic knowledge, and contribute to the richness of the academic experience are expected and encouraged aspects of the faculty role. However, excessive levels of these activities can interfere with the amount of time an individual has to commit to their role as a faculty member at the School. Faculty are responsible for seeking advice from their department chair prior to engaging in any activities that could conflict with the amount of time they have available to devote to research, teaching and service responsibilities to the department and School. In particular, faculty should seek approval from department chairs if their external activities exceed 24 days per year or if external teaching activities total more than 5 days per year.

IV. Conflict of Interest

A financial conflict of interest (FCOI) exists when a faculty member's judgment or research may be construed as being biased as the result of financial or fiduciary arrangements made with an entity outside of the University. The conflict may be either real or perceived. Either way, such conflicts or potential conflicts can adversely affect confidence in an investigator's research or other activities. As a result, all outside activities must be reported to the School as they arise or within 30 days using the University's online reporting system, *eDisclose*: <http://edisclose.jhu.edu> even though the majority of these outside activities are not FCOIs. It is important to disclose all

outside activities in a timely manner because late (i.e., ≥ 30 days) disclosure of an activity that is subsequently determined to be an FCOI may lead to serious consequences, particularly when related to a faculty member's research. There is no "de minimus" level below which a financial interest is exempt from reporting and outside activities do not need to be financially compensated to be reported. Disclosures should be updated when there is a change to the activity or relationship. In addition to making transactional disclosures as they arise, faculty members must provide an annual certification that confirms the disclosures in their *eDisclose* portfolio are accurate and current and that they have nothing to add or update, or that they have no outside activities or financial interests that must be disclosed.

The following activities must be disclosed:

- Consulting for industry or other for profit entity whether paid or unpaid. For additional information, see PPM Faculty – 10, Policy on Interaction with Industry and Outside Interests
- Speaking, lecturing, teaching and service on advisory committees or review panels at outside institutions except when provided to a U.S. state, federal or local government agency, teaching hospital, medical center or institution of higher education or related research institute.
- Holding a fiduciary role with an organization such as founder, officer, manager or the board of directors.
- Involving a faculty member's spouse, child or other family member in sponsored projects, either directly or through a subcontract.
- Publishing, editing or authoring activities that are compensated.
- Participating in clinical care or practice that is not included in a faculty member's institutional responsibilities or appointment.
- Owning equity interest in any firm that supports or has been asked to support, or may directly benefit from faculty scholarship, practice, teaching or service. This includes participation in a Small Business Innovation Research [SBIR] or Small Business Technology Transfer [STTR] grant.
- Owning any equity interest in, or receipt of income from, licensing royalties or entitlement to equity and/or royalties from any firm that is developing or marketing commercial products based on faculty scholarship, practice, teaching or service.
- In addition, faculty members must disclose all travel expenses that are paid either directly to them or on their behalf if they reach or exceed \$5,000 from a single entity within a 12 month period.

Additional details on how, when and what to report are contained in *The Handbook on Reporting Conflict of Interest and Commitment*: <https://my.jhsph.edu/FacultyDocuments/COI%20Handbook.pdf>

Other Situations that Require Disclosure

Other types of activities may be less common but also present either a conflict of interest, conflict of commitment, or other conflict with University policy and must be disclosed in advance. The following list provides examples of circumstances that should either be disclosed or avoided.

1. A proposed arrangement involves or commits the use of facilities or resources belonging to The Johns Hopkins University.

Under normal circumstances, adequate disclosure can be made by following the standard procedure of grant or contract proposal review in the faculty member's department and by the Office of Research Administration prior to obtaining final institutional signature. However, in some cases, additional information may be necessary if, for example, the University will be investing its resources and sharing in the risks of a venture. The University's policies on technology transfer, copyrights and inventions are stated in the JHU Intellectual Property Policy which was revised and adopted by the Board of Trustees on October 5, 2011: http://jhuresearch.jhu.edu/JHU_Intellectual_Property_Policy.pdf

2. An outside arrangement provides for transfer of intellectual or tangible property rights including patent ownership or licensing to an organization other than the University or the organization has requested use of intellectual property (e.g., inventions, know-how), tangible property (e.g., research materials), or other products (e.g., computer software) of a faculty member's scholarly work. The University's Intellectual Property Policy describes fully the University's position on these matters.
3. An outside arrangement for a professional activity or research is being considered that would restrict the faculty member's public disclosure of the existence of the arrangement.

It is the University's policy that a faculty member must not undertake any activity in which the sponsor requires confidentiality of sponsorship.

4. An outside arrangement would restrict the faculty member's public disclosure of information developed by the faculty member.

The faculty member must ascertain whether an outside agreement establishes requirements for confidentiality that might compromise his or her own fundamental rights of academic freedom or those of other faculty members or students. Academic freedom means, in part, unhindered discussion and publication of results of research.

5. A faculty member's relationship to an entity might appear to influence either the conduct of the University's business or the conduct of research within the University. This includes circumstances in which the faculty member directly or indirectly profits from the selection of a University supplier or contractor because the faculty member has a position or serves as a paid consultant with the company or has either equity interest or receives direct compensation.

6. An outside entity provides, or plans to provide, financial or material support for a faculty member's research and that faculty member has a financial or fiduciary interest with that outside entity.

When a faculty member has a financial or fiduciary interest in an entity that also provides research funding or material support for research (e.g., reagents, pharmaceuticals) it can create a perception that the implementation or interpretation of research may be biased in favor of the outside entity. Disclosure of this relationship will result in a management plan that is in everyone's best interest, including that of the faculty member.

7. An outside entity requests or plans to use the name of The Johns Hopkins University or any of its schools or divisions.

An academic relationship can be of great value to a non-academic organization. While there is no way to separate a faculty member completely from his or her association with the University, there is a distinction as to whether a faculty member is acting within their institutional role within the University or not. Any written agreement with a faculty member directly or indirectly providing an external organization with an opportunity to use the name of The Johns Hopkins University (or any derivative such as "Johns Hopkins" or "JHU"), or any of its schools or divisions, must be approved by appropriate University and School authorities.

V. Conflicts of Interest in Human Subjects Research

Potential conflicts of interest in human subjects research deserve special consideration because of their potential to adversely affect the rights and welfare of research participants. Faculty members are required to report any potential conflicts of interest on their applications to the JHSPH Institutional Review Board (IRB) which are, in turn, referred to the Conflict of Interest Committee (see section IX, below) for review.

The Conflict of Interest Committee will review the information and determine whether a management plan is necessary. The Committee will provide its determination to the IRB. The IRB can then: (1) accept the determination and associated management plan if there is one; (2) accept the plan but impose additional conditions (e.g., the faculty member may be prohibited from participating in recruitment or consent processes); or conclude, in rare instances, that the conflict is so potentially detrimental that human subjects research cannot proceed.

VI. Annual Certification

Faculty members are required to certify, on an annual basis, that the disclosures in their *eDisclose* portfolio for the prior year are correct, current and reflect their full range of outside interests. Faculty will be notified of the annual certification process each year by email.

VII. Conflict of Interest and Commitment Training

In accordance with federal regulation, all faculty members are required to complete Conflict of Interest training every four years and whenever the institution's policy changes. The course for all Johns Hopkins University faculty members can be accessed at:

<http://lms4.learnshare.com/l.aspx?CID=89&A=2&T=412863>

VIII. Conflict of Interest Review and Management

The Conflict of Interest Committee (COIC) is a standing committee comprised of faculty members and other representatives of the School and University. The Committee reviews disclosures of external activities that pose potential conflicts, determines whether a potential conflict of interest exists and imposes a management plan if necessary.

Faculty disclosures are treated as confidential material and available only to the COI staff, the Associate Dean for Research and the Associate Dean for Research Administration. Disclosures that require COIC review are provided to committee members. Should significant FCOI issues arise, information about the conflict will be provided to the department chair, and at times, the Dean. The Committee informs the faculty member of the conditions required to manage the conflict in writing. Management conditions can range from requiring disclosure of the relationship with an external entity to appointing an independent oversight committee for the study to requiring the faculty member to place equity in an escrow account. If the Committee finds that the conflict cannot be managed, the Committee can prohibit the proposed external activity.

Faculty members may appeal a Conflict of Interest Committee determination or management plan. The appeal should be made to the Conflict of Interest Committee in writing and include the basis for the appeal. If the Committee does not overturn or modify its original determination, a second level of appeal can be made to the Dean of the School. The decision of the Dean will be final.

IX. External Reporting

There are additional reporting requirements when a financial conflict of interest (FCOI) exists in federally funded research, that is, for situations in which the faculty member has a financial interest in the research that can be construed as potentially affecting the design, conduct or reporting of the research. In compliance with federal regulations, if the Conflict of Interest Committee determines that an FCOI exists in Public Health Service (PHS) funded research, the School is obligated to report this to the PHS awarding component prior to the expenditure of funds under the award. The report will include details regarding the outside interest, the nature of the conflict, and how the conflict has been managed, reduced or eliminated by a management plan in accordance with 42 CFR Part 50 Subpart F. When a faculty member fails to report an FCOI in a timely manner (i.e., prior to submission of an application for PHS funding, or within 30 days of acquiring or discovering the financial interest), the School must complete a retrospective review of the research project to determine whether the design, conduct or reporting of the research was biased.

When an FCOI is reported to the PHS awarding component in compliance with federal regulations, specific information about the FCOI must also be made available to the public when the University receives a written request for that information.

X. Sanctions for Non-Compliance

Failure to comply with the policies on conflict of commitment and conflict of interest and with the Conflict of Interest Committee management plan is subject to review under the School's Procedures for Handling Allegations of Unsatisfactory Performance or Unacceptable Behavior (PPM Faculty – 8) and Procedure for Scientific Misconduct (PPM Faculty – 7). Potential sanctions under these policies range from a warning from the Dean and a letter to the faculty member's file, to suspension for a specified period of time, to termination.

If the failure of an investigator to comply with this conflict of interest policy has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, in accordance with 42 CFR Part 50 Subpart F, Section 50.606 (a), the School will promptly notify the PHS Awarding Component of the findings and corrective action(s) taken or to be taken. The PHS Awarding Component will consider the situation and may take appropriate action or refer the matter to the Institution for further action, potentially including directions on how to maintain appropriate objectivity in the funded project.