

	Johns Hopkins School of Medicine <b>Office of Policy Coordination</b> <b>Conflict of Interest</b>	<i>Policy Number</i>	COI002
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		<i>Supersedes</i>	N/A

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## **I. INTRODUCTION**

- A. As part of a University devoted to the development and advancement of science and medicine, faculty members and other Investigators engage with industry, government, and professional associations to further their knowledge and Research, and to contribute to the richness and diversity of the academic community.
- B. These relationships are governed by core principles:
1. Each member of the faculty of the Johns Hopkins University (“JHU”) School of Medicine (“SOM”) has an obligation to act in the best interest of the University and in furtherance of the University’s mission. Faculty must not let Outside Activities or Financial Interests interfere with those obligations. Outside Activities are considered a privilege for which one must seek approval from the Department Director and fully report the activity to JHU.<sup>1</sup>
  2. It is the fundamental premise of this policy that faculty are expected to devote their primary professional loyalty, time, and energy to their teaching, Research, patient care, and administrative responsibilities at the SOM.
  3. Full-time faculty members recognize that their primary responsibility is to JHU. Acceptance of a full-time appointment entails an intellectual commitment to the furtherance of the academic objectives of JHU and the SOM. Full-time faculty should assign first priority to the needs and goals of JHU.
    - a. Salaried faculty whose appointments are less than full-time are expected to devote professional loyalty, time, and energy to their teaching, Research, patient care, and administrative responsibilities, in accordance with their agreed-upon time commitments.
    - b. The specific responsibilities and professional activities that constitute an appropriate primary commitment should be based on an understanding between the faculty member and his or her Department Director.
    - c. Non-salaried part-time faculty should refer to the [Blue Book](#) for applicable policies.
  4. Disclosures made pursuant to this policy will be reviewed, as appropriate, for conflicts of interest with Research. These reviews will be governed by SOM and JHU policies on conflict of interest.
  5. Disclosures made pursuant to this policy will be reviewed, as appropriate, for compliance with other institutional policies such as, for example, the Johns Hopkins Medicine (“JHM”) Policy on Interaction with Industry.

<sup>1</sup> Department Directors’ activities are approved by the Dean or his/her designee.

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## II. DEFINITIONS

Covered Party	<ul style="list-style-type: none"> <li>Full-time or salaried part-time faculty member at the SOM.</li> <li>Other individuals may be governed by this policy in full or in part pursuant to contractual arrangements involving the Institution.             <ul style="list-style-type: none"> <li>This includes non-faculty Investigators who participate in Research conducted under the auspices of the Institution and Investigators on sub-awards from the Institution, subject to modifications specified herein.</li> </ul> </li> </ul>
Department Director	<ul style="list-style-type: none"> <li>Head of an academic department (e.g., department chair or Department Director).             <ul style="list-style-type: none"> <li>Includes division directors and/or other designees appointed by the Department Director.</li> </ul> </li> </ul>
Financial Interest	<ul style="list-style-type: none"> <li>Any pecuniary interest.             <ul style="list-style-type: none"> <li>Includes income, honoraria, or other payment for services, equity such as stock, stock options, or other ownership interests, actual royalty or other distributions, and/or an entitlement to future royalty or other distributions.</li> </ul> </li> </ul>
Institution	<ul style="list-style-type: none"> <li>JHU, Johns Hopkins Healthcare System Corporation (“JHHSC”), and/or any of their constituent entities.</li> </ul>
Institutional Responsibilities	<ul style="list-style-type: none"> <li>The responsibilities and roles faculty and Investigators are assigned in the course of their appointment and/or employment by the Institution. This includes, for example, clinical practice, teaching, Research, administrative roles, and committee service.</li> </ul>
Investigator	<ul style="list-style-type: none"> <li>Project director or principal Investigator and any other person responsible for the design, conduct, or reporting of Research. Includes collaborators and consultants.</li> <li>All study team members on Institutional Review Board applications.</li> <li>This definition is independent of whether one is appointed or employed by the Institution.</li> </ul>
Outside Activity and/or Financial Interest	<ul style="list-style-type: none"> <li>Exists when a Covered Party provides a service to and/or has a Financial Interest in an Outside Entity independent of any institutional agreement between that entity and the Institution.</li> </ul>
Outside Entity	<ul style="list-style-type: none"> <li>Any for-profit or not-for-profit entity, whether private or governmental, other than the Institution. This includes foundations and professional organizations such as academic societies.</li> </ul>
Research	<ul style="list-style-type: none"> <li>A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. Includes basic and applied Research and product development. Includes, but is not limited to, any such activity for which Research funding is available; for example, Research grants, Research contracts, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, and Research resources awards.</li> </ul>

## III. OUTSIDE ACTIVITIES AND FINANCIAL INTERESTS TO BE DISCLOSED

- A. A Covered Party must disclose any Outside Activities and/or Financial Interests that reasonably appear to be related to his/her institutional responsibilities.<sup>2</sup>
1. Outside Activities should be disclosed regardless of whether any compensation will be received.

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2. A Covered Party also must disclose any compensated Outside Activities and Financial Interests of his/her spouse, domestic partner, or dependent children if these activities or interests reasonably appear to be related to the Covered Party's Institutional Responsibilities.
  3. Disclosures involving an Outside Activity should specify the name of the Outside Entity to which the service will be provided, not the name of an intermediary organization engaged to handle logistics and/or payment.
- B. Examples of Outside Activities and Financial Interests a Covered Party must disclose include, but are not limited to:
1. Consulting or advising
  2. Serving on a scientific or other advisory board
  3. Speaking or lecturing
  4. "Expert witness" service or other legal consulting or testimony
  5. Financial Interest in or from an Outside Entity that has optioned or licensed JHU intellectual property or intellectual property developed by a Covered Party outside of JHU ( (e.g., patent applications, patents, copyrights)
  6. Ownership of equity, stock, stock options, or other Financial Interests
    - a. This includes ownership in or compensation from a start-up company, whether as a founding member or as compensation for the provision of consulting, advising, or other services.
    - b. This does not include ownership of mutual funds and retirement accounts, provided the Covered Party does not directly control investment decisions made in those vehicles.
  7. Fiduciary and management roles of Outside Entities
    - a. This includes, but is not limited to, service on boards of directors, or as an officer, manager, or medical director.
- C. A Covered Party who is an Investigator on Public Health Service ("PHS")-funded Research projects or applications for PHS funding must disclose each occurrence of reimbursed or sponsored travel related to his/her Institutional Responsibilities if the value of the reimbursed or sponsored travel occurring during the 12 months prior to the disclosure, when aggregated for a particulate Outside Entity, is \$5,000 or more.
1. This includes the value of sponsored or reimbursed travel for the Covered Party's spouse, domestic partner, and dependent children, if applicable.
  2. Disclosure must include the purpose, sponsor/organizer, destination and duration of each occurrence.
- D. The following activities, Financial Interests, and/or travel are exceptions and should not be disclosed:
1. Activities governed by a properly reviewed and authorized agreement between the Institution and an Outside Entity
  2. Seminars, lectures, or teaching engagements sponsored by a United States ("U.S.") federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital, medical centers or teaching hospital, or a research institute affiliated with an Institution of higher education.
  3. Participation on advisory committees or review panels for a U.S. federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital, medical centers or teaching hospital, or a research institute affiliated with an Institution of higher education.
  4. Outside Activity conducted by spouses, domestic partners, and dependent children without compensation.
  5. Travel paid for or reimbursed by the Institution.
  6. Travel that is sponsored or reimbursed by U.S. federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital, medical centers or teaching hospital, or a research institute affiliated with an Institution of higher education.
  7. Travel sponsored or reimbursed for the spouse, domestic partner, or dependent children if the spouse, domestic partner, or dependent child is employed by the Outside Entity or if the travel related to the spouse, domestic partner, or dependent child's own employment responsibilities.
- E. Additional reporting for full-time and salaried part-time faculty:

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1. Additional information about Outside Activities and/or Financial Interests may be requested at any time by the Department Director or the Dean<sup>3</sup> in connection with any of the following: appointments, promotions, administrative assignments, performance reviews, requests for institutional clearance, certification of Research, application for support of academic endeavors, purchases of equipment, relevant inquiries or investigations, or disciplinary reviews.

<sup>2</sup>Non-faculty Investigators must disclose only compensated Outside Activities that are directly related to their Institutional Responsibilities in Research. Investigators on sub-awards must disclose only compensated Outside Activities that are directly related to the work they will conduct for the Institution.

<sup>3</sup>The Dean may ask a designee, such as the Vice Dean for Research, to request such a report. In the context of this policy, the term “Dean” used hereinafter shall include his or her designee.

#### **IV. DISCLOSURE SUBMISSION AND REVIEW PROCEDURES**

##### A. Disclosure Submission:

1. Disclosure of all Outside Activities and Financial Interests must be made via the online disclosure [system](#). Disclosures must be made prior to undertaking an Outside Activity and, where applicable, no later than at the time of application for PHS funding and prior to expenditure of any project funds.
2. Disclosures must be updated no later than 30 days from the date of acquiring or discovering a new Financial Interest or a change in a Financial Interest.
3. Occurrences of travel must be disclosed within 30 days following the end of the travel, if the aggregate value of sponsored or reimbursed travel during the 12 months prior to disclosure is \$5,000 or more.
4. In addition to disclosing Outside Activities and Financial Interests, full-time and salaried part-time faculty must complete an annual certification to ensure that their disclosures are accurate and up-to-date.

##### B. Disclosure Review:

1. All disclosures will be reviewed by the Office of Policy Coordination ("OPC") for compliance with this policy, the [JHU Policy on Individual Financial Interests and Conflict of Interest in Research](#), and other applicable policies.
2. Disclosure information is available for review by Department (and in some cases division) Directors and administrators. Department directors may require that their faculty members obtain their review and approval prior to disclosing in eDisclose. Department directors may re-evaluate their approval at any time.
3. The outcome of the review will be communicated to the faculty member and the Department Director in writing via eDisclose. The Outside Activity or Financial Interest Disclosures is not considered approved until this written approval has been sent to the faculty member.

##### C. Maintenance of Records:

1. Disclosures will be maintained in the JHU online disclosure system for three years after project termination and close-out.

#### **V. REVIEW AND MANAGEMENT OF OUTSIDE COMMITMENTS**

- A. Determining whether a particular Outside Activity or Financial Interest constitutes an acceptable or unacceptable time commitment is the responsibility of the faculty member's Department Director, who may seek consultation with OPC.

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- B. Department Directors may place restrictions on or deny any Outside Activity or Financial Interest if they believe the activity or interest is likely to negatively impact a faculty member's ability to fulfill his or her University responsibilities due to the amount of time required by, or the nature of, the Outside Activity or Financial Interest. For such a determination to be made, directors may evaluate areas of faculty responsibility and productivity, including but not limited to their various forms of service (including clinical care for physicians), Research, and teaching.
- C. Any compensation associated with an Outside Activity as defined in section B of this policy must be provided directly from the Outside Entity to the Covered Party and may not be directly deposited into any Institutional account.
1. In some cases, an activity may be conducted under an institutional agreement between an Outside Entity and the Institution. A Covered Party or his/her department administrator must have the institutional agreement reviewed, approved, signed, and managed by the appropriate Institutional offices, including the appropriate research administration office.
- D. An Outside Activity and/or Financial Interest in a for-profit entity should generally be administered under a private agreement between the Covered Party and the entity.

## **VI. REVIEW FOR CONFLICT OF INTEREST**

Review for conflict of interest with Research is conducted in accordance with the [JHU Policy on Individual Financial Interests and Conflicts of Interest in Research](#) and the JHU and JHHSC Policy on Institutional Conflict of Interest.<sup>4</sup>

<sup>4</sup> When applicable review will also be conducted in accordance with the JHU Policy on Conflict of Interest and Conflict of Commitment, which covers all employees in all units of JHU.

## **VII. OUTSIDE ACTIVITIES SUBJECT TO ADDITIONAL CONDITIONS OR LIMITATIONS**

Regulated Activities include but are not limited to:

### A. Patient Care Outside the Johns Hopkins University and Johns Hopkins Health System

*Note:* This section applies to full-time faculty only.

1. Faculty members may not provide patient care at a facility or practice other than a Johns Hopkins facility or practice unless the patient care services are the subject of a contract between Johns Hopkins and the outside facility or practice. All fees or other remuneration for patient care services of faculty, and the right to bill and collect such fees or other remuneration, belong exclusively to JHU, and faculty are not permitted to bill, collect or retain any fees for patient care services they provide, regardless of where or when such services are performed. Contracts to provide patient care outside a Johns Hopkins facility or practice and within the U.S. are exclusively administered by the SOM Clinical Practice Association. Contracts to provide patient care outside a Johns Hopkins facility or practice and outside the U.S. are exclusively administered by Johns Hopkins Medicine International, LLC.
2. Exceptions:
  - a. If a faculty member proposes to provide patient care services at a non-Johns Hopkins facility or practice in the U.S. absent a contract between Johns Hopkins and the outside facility or practice, s/he must request and receive approval from his/her department director and the Vice Dean for Clinical Affairs prior to initiating the service and must confirm that there is appropriate malpractice insurance coverage. Failure to obtain approval may result in action to collect any fees or other remuneration received by the faculty member for such services and a denial of insurance coverage for any claims resulting from such services.
  - b. If a faculty member proposes to provide patient care services at a non-Johns Hopkins facility or practice outside the U.S. absent a contract with Johns Hopkins Medicine International, LLC, s/he must request and receive approval from his/her Department Director and the Vice Dean for Clinical Affairs prior to initiating

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the service and confirm that there is appropriate malpractice insurance coverage. Upon return to the U.S., the faculty member must report to the Department Director and Johns Hopkins Medicine International all amounts received for the provision of patient care, including amounts received as fees or other remuneration for patient care services and gratuities and turn over to the department all such amounts received for handling in accordance with JHU, SOM, and department procedures. Failure to obtain approval; to make the required report; or to turn over funds or other property received may result in action to collect any fees, other remuneration, or gratuities received by the faculty member for such services and a denial of insurance coverage for any claims resulting from such services.

#### B. Speaking for Industry

1. Service as a speaker for industry is prohibited if the arrangement has any of the characteristics listed below. Training others to engage in a speaking activity that has any of these characteristics also is prohibited:
  - a. the company has the contractual right to dictate or control the content of your presentation or talk; or
  - b. the company creates the slides or presentation material and has final approval of the content and edits; or
  - c. the speaker is expected to act as a company's agent or spokesperson for the purpose of disseminating company-generated presentation materials or promoting company products.
2. See the [Policy on Speaking for Industry](#) and the [Policy on Interaction with Industry](#).

#### C. Engagement in Research

1. Faculty may consult with or advise an outside entity regarding the entity's research under a private agreement. However, when it is anticipated that the Covered Party's services for the entity will result in qualification as an author in accordance with International Committee of Medical Journal Editors (ICMJE) standards, it is expected that the Covered Party will provide the services under an institutional research agreement.<sup>5</sup>
2. On occasion, when faculty provide consulting or advising services under private agreements they may ultimately qualify for authorship of resulting research publications according to ICMJE standards. In these instances, the faculty member must ensure the publication includes a disclaimer that states (a) he/she engaged in the research as a private consultant or advisor and not in his/her capacity as a Johns Hopkins faculty member and (b) he/she was compensated for the consulting or advising service in [income/stock/equity/other form of compensation]. Faculty members who qualify for authorship in the course of private consulting are expected to follow all ethical standards of the research community. The faculty member should also update his/her existing consulting or advising disclosure to include the authorship role.

#### D. Other

1. Endorsement & Promotion
  - a. Any Outside Activity that could imply or constitute endorsement or promotion of any commercial product, technology, service, or company, is prohibited. See the [JHM Branding & Use of Name Toolkit](#).
2. Proprietary Information
  - a. Any Outside Activity that involves the use of information that is proprietary to the Institution is prohibited. Clinical or outcomes data about patients may not be used under private activity and may not be provided to a third party (whether not-for-profit or commercial company) under a private agreement. Provision of any proprietary information, including clinical and outcomes data, must be the subject of an institutional agreement. See the [JHU Intellectual Property Policy](#).
3. Use of Name
  - a. Any Outside Activity that involves use of the names, logos, or brand marks of the Institution without explicit permission from the institution is prohibited. See the [JHM Branding & Use of Name Toolkit](#).
4. Academic Freedom

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- a. Any Outside Activity that compromises the basic scholarly independence and freedom of action that are central to University life is prohibited. Outside Activities that restrict or interfere with a faculty member's ability to conduct Research and other academic activities such as publishing or presenting Research results are prohibited. See the [JHU Policy on Conflict of Interest and Conflict of Commitment](#).
5. Institutional resources
  - a. Any Outside Activity conducted that involves the use of resources of the Institution is prohibited unless there is explicit, documented approval by one's Department Director (or by the Dean, in the case of Department Directors). In general, an Outside Activity involving the use of resources of the Institution must be the subject of an institutional agreement. See section E(3) of this policy and the [JHU Policy on Conflict of Interest and Conflict of Commitment](#).

<sup>5</sup> If a faculty member proposes to participate in an IRB or IACUC protocol outside of the Institution under a private agreement but does not anticipate he/she will qualify for authorship of resulting research publications according to ICMJE standards, his/her proposed participation must be referred to the SOM Office of Human Subjects Research or JHU Animal Care and Use Committee for a determination as to whether the arrangement is permissible.

## **VIII. TIME LIMIT**

Engaging in an Outside Activity is considered a privilege. Outside Activities should not distract faculty members from fulfilling their responsibilities, and devoting professional loyalty, time, and energy to their teaching, Research, patient care and academic development. Therefore, the amount of time spent on Outside Activities that are compatible with fulfilling one's responsibility to JHU and one's appropriate academic pursuit needs to be determined by the Department Director after discussion with the faculty member.

## **IX. SANCTIONS FOR NON-COMPLIANCE**

Violations of this Policy on Disclosure and Professional Commitment are subject to the [SOM's Procedures for Dealing with Issues of Professional Misconduct](#).