Report of The Johns Hopkins External Committee on Institutional Conflicts and Use of Name

I. Background

In May 2006, President William R. Brody of The Johns Hopkins University appointed an external committee to review and make recommendations concerning institutional conflicts of interest and use of the Johns Hopkins name in contracts that the University or The Johns Hopkins Health System and Hospital may enter into with private businesses or non-profit organizations (the University and the Health System are collectively referred to as "Johns Hopkins"). The committee was not asked to address issues concerning *individual* conflicts of interest, as the Johns Hopkins Institutions already have well-developed policies in place.

Specifically, President Brody asked the committee to:

> 1) develop standards and criteria for use in decision making regarding proposed relationships with businesses and other organizations, with specific reference to institutional conflicts of interest, adherence to the Johns Hopkins mission, and use of the Johns Hopkins name, particularly in a commercial setting;
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> 2) propose a roadmap for an effective process for evaluating proposed relationships, including, at least generally, recommended procedures for identifying and resolving issues; and
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> 3) present policy recommendations for how best to monitor compliance with applicable policies and correct instances of non-compliance.

In reading this report, it is critical to recognize that The Johns Hopkins Health System and The Johns Hopkins University are separate legal entities and the parent organizations of various other entities. For example, The Johns Hopkins Hospital and two other hospitals are subsidiaries of the Health System. There are also various other Johns Hopkins entities owned 50/50 by the University and the Health System. Thus, reference to "Institutions" in this report is one way to refer to both parents and all of the affiliated organizations.

In developing this report, the committee was provided with a set of existing Johns Hopkins policies and related background information and held five telephone conferences over summer and fall 2006. In addition, committee members interviewed nine Hopkins institutional leaders. The committee also drew on information provided by the General Counsels of the University and the Health System, who served as staff to the committee.

II. Introduction

The committee endorses the principle that all activities carried out at not-for-profit universities and hospitals such as the Johns Hopkins Institutions should be undertaken with integrity and should be consistent with and supportive of their missions. Furthermore, the public places great trust in the unique excellence, objectivity, and commitment to public service of educational, research, and health care institutions such as Johns Hopkins. Thus, Johns Hopkins's values, mission, and integrity have become synonymous with its name.

Relationships and collaboration with for-profit entities are necessary components of the missions of not-for-profit educational, research, and health care institutions. Such relationships create opportunities to expand knowledge, promote understanding, and serve the public good. They have the potential, however, to create institutional conflicts of interest, both in fact and appearance, which may undermine the mission and values of the non-profit institutions as well as the public's trust in their integrity and objectivity. This is particularly true when the relationship is with a for-profit entity. For example, if a university or one of its officials has a significant financial interest in a company whose product it is studying for safety and efficacy, then the public may perceive that the institution is biased in favor of the company and that the research results are flawed and not reliable.

To address these types of potential institutional conflicts of interest, the committee recommends that Johns Hopkins adopt a broad policy, and in some instances specific operating procedures, to ensure that institutional conduct in relationships with other entities: 1) is consistent with Johns Hopkins's values and mission, 2) preserves and enhances Johns Hopkins's integrity and objectivity in fact and in public perception, and 3) maintains and promotes the public's trust in the Johns Hopkins name. Given the broad and decentralized nature of the activities of the Johns Hopkins Institutions, Johns Hopkins should consider adopting an umbrella policy, setting forth general principles and minimum standards that each division or sub-entity is required to adopt in establishing specific procedures and standards applicable and appropriate to their own activities. However, division policies must be consistent with the institution-wide policy, and their development should be coordinated and reviewed for institutional consistency.

The committee was not asked to recommend specific policies. Indeed, committee members might differ about the degree of specificity and scope of policies needed to accomplish the purposes described above. Nevertheless, the committee endorses a set of attributes or goals that such policies and/or procedures should have or serve. The committee also proposes a list of standards and criteria that should be considered by Johns Hopkins — through whatever policies and procedures it might adopt — in assessing, evaluating, and managing potential institutional conflicts of interest and, separately, for use of the Johns Hopkins name. Finally, the committee emphasizes two critical requirements of making such a policy effective: 1) ensuring that adequate resources are allocated to implement the adopted policy, and 2) implementing an educational program to facilitate leadership buy-in and to enhance awareness of the policy across the Johns Hopkins Institutions and their employees.

III. Policy on Institutional Conflict of Interest: Goals and Attributes

A. Scope of an Institutional Conflict of Interest Policy

The committee recommends that Johns Hopkins's institutional conflict of interest policy describe the scope of activities to be covered, the kinds of institutional interests that create institutional conflicts (including dollar thresholds for materiality), who is covered by the policy both generally and specifically, and the requirement for managing conflicts once identified.

Risks to the institutions' mission and values will vary depending on the activities affected by the possible conflict of interest. Thus, a policy should establish procedures for identifying, eliminating, and/or managing institutional conflicts of interest that are appropriate for the level of risk involved and the affected interests. At the most general level, the committee recommends that the Johns Hopkins institutions adopt policies stating that the objectivity and integrity of institutional decision making in all activities must not be compromised by institutional conflicts of interest.

B. Activities Covered

An institutional conflict of interest policy should apply to research, teaching, clinical care, and all business and other relationships. Beyond a general policy statement, Johns Hopkins policies and procedures should identify those areas of greatest actual or perceived risks to its values and actual or perceived risks to the health and safety of others.

The highest priorities should be given to 1) human subjects research and clinical care where the lives, health, and safety of individuals are directly at stake, and 2) institutional conflicts that in fact or appearance may undermine Johns Hopkins's commitment to truth, objectivity in research, independence, and academic integrity.

Contracts with commercial businesses are central to many aspects of the institutions' missions, for example, technology transfer agreements, industry-sponsored clinical trials, and purchases of medical equipment, drugs, and other supplies. Johns Hopkins must be careful to develop appropriate institutional conflict of interest policies that do not discourage, impede, or make more costly such contracts. Therefore, in deciding for policy purposes how much disclosure to require, the specific activities to be covered, and the period of time over which a policy should be implemented, Johns Hopkins should consider the possible costs of a policy as well as the beneficial purposes served.

C. Financial and Fiduciary Interests

Risks and perceived risks to the institutions' missions and values created by institutional conflicts will vary according to the nature of the financial or other interest involved. The greater the likelihood that an institutional interest creates an appearance of a conflict and might be perceived as unduly influencing an institutional decision, the greater the need for some level of disclosure and management.

Covered financial interests should include equity held by the institutions, royalties for licensing of intellectual property, income received by the institutions for consulting and other services, and gifts and other interests held or received by the institutions that might be perceived as affecting the integrity of decisions.

The policy should have dollar thresholds for certain institutional financial interests, although all equity interests in non-public companies should be reviewed for possible conflicts.

In addition, because of the perception that the personal financial interests of high-ranking officials of the institutions may unduly affect the objectivity of decisions made by them or others, an institutional conflict of interest policy should require disclosure of such interests. Disclosures should be updated as circumstances change.

Some may view required disclosure of individual interests of officials to be unnecessarily intrusive and bureaucratic. These are legitimate concerns that have led some institutions to decide against such requirements except as may be required by tax laws applicable to not- for-profit institutions (for example, intermediate sanctions under Internal Revenue Code ⊥ 4958). To mitigate these concerns, Johns Hopkins should consider adopting disclosure requirements with reasonable materiality thresholds (such as interests over a certain minimum dollar amount) so that the individuals need only disclose interests over a set amount and are not required to provide the specific amounts owned (for example, "all interests above $25,000"). Further, mutual funds and other investments where the individual exercises no control over individual choices of publicly traded securities may be excluded from specific disclosure requirements. However, there should be a general prohibition on an official participating in a decision for which the official has an interest in a company affected by the decision.

In addition to disclosure of institutional financial interests and financial interests of high level officials, the institutional conflict of interest policy should cover board of director and other positions held by such individuals at outside companies. Such positions create fiduciary duties owed to the company, and these duties may be perceived as creating conflicts of interest in any dealings with the Johns Hopkins Institutions. Therefore, all such board and other positions should be subject to disclosure so that they can be assessed and any perceived conflict of interest can be managed.

In some instances, a university or hospital may ask one of its officers or other employees to serve on a board of directors of an outside entity as a representative of the institution. For example, the University may ask an employee to serve as its representative on a non-profit community board, or the Hospital may create a new entity by entering into an agreement with a company in the health industry and ask one of its officers to serve on its board (i.e., without private compensation to the Johns Hopkins officer or employee). In these circumstances, where Johns Hopkins's interests and the interests of the separate entity are closely aligned, such board membership usually does not create a conflict with the individual's duties to Johns Hopkins. In contrast, in other circumstances membership of a Johns Hopkins representative on a private board may create possible conflicts between the different fiduciary duties that the individual owes to Johns Hopkins and to the other entity. For example, where the University licenses a patent to a start-up technology company or enters into a consulting arrangement with a private company and is offered a position on the board of the company, such membership may create an unmanageable conflict of interest and ordinarily should be declined.

Rigid rules in this area may not be possible and, ultimately, Johns Hopkins needs to review each situation on its own merits. In general, if Johns Hopkins exercises substantial control over the entity (for example, where it might be considered a joint venture or really a part of Johns Hopkins), or if the two entities share a common purpose, service on a board in an official capacity may be appropriate. By contrast, where the company is in a truly arm's-length and predominantly commercial relationship with Johns Hopkins, particularly when it is a for-profit entity with its own securities laws and other legal obligations, then, for liability, conflict of interest concerns, and other reasons it may not be advisable for Johns Hopkins to designate an official or other employee to serve on the board.

D. Disclosure and Management

Johns Hopkins should consider the level of disclosure and management needed based on both the kind of activity being considered and the type of institutional interest at issue. Some situations present low risks. For example, where the institutional financial interest is part of the institution's endowment, procedures to shield or "firewall" endowment decisions from research, educational, and clinical decisions are likely sufficient protection. As a further low-risk example, the financial interest of a senior official in one academic division of the university is not likely to have any actual or perceived effect on decisions in another division, and, consequently, procedures, if any, for disclosing and managing any such "horizontal conflicts" should be tailored to the minimal risk involved.

In other higher risk circumstances, however, the nature of the financial interest will require more active disclosure and management. For example, where the University holds equity in a closely held business, and this interest is held outside of the endowment (for example, equity taken as part of a technology licensing transaction, even when held in escrow by a different office and with specific rules on when the interest will be sold), conflicts created by doing business with this company need to be disclosed and carefully managed. Similarly, disclosure should be required when Johns Hopkins receives substantial annual cash payments for consulting or other services or when it has received a very large gift from a donor.

Information about institutional interests should be collected and stored in a secure data base. Procedures should be established to cross-check such financial interests against proposed contracts and activities so that any identified institutional conflict can be properly managed. This cross-checking might be limited, at least at the outset, to higher risk activities such as human subjects research and also to areas such as institutional consulting where there is great potential for perceived conflicts.

The analysis of conflicts of interest is a dynamic process and with respect to any particular contract or relationship it may change over time. Therefore, it is important to have a process to revisit possible conflicts of interest based on changed circumstances.

E. Implementation

As noted above, the risks of real and perceived institutional conflicts vary by activity and by financial interest. Further, the experience of Johns Hopkins and other institutions that have or may adopt institutional conflicts of interest policies will help inform the institutions as to their costs and benefits — what works, what are the costs, and what is practical? Therefore, implementation of a policy and its application to particular activities and interests should be developed over time. Further, Johns Hopkins should build into any policy a review procedure by which the effectiveness of the policy is reviewed on a regular basis so that changes and improvements can be made, as appropriate. In implementing a policy, it is critical that a culture of responsibility be fostered, with full participation by leadership and a communications policy that educates employees and encourages them to raise concerns about the policy or its implementation.

To ensure accountability, the Johns Hopkins Institutions should ask those individuals and committees who are charged with implementing these policies to provide an annual report to the Presidents of the Institutions and to their Boards of Trustees with a summary of activities and a discussion of significant issues.

IV. Standards and Criteria

The following factors and principles may be relevant and should be considered in assessing and evaluating potential institutional conflicts of interest, including deciding what action to take, for example, whether to proceed with the activity and manage the conflict by a screen, abstention, or otherwise; whether to prohibit the activity; or whether to dispose of the institutional interest:

1. The degree to which the conflict creates a real versus a perceived concern about objectivity and integrity. Situations in which the public may perceive a conflict need to be identified and managed, but how the conflict is managed may differ when circumstances suggest the real possibility of actual risk to integrity, independent judgment, or patient safety.

2. The risks to life, safety, and health if, in fact, there were to be a violation of standards of objectivity.

3. The relationship between the proposed activity and the mission of the institution.

4. Whether the possible conflict creates risks of violations of law and/or whether there are regulatory considerations guiding the decision.

5. Whether the institutions' missions and core values are being given primacy over competing financial interests.

6. Whether the possible conflict arises out of a relationship in which there are restrictions on freedom and openness of inquiry, for example, a contract with a confidentiality restriction, exclusivity, or other terms that may be secondary or contrary to the institutions' mission.

7. Is there possible harm to the Johns Hopkins reputation?

8. Whether the conflict creates an appearance that truth and the search for knowledge may be compromised, for example, through threats to academic freedom.

9. Consistency with tax-exempt status.

10. Whether there is a practical ability to modify the terms of a proposed contract and/or to give up or modify the financial interest that causes the conflict.

11. The costs and benefits of a decision to reject a proposed relationship because of a possible conflict.

12. The costs and benefits of a decision to go forward despite

the possible conflict.

13. The costs and benefits of forcing the institution and/or a high-level official to give up a financial interest or outside activity.

14. Whether it is practical and effective to establish a screen as a way to manage the conflict.

15. Whether there are liability concerns that flow from going forward with a conflict (for example, could a consumer claim damages based on the Johns Hopkins role in a transaction or on a board)? In all cases, possible conflicts should be resolved in a way that promotes the well-being of the institutions' main constituents, students, patients, and faculty. Moreover, the conflict should be resolved in a way to promote and protect the public' trust in the objectivity and integrity of the institutions.

V. Use of Name: Standards and Criteria

The committee limited its inquiry to a discussion of the standards and criteria that might be used by the Johns Hopkins Institutions in deciding when and under what circumstances other entities may be allowed to use the Johns Hopkins name. The committee focused its discussion on transactions with a commercial purpose, although similar concerns might arise in transactions involving non-profit entities.

The committee concluded that Johns Hopkins should have clear procedures for reviewing and approving use of the Johns Hopkins name by other entities. The procedures should state who has authority to grant approval. In addition, there should be a mechanism for approval by Johns Hopkins leadership for proposed uses of name that may affect the fundamental values and interests of the institutions. Through whatever procedure or practice the Johns Hopkins Institutions use to decide use of name issues, the committee recommends that consideration be given to the following criteria:

1. The activities with which the Johns Hopkins name is associated must be consistent with the Johns Hopkins mission and values.

2. The activities with which the Johns Hopkins name is associated must be consistent with appropriate standards of quality and excellence. For example, academic and clinical affiliations must be appropriately vetted to be sure that the standards of the affiliated entities conform to Johns Hopkins standards.

3. The association with Johns Hopkins as stated by the other

party must be accurate and not misleading. The relationship should not be overstated and the third party should not imply some kind of approval that does not exist. The interests of third parties who may rely on the Johns Hopkins name need to be considered.

4. No use of the Johns Hopkins name should be allowed that would undermine the public trust in what the Johns Hopkins name stands for or that would damage or depreciate the value of the name over time. Sale of the Johns Hopkins name for uses that do not promote or support the Johns Hopkins mission (for example, for purely commercial purposes) may over time devalue the meaning and worth of the name.

5. If Johns Hopkins does agree to use of its name by another party, Johns Hopkins should establish contractual and procedural safeguards to monitor the use to ensure that the on-going use is appropriate.

6. If Johns Hopkins provides a service along with use of name, that service must be consistent with the Hopkins mission and, ideally, add value consistent with its mission.

7. If the use of the Johns Hopkins name carries with it a representation to a third party (the public, shareholders, the government) as to quality, excellence, or safety, then Johns Hopkins should exercise enough control over the transaction to ensure that any such representation, express or implied, is accurate and will continue to be so for the life of the permitted use.

8. If the use of name is exclusive among competitors and/or in a geographic region, such exclusivity should support the services provided and build value. (Use of name exclusivity is of less concern than exclusivity of services.)

9. If Johns Hopkins is providing a service along with use of name and the service is exclusive among competitors or within a geographic area, such exclusivity should be appropriate for licensing intellectual property and publishing content, and such exclusivity should be consistent with the Johns Hopkins missions and core values.

10. The degree of control that Johns Hopkins can exercise — directly or through contract — over the entity using the name. What is the degree of Johns Hopkins' involvement in the entity? The more control and involvement that exist, the more appropriate it may be for the entity to use the Johns Hopkins name. By contrast, more separate entities with less involvement by Johns Hopkins in the activity with which its

name is associated, the greater the risks and the more scrutiny required.

11. Johns Hopkins should reject any such use of name that can reasonably be viewed as endorsement or approval of a commercial product by a Johns Hopkins institution. In general, to avoid the appearance of an endorsement, Johns Hopkins should not allow its name to be used on any commercial product sold by a third party. When its name is used where there may be confusion about a possible endorsement, Johns Hopkins should require disclaimers to the effect that it does not endorse or approve products of private companies.

In general, Johns Hopkins should avoid use of name approval that reasonably implies approval of a private company. Where there may be confusion on this point, Johns Hopkins should require appropriate disclaimers. As a general matter it is more appropriate to allow use of the Johns Hopkins name in connection with publishing academic or health content than selling or advertising a product or the services of a third party. Uses of name that describe a fact ("Johns Hopkins buys our product" or "licenses a patent to us" or "conducted our clinical trial") may be appropriate but each case should be reviewed to avoid an appearance of an endorsement or approval. The particular facts of each usage, for example, where and how the name is used, what else is stated, size of type, links on a web page, need to be examined to avoid the appearance of improper commercial endorsements.

Mr. Stephen D. Potts, Chair
Dr. Charles Sanders
Ms. Carol R. Marshall
Dr. James W. Wagner

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