

## Conflict of Interest and Commitment Policy

### A. DEFINITIONS

#### **Conflict of Interest**

Conflicts of Interest may take many forms but generally occur when a faculty member's obligations to the University could be compromised by his or her external agreements, particularly financial ones that provide research or other funding.

#### **Conflict of Commitment**

A Conflict of Commitment occurs when a faculty member's time and attention devoted to external activities interferes with their ability to fulfill their obligations to the School.

#### **Industry Speakers' Bureau**

An Industry Speakers' Bureau occurs when the Company involved does one or more of the following:

- A company has the contractual right to dictate what the faculty member says.
- A company (not the faculty member) creates the slide set (or other presentation materials) and has the final approval for all content and edits.
- The faculty member receives compensation from the company and acts as the company's employee or spokesperson for the purposes of dissemination of company-generated presentation materials.

### B. GUIDING PRINCIPLES

1. All financial and fiduciary interests that might appear to present a conflict of interest related to research and practice activities must be reported to and reviewed by the Committee on Conflict of Interest and Commitment (COCIC)
2. There is no "de minimus" level below which a financial interest is exempt from reporting.
3. The COCIC may recommend either prohibition of the proposed research or practice activity or procedures for management of the conflict of interest.
4. Research Project Notification (RPN) forms submitted to the Johns Hopkins Institutional Review Boards include a question concerning relevant financial interests. If a covered party has a relevant financial interest, as described above, the question on the RPN form must be answered in the affirmative. All RPNs containing an affirmative answer to the question concerning relevant financial interests will be referred to the SON COCIC and may be referred to the School of Medicine Committee on Outside Interests for review.
5. It is presumed that faculty may not participate in research projects involving human subjects while having a significant financial interest in the research project or in a financially interested company. Exceptions may be granted if the investigator provides the SON COCIC with a compelling justification for participating in a specific research project while maintaining certain significant financial interests.

6. Managing technology transfer and patents and/or licenses derived from research: When a faculty member proposes to participate in corporate sponsored research related to a license agreement between the School of Nursing or Institute for Johns Hopkins Nursing and the same outside sponsor, the faculty member must contact the appropriate office negotiating the license agreement and the SON Associate Dean for Research for prior review and approval, before entering the research agreement.

### **C. POLICY**

The faculty recognizes its obligation to report extramural professional activities annually and to seek prior review and approval of proposed extramural professional activities, which may present possible conflicts of interest or commitment with responsibilities to the University.

Appointment to the faculty of The Johns Hopkins University School of Nursing (JHU SON) carries the responsibility of directing one's principal professional effort and energy to the objectives of the School through teaching, research, practice and service. External consulting and service activities that provide for maintenance and development of professional skills, facilitate the transfer of knowledge, and contribute to the richness of the academic experience are faculty privileges and are encouraged. Such external activities, however, shall not interfere with the timely and high quality performance of teaching, research, professional practice, service and other academic roles in the School.

Some external activities, such as consulting (with or without a fee) may represent possible conflicts of interest and commitment. In order to preserve the public trust, prior to entering into an external consulting agreement, each faculty member shall report his/her external professional activities to their Department Chair, Associate Dean for Academic Affairs, and the Associate Dean for Research. Free disclosure is the best preventive measure against uncertainty.

Identification of possible conflicts of interest and/or commitment is the responsibility of each individual faculty member. Potential conflicts are best resolved, a priori, by good faith discussions between faculty members and their Department Chair, Associate Dean for Academic Affairs, and the Associate Dean for Research.

### **Industry Speakers' Bureaus**

Faculty must retain final control and authority over the content of professional material presented by them and must not allow such communications or presentations to be subject to prior approval by any commercial interest other than approval for the use of proprietary information. Faculty may not participate in speaking engagements (whether under written agreements or otherwise) that would violate this policy. Participation in an Industry Speakers' Bureaus could pose a potential Conflict of Interest or Conflict of Commitment depending on the characteristics of the agreement.

#### **D. EXAMPLES OF APPROPRIATE DISCLOSURE**

Trust, good faith and candid discussion of controversial issues among colleagues have always been central to the life of this School. The activities of faculty members must be governed by thoughtful and shared consideration of particular circumstances, rather than rigid rules. The requirement for disclosure is meant to ensure that all situations involving possible conflicts of interest and commitment will be considered candidly and fairly. Disclosure thus serves to protect individual faculty members, the Johns Hopkins University, and academic freedom in general.

The purpose of the following list of situations is to assist members of the faculty in recognizing those situations presenting a possible conflict of interest and commitment. It is not intended to place specific restrictions on external activities or situations requiring disclosure or to inhibit members of the faculty from enlarging their professional activities and involvement. A written report must be made promptly in any of the following circumstances:

1. Whenever outside commitments are not compatible with fulfilling the faculty member's primary responsibility to the University.

The maximum time spent on outside commitments which is compatible with fulfilling the primary responsibility to the University needs to be determined by the Department Chair after discussion with the faculty member (or by the Dean for Associate Deans). Intermittent activities such as visiting lectureships and consultations are desirable and bring honor and credit to the faculty member and to the University. However, excessive time devoted to these activities can compromise the faculty member's ability to meet his or her obligations to Johns Hopkins. In addition, faculty members at ranks below full professor must consider the impact of secondary commitments on their ability to fulfill the criteria for promotion. Activities that must be reported include ongoing or repetitive arrangements with an outside organization for activities such as consultation, research, laboratory testing, teaching, writing, or membership on advisory groups and councils.

2. Whenever the name of The Johns Hopkins University or any of its schools or divisions might be used by another party.

Since an academic relationship can be of great value to a non-university organization, opportunities for external activities may be offered to faculty in part because of their association with The Johns Hopkins University. It must be remembered that there is no way to separate a faculty member completely from his or her association with the University. Disclosure prior to undertaking an external activity or arrangement serves to protect the faculty member and the University from possible disrepute or embarrassment and the faculty member from making commitments that interfere with their primary obligations to the School. Faculty members must be discriminating in the selection of external activities, regardless of whether they are professional or non-professional in character, or whether the obligation is to be discharged in "off hours" or during vacation. 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.

3. Whenever 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 proposal (grant/contract) review in the School and by the Research Administration Office 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 Intellectual Property policy, adopted by the Board of Trustees on June 8, 1992, with minor modifications made by the Provost on October 29, 1992.

4. Whenever outside activities require a written agreement.

With the exception of agreements for faculty to provide occasional guest lectures or for the publication of faculty writings, all written agreements relating to outside activities must be reviewed to insure that they do not conflict with institutional policy. Review is required regardless of duration of the activity

5. In special circumstances.

A complete written report of all outside activities may be requested by the Dean in special circumstances such as in connection with appointments, promotions or administrative assignments. The Dean, the Department Chair, or their designees may also request a written report from faculty members in connection with requests for institutional clearance or certification of research (e.g. for research on animals or humans), application for support of academic endeavors or purchases of equipment, or similar requests.

6. Whenever an external arrangement provides for transfer of intellectual or tangible property rights including patent ownership or licensing to an organization other than the University.

A faculty member must disclose any relationship he or she is considering or is engaged in with another organization when any of the following conditions are part of the arrangement: (a) the organization anticipates or is currently providing financial or other support for the faculty member's work; or (b) the organization has requested use of intellectual property (e.g., inventions, knowhow) or tangible property (e.g., research materials) or original works or authorship (e.g., computer software) of that faculty member's scholarly work or the work of a subordinate faculty or staff member. The University's Intellectual Property policy describes fully the University's position on these matters.

7. Whenever an external arrangement (sponsored research or professional practice/consulting) 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.

8. Whenever an external arrangement would restrict the faculty member's public disclosure of information developed by the faculty member.

In the case of a relationship with an external organization, the faculty member must ascertain whether there are 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.

9. Whenever a faculty member's relationship to an external party might appear to influence either the conduct of the University's business or the conduct of research within the University.

10. University policy states that a faculty member (and the faculty member's spouse or domestic partner, and dependent children) may not hold or control stock (excluding mutual funds) in a company that is supporting concurrently his or her academic work through financial or in-kind means. Therefore, the following situations also require disclosure:

- Ownership interests in any organization benefiting from a faculty member's research or practice activities and;
- Situations in which a faculty member is in a position to influence University decision making regarding purchasing products or services from an organization in which:
  - The faculty member holds an equity interest (Equity is defined as stock or stock options owned directly, through partnerships, trusts, or corporations, by the faculty member; ownership of mutual funds is excluded);
  - The faculty member holds a position in the organization or on its governing Board;
  - The faculty member serves as a paid or unpaid consultant to the organization.

11. Disclosure must be made of a relationship with an organization when the organization proposes to conduct business with the University (or an affiliated organization) under circumstances that the faculty member may influence or may appear to influence the decision-making process on behalf of either party.

12. Whenever any remuneration for clinical practice is proposed in addition to the faculty member's salary support through the University.

All earnings from the practice of nursing by full-time faculty members are collected and distributed in accordance with the Faculty Practice Plan of The Johns Hopkins University School of Nursing. Any faculty clinical practice occurring outside of the

Plan must be reported and approved prior to initiating the activity. Verification of professional liability insurance to non-Hopkins organizations will be provided only after a report is made to, and approved by, the Department Chair.

The existence of malpractice coverage with a carrier other than through The Johns Hopkins University does not preclude the requirement that the faculty member disclose plans for outside clinical practice and obtain permission for such activities in the manner prescribed above.

## **E. IMPLEMENTATION GUIDELINES - CONFLICT OF INTEREST AND COMMITMENT**

Full-time appointment to the faculty of The Johns Hopkins School of Nursing (JHU SON) signifies peer recognition of an individual's achievements and excellence in academic areas of research, teaching, practice 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 teaching, research, practice 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 sponsored projects (grants, contracts, etc.) administered by the University and activities supported by University General Funds such as teaching, scholarship (research or professional practice) and service conducted as a University employee.

External activities are those not meeting the above criteria and would include, for example, services as a consultant for remuneration, service on public or private boards and advisory committees whether compensated or not, possessing an ownership interest in a private business or assuming any academic activities at another institution. An arrangement to undertake an external activity with a commercial organization, or a public or private institution or agency other than The Johns Hopkins School of Nursing, in a teaching, research, practice or consultant capacity should be made only after appropriate disclosure and approval. In addition, faculty members are expected to be discriminating in the selection of external activities in order to avoid impairment of the University's reputation and that of its faculty.

Faculty should avoid activities that could be perceived as compromising their basic scholarly independence and freedom of action that are central to university life. Where there is the possibility or appearance of a conflict between a faculty member's obligations to another organization and those to the University, the faculty member must discuss and then disclose in writing his or her plans with their Department Chair or the Dean before making a decision.

## **F. WRITTEN DISCLOSURE**

Extramural consulting and service activities that provide for development and maintenance of professional skills, facilitate the transfer of knowledge, and contribute to the richness of the academic experience are faculty privileges and are encouraged.

To be certain, however, that these privileges are not abused, the Department Chair and the Associate Dean for Academic Affairs shall monitor the level of commitment to external activities to ensure they do not interfere with acceptable performance of the faculty member's commitment to the School. Indicators of "acceptable" performance include the following as appropriate:

1. Meeting expectations as an adviser, including being accessible to advisees
2. Meeting expectations as a peer reviewer by being responsive to requests for review of proposals and theses
3. Meeting expectations for publishing scholarly works
4. Providing high quality course instruction, supported by student evaluations, and other indicators
5. Serving on relevant national, state, and local advisory committees, participating in professional meetings and societies, serving on editorial boards and grant review committees
6. Serving on school, departmental and University committees, including evidence of regular attendance and participation
7. Meeting expectations of administrative roles in a timely manner
8. Meeting financial and project expectations on funded research as PI or co-investigator
9. Meeting salary support expectations
10. Managing technology transfer and patents and/or licenses derived from research

Full written disclosure is the best preventive measure to avoid any conflict or appearance of conflict between the obligations of members of the faculty to the University on the one hand and personal interests and other competing activities on the other.

Members of the faculty must disclose in writing all external activities which pose an

actual or potential conflict of commitment or which appear to pose a conflict of commitment. A determination as to whether a conflict exists or will arise in a particular situation will always be a matter of individual judgment based on all the facts.

While informal discussion with the Department Chair, Associate Dean for Research, the Dean or other University officials may guide a faculty member's decisions, the faculty member also must make a written statement of disclosure whenever consideration is given to entering into an arrangement which may conflict or appear to conflict with that faculty member's obligation to the University. If University students or staff are in any way associated with, or their efforts committed by, the proposed arrangement, the nature and extent of their involvement must be explicitly outlined regardless of whether academic credit is provided for the experience or separate remuneration is paid to them. This information should be provided **at least two weeks** prior to the planned execution of any agreement.

It is the responsibility of the Department Chair, the Associate Dean for Academic Affairs, or another University official to respond in writing to the faculty member in a timely manner of receipt of a written disclosure of a potential conflict of commitment. Should the response be a request for further information before a decision can be made, the faculty member must postpone the new arrangement until permission is given. The circumstances under which written disclosure must be made promptly in any of the circumstances described in below.

## **G. PROCEDURES FOR ANNUAL REPORTING**

On an annual basis, faculty are expected to report in writing concerning:

- All paid and unpaid consulting activities;
- Ownership of any equity interest in any firm that supports (or has been asked to support) his or her scholarship (research or professional practice, teaching or service, (this includes participation in a Small Business Innovation Research [SBIR] or Small Business Technology Transfer [STTR] grant);
- Ownership of any equity interest in any firm that is developing or marketing commercial products based on his or her scholarship (research or professional practice), teaching or service; and
- Circumstances in which the faculty member directly or indirectly profits from the selection of a University supplier or contractor because the faculty member: (a) holds an equity interest in, (b) holds a position or serves on the governing board of (c) serves as a paid consultant to, or (d) receives other direct compensation from the supplier or contractor,
- Teaching at another institution.

Faculty will complete annual Faculty Activity Report. The Department Chair will forward the reports to the SON COCIC for review. The SON COCIC will review the forms and request additional information\_in cases where there appears to be a conflict or the potential for one.

## 1. Review

In its review, the COCIC considers the following factors:

- a) impact on the integrity of research data;
- b) risks to the rights and safety of human research subjects
- c) risks to the rights and obligations of students and trainees participating in research;
- d) impact on the availability of research results to the scientific community for use in the public interest;
- e) appearance of a conflict of interest.

## 2. Determination/Management

Upon completing its review, the COCIC will recommend to the Dean that the proposed arrangements be either a) prohibited, or b) permitted, subject to specific management conditions. After reviewing the recommendation of the COCIC, the Dean will render a final decision and will communicate that decision, with a description of any specific management conditions, to the faculty member in writing. The Dean shall report his decision in each case to the COCIC.

For proposed arrangements involving human subjects research the COCIC will make a recommendation to the Dean and to the IRB.

If the COCIC determines that a conflict of interest may be permitted, it will recommend that management of the conflict of interest be implemented.

Examples of management include, but are not limited to:

- a) *Disclosure* - Disclosure is required in every case approved by the Dean, including: i) public disclosure of the financial interests of the faculty member, and ii) disclosure to the appropriate co-investigators, members of the laboratory or research group, and students or trainees, and iii) disclosure on human subject consent forms;
- b) *Oversight* - appointment of a disinterested individual or group to monitor the relevant research activity. An oversight committee might be charged, at a minimum, with reviewing abstracts and manuscripts before they are submitted for publication to ensure that the research is conducted and reported according to scientific and ethical standards and that conflict of interest management measures are observed. In other cases, an oversight committee might meet quarterly and review protocols, subject accrual, complications, and other issues as appropriate;
- c) *Severance of relationships that heighten or create actual or potential conflicts* - for example, relinquishing a seat on a board of directors or terminating a consulting arrangement with an outside entity in order to reduce the financial or fiduciary conflict of interest.

The COCIC may recommend other conditions or restrictions on the proposed

arrangements if it will contribute to the elimination, reduction, or management of the conflict of interest.

### 3. Reporting to Funding Agencies

If the review involves a proposal for funding from a Public Health Service (PHS) agency, JHU SON will report to the PHS Awarding Component when it identifies the existence of a conflicting interest (but not the nature of the interest or other details), prior its expenditure of any funds under the award. The School of Nursing will assure that the interest has been managed, reduced, or eliminated in accordance with 42 CFR Part 50 Subpart F. For any interest that is identified as conflicting subsequent to the initial report under the award, the report will be made and the conflicting interest managed, reduced, and eliminated, at least on an interim basis, within sixty days of that identification.

The annual reporting form can be completed by clicking on the following link and logging in to the secure website.

<http://www.nursing.jhu.edu/intranet/cnr/coi/>

## **H. APPEALS**

The faculty member may appeal the decision to the Provost. The appeal shall be made in writing setting forth the grounds for the appeal and must be received by the Provost within two weeks following the date of the decision from which the appeal is taken. The decision of the Provost in the matter shall be final.

## **I. FAILURE TO COMPLY**

Failure to comply with the policies on conflict of commitment and conflict of interest and with COCIC recommendations adopted by the Dean and IRBs is subject to review under the School of Nursing's Scientific Misconduct Policy.

If the failure of a faculty member 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), JHU SON must 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 make 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.

## **J. CONFIDENTIALITY OF DISCLOSURES**

All reports in which equity holdings are disclosed shall be maintained in a secure location, separate from other faculty records. Access to these reports shall be limited to the Department Chairs, Associate Dean for Academic Affairs, the Associate Dean for Research, the Dean, and members of the SON COCIC. The Provost and the President

shall have access to the records/reports in the case of any appeal. Under ordinary circumstances, reports will be maintained for five years and then destroyed.

## **K. LEGAL AND REGULATORY OBLIGATIONS**

Covered parties have obligations under various federal laws and regulations governing financial interests related to research. This policy is designed to comply with the federal regulations governing objectivity in research (for example, 42 CFR Part 50 Subpart F, Section 50.604 (a)). Certain additional provisions of these regulations are set forth below.

### **Public Health Service (PHS)/National Science Foundation (NSF)**

1. In accordance with 42 CFR Part 50 Subpart F, Section 50.604 (a), the Institution conducting Public Health Service (PHS)- funded research must maintain an appropriate written, enforced policy on conflict of interest that complies with federal regulation. In addition, the institution will comply with the regulation as follows:
  - a. If the Institution carries out the PHS-funded research through subrecipients, such as subgrantees, contractors, or collaborators, the Institution must take reasonable steps to ensure that investigators working for subrecipients comply with 42 CFR Part 50 Subpart F, either by requiring those investigators to comply with the Institution's policy or by requiring the subrecipients to provide assurances to the Institution that will enable it to comply with the regulation<sup>1</sup>.
  - b. The Institution must maintain 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.
2. Individuals who seek research funding from either PHS (including NIH) or NSF must comply with applicable regulations (Human Subjects Protection (45 CFR Part 46)) to (for PHS) "ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research." Under the regulation, investigators are required to disclose to an official(s) designated by the institution a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by the research proposed for funding by the PHS." For a copy of the complete regulations, contact the Office of Policy Coordination.

### **U.S. Food and Drug Administration (FDA)**

The FDA requires applicants, under various regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860), to submit to FDA a list of clinical investigators who conducted covered clinical studies and to certify the absence of and/or disclose the existence of certain financial arrangements. For a copy of the complete policy, contact the Office of Policy Coordination.

Individuals holding Investigational New Drug applications (IND) applications and Investigational Device Exemptions should consult FDA concerning applicable rules and regulations.

### **Securities and Exchange Commission (SEC)**

The SEC enforces regulations concerning equity ownership, including insider trading, which may affect covered parties who hold equity in a financially interested company. For additional information, covered parties should seek advice from personal counsel. It is the obligation of the financially interested individual to ensure that compliance with applicable SEC regulations.

### **Other Sponsors**

Outside sponsors may have specific requirements regarding the financial interests of covered parties. For more information, contact the sponsor or the Office of Research Administration.

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<sup>1</sup> Subrecipients must report identified conflicts of interest to Johns Hopkins University School of Nursing (JHU SON); JHU SON must report to the NIH the existence of any conflict of interests arising from those entities and assure the interests have been managed, reduced, or eliminated in accordance with the regulations.