**Guidelines for CCOI Review of**

**Proposals to Serve in a Fiduciary Capacity**

**Introduction**

The School of Medicine’s policy on conflict of interest and conflict of commitment states:

*Full-time faculty members of The Johns Hopkins University School of Medicine recognize that their primary responsibility is to The Johns Hopkins University. To fulfill that responsibility, they are expected to devote their energies to activities that further the academic objective of the Institution.*

Acceptance of a full-time appointment entails a commitment to assign first priority to the objectives of the University and to strive for safety, objectivity, and independence in the conduct of research and scholarship, clinical care, and teaching. At the same time, participation by faculty members in activities of government, professional associations, industry, and other private institutions may serve the academic interests of the Institution and promote the dissemination of knowledge generated at the University. Yet these interactions must not compromise or appear to compromise a faculty member’s primary responsibility to the core missions of the Institution.

An ad hoc committee, formed to develop guidelines for use by the Committee on Outside Interests, through a series of meetings and research, concluded that a fiduciary role in an outside company by any covered party**[[1]](#footnote-1)** may be beneficial to both parties. The covered party may gain valuable insight into corporate decisions that affect the development of potentially useful medical and scientific products; the company may benefit from the expertise of the covered party. Nevertheless, there is potential for fiduciary roles to generate conflicts of commitment and conflicts of interest. Conflict of commitment, e.g., the time devoted to outside activity, is a matter for review and management by the department director. Conflicts of interest are addressed by the Committee on Outside Interests (COI).

The School of Medicine’s conflict of interest (COI) policy requires that any covered party proposing to assume a management position, board of directors seat, or other fiduciary role in any organization (non-profit or for profit) submit that proposal to the COI for review in advance of accepting such a position. The existing COI policy presumptively prohibits fiduciary roles when the covered party is concurrently conducting related human research and provides mechanisms and criteria for exceptions to the policy. The COI considers distinctions between Board of Directors services and officer roles when making their determinations.

For purposes of these guidelines, in particular items 7-9 under the Guidelines for Review, a *start-up* is a company established for the purpose of developing a technology or service or a closely related group of technologies of services. A *faculty start-up* is one in which the covered party is a founder and receives equity or remuneration in addition to shares of licensing proceeds (fees, equity, royalty), if any, distributed to inventors by the University. A *non-faculty start-up* is one in which the covered party is not a founder and his/her sole role and interest are service on the board and direct remuneration for such service.

Because the value of a start-up company generally depends on the results of research or testing of its core product(s), its success is closely tied to that research and the value of its equity may be very volatile. The directors’ legal exposure may be greater than in an established or publicly-traded company. For these reasons, start-ups involve more risk than established companies.

The following guidelines are designed to assist the COI in evaluating the proposed fiduciary role beyond the existing COI policy.

**Guidelines for Review**

Fiduciary roles may be permitted after COI review in cases where COI judges the risks to be both acceptable and manageable and the Dean concurs. In determining the level of risk and whether it is acceptable, COI will consider a number of factors, including those outlined below.

**A fiduciary role may be permitted in the following situations, listed in increasing order of risk to the Institution and to the covered party’s academic duties:**

1. **Company is publicly traded**
* No research sponsored by the company, involving the company’s product, or “in the field”[[2]](#footnote-2) on the part of the covered party or subordinate[[3]](#footnote-3)
1. **Non faculty start-up company not based on JHU technology**
* No research sponsored by the company, involving the company’s product, or “in the field” on the part of the covered party or subordinate
1. **Company is publicly traded**
* Research in the field, but no research sponsored by the company or involving its products, on the part of the covered party or subordinate
1. **Company is privately held; not a start-up**
* No research sponsored by the company, involving the company’s product, or in the field on the part of the covered party or subordinate
1. **Company is publicly traded**
* Research sponsored by the company or involving its products on the part of the covered party or subordinate
1. **Non-faculty start-up company based on JHU technology** (*for example, i. company has licensed JHU technology from JHU, or ii. an invention, waived back to inventor, is licensed or assigned to the start-up by the inventor*)
* No research sponsored by the company, involving the company’s product, or “in the field” on the part of the covered party or subordinate

**Approval generally will not be granted in the following situations:**

1. **Company is privately held; not a start-up**
* Research sponsored by the company, involving the company’s product, or in the field on the part of the covered party or subordinate
1. **Faculty start-up company not based on faculty member’s licensed technology**
* Sponsored, directly related research, or research “in the field” on the part of covered party or subordinate
1. **Faculty start-up company based on JHU technology** (*for example, i. company has licensed JHU technology from JHU, or ii. an invention, waived back to inventor, is licensed or assigned to the start-up by the inventor*)
* Research sponsored by the company, involving the company’s product, or “in the field” on the part of covered party or subordinate
* Faculty are advised to consult JHTT
1. **Any “financially interested company”**[[4]](#footnote-4) **in cases involving human subject research**

The SOM’s COI policy presumptively prohibits fiduciary roles when the covered party is conducting human subject research involving a financially interested company.

The covered party may request an exception if he/she believes there is a compelling rationale for maintaining a fiduciary role in the company. If COI accepts the rationale and believes the conflicts can be managed, an exception may be granted. The COI will recommend a time limit to be placed on the fiduciary role and may recommend other management. The covered party’s department director must be fully aware of all the circumstances and must approve of the proposed fiduciary role.

**Requests for exceptions may include**

* + A summary of the company’s business plan
	+ Specific description of the role of covered party on the BOD
	+ Proposal for managing conflicts of interest potentially affecting research integrity, use of institutional resources, and students/trainees

**Proposal-related Information**

COI will obtain answers to the following questions from covered parties proposing to serve in a fiduciary capacity.

* + - Why is the covered party being asked to serve in a fiduciary capacity?
		- Is there related research? Is this research company-sponsored?
		- Does the covered party have purchasing responsibilities for goods or services offered by the company or its competitors?

**COI Management Measures for Fiduciary Roles**

Management strategies employed by COI if the fiduciary role is approved may include, but are not limited to, one or more of the following:

* + Disclosure in all relevant publications, presentations and in relevant settings
	+ A required written agreement with the company incorporating the Johns Hopkins Uniform Provisions
	+ Annual report to COI
	+ Proof of Directors’ & Officers’ insurance
	+ Limit on duration of service, e.g., one year set by COI or the covered party’s department director
	+ Manuscript review by an appropriate independent reviewer
	+ Oversight or monitoring of research for data integrity; appropriate allocation of resources; and protection of students and trainees
	+ Stock escrow or similar measures
1. The term “covered party” is defined in the Policy on Conflict of Interest as including faculty, staff, trainees, students, administrators and researchers who are compensated or otherwise supported by The Johns Hopkins University School of Medicine for their services or who appear to act as agents of the School of Medicine in using, controlling, or assigning to others the use of School of Medicine facilities and resources in the conduct of research. Johns Hopkins Health System staff who are participating in research under the auspices of the School of Medicine also are considered covered parties. The CCOI policy requires that the financial and fiduciary interests of their spouse, domestic partner, and minor dependents be reported by covered parties and states they may be subject to review and management to the extent that they introduce real or perceived conflicts on the part of covered parties. [↑](#footnote-ref-1)
2. The phrase “in the field” may mean, for example, research involving a similar diagnostic or therapeutic strategy of a *financially interested company* (see footnote 4 for definition) but targeting different organ systems; or research involving complementary or competitive approaches to treatment of the same disease or disorder. By examining the company’s business and the scope of research conducted by the covered party and under the covered party’s supervision, CCOI will judge whether his/her research or that of a subordinate is “in the field.” [↑](#footnote-ref-2)
3. The term subordinate will refer to those who report directly to the covered party (e.g., whose salary and promotion are determined by the covered party) and may also include individuals who do not directly report to the covered party but whose division, laboratory, or unit is under the overall supervision of the covered party. In any individual case, the CCOI will determine whether the integrity or safety of the research activity of a subordinate – whether or not a direct subordinate -- is placed at risk by the proposed board of directors service. [↑](#footnote-ref-3)
4. A financially interested company is defined in the School of Medicine’s Policy on Conflict of Interest as follows: “Financially interested company means a commercial entity whose financial interests would reasonably appear to be affected by the conduct or outcome of the research. Examples include, but are not limited to, companies that hold patent rights for discoveries, drugs or devices being studied in research protocols or companies that provide financial or in-kind support for research projects. This term includes companies that compete with the sponsor of the research or the manufacturer of the investigational product, if the covered party knows that the financial interests of such a company would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a financially interested company (e.g., a contract research organization).” [↑](#footnote-ref-4)