

POLICY ON CONFLICT OF COMMITMENT AND CONFLICT OF INTEREST

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Sections I-V of this policy became effective on June 1, 1994. Section VI of the policy, concerning conflicts of interest with research and the role of the Committee on Outside Interests, was adopted on June 26, 2002.

I. PRIMARY COMMITMENT OF FULL-TIME FACULTY

Despite the increasing frequency and complexity of the relationships of the University and its faculty with industry, government, and other entities, these relationships are governed by one basic principle:

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 objectives of the School.

Acceptance of a full-time appointment entails a commitment to give one's best efforts to this end and to assign first priority to the needs and goals of The Johns Hopkins University. At the same time, it is recognized that participation of faculty members in activities of government, professional associations, industry, and other private institutions may serve the academic interest of the University. The experience and enhanced national status that such participation brings to the faculty member is shared indirectly by the University, and these outside activities often contribute to the richness and diversity of the academic community. Moreover, as a result of such activities, society may benefit from the dissemination of knowledge and technology developed within the University.

A commitment to serve an institution, agency, or industrial organization other than The Johns Hopkins University should be made only after giving serious consideration to the amount of time and effort that can be given to another entity while satisfying the faculty member's primary commitment to the University. In addition, faculty members are expected to be discriminating in the selection of

outside commitments in order to avoid impairment of the University's reputation as an academic institution. Faculty should avoid commitments that could compromise the 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 report in writing his plans with the department director (or the Dean, for department directors) before making a commitment.

II. NECESSITY FOR A WRITTEN REPORT OF POTENTIAL CONFLICTS

Determination of whether a conflict of commitment or conflict of interest exists in a particular instance will always be a matter of judgment involving all the facts of the situation. While informal discussion with the Dean, department director, or other University representatives may provide guidance for decisions, faculty members must prepare a written report before undertaking any commitment that may conflict or appear to conflict with the primary commitment to the University. The written report should be made as described in Sections III and IV below.

A full written report is the best preventive measure to avoid any real or apparent conflict between the obligations of faculty to the University and to their personal interests and other competing commitments.

III. SITUATIONS IN WHICH A WRITTEN REPORT MUST BE MADE¹

Trust, good faith, and open 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 individual circumstances, rather than rigid rules. The requirement for reporting in the situations outlined below is meant to ensure that conflicts of commitment and conflicts of interest will be considered openly and fairly and that appropriate action will be taken to resolve those conflicts. Reporting thus serves to protect individual faculty members, The Johns Hopkins University, and academic freedom in general. A written report must be made promptly in any of the following circumstances:

¹ The purpose of this list is not to place specific restrictions on outside activities or situations requiring disclosure; it indicates only when a report must be made.

A. Whenever the aggregate time for all outside commitments exceeds 26 days per year.

The maximum amount of time spent on outside commitments² which is compatible with fulfilling the primary responsibility to the University needs to be determined by the department director after discussion with the faculty member (or by the Dean, for department directors). The 26-day level is considered to be a threshold for reporting and not necessarily a limit on outside activities.

Intermittent activities such as visiting lectureships are desirable and bring honor and credit to the faculty member and to the University, but excessive time devoted to these activities can compromise the faculty member's ability to meet his or her obligations to the University. 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.³

Individual lectureships, conferences and scientific or professional meetings need not be included in the 26-day threshold unless those activities otherwise constitute or include activities described elsewhere in this policy. On the other hand, 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.

B. 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. (See reporting procedures in Section IV.)

C. In special circumstances.

A complete written report of all outside activities may be requested by the department director or Dean in special circumstances such as in connection with appointments, promotions or administrative assignments.

The Dean or his 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.

² Outside commitments include all services to entities other than The Johns Hopkins University.

³ The obligations of full-time faculty members and the criteria for promotion are outlined in Policies and Guidelines Governing Appointments, Promotions, and Professional Activities of the Full-Time Faculty of The Johns Hopkins University School of Medicine.

D. Whenever the name of The Johns Hopkins University or the School of Medicine might be used by another party.

Since an academic relationship can be of great value to a non-university organization, opportunities for outside activities may be offered to faculty in part because of their association with The Johns Hopkins University School of Medicine. It must be remembered that there is no way to divorce the faculty member completely from association with Johns Hopkins. Reporting prior to undertaking a secondary commitment serves to protect the faculty member, the University, or both from possible discredit or embarrassment. Thus, faculty members must be discriminating in the selection of secondary commitments, regardless of whether they are professional or non-professional in character, and regardless of whether the obligation is to be discharged in “off hours” or during vacation. If a non-university organization wishes to use the University’s name, symbols or logos, written approval must be obtained prior to such use. To obtain a copy of the University’s statement on the use of its name, symbols or logos or to request approval, contact the Director of Public Affairs, JHMI.

E. Whenever a proposed agreement involves the use of facilities or resources belonging to or utilized by The Johns Hopkins University.

A report must be made if the University will be investing its resources and sharing in the risks of a venture or in any other way subsidizing the activity, whether or not sharing in any revenues generated by the activity. The Johns Hopkins University Intellectual Property Guidelines govern a faculty member’s participation in any agreement under which an outside entity will profit from the resources, including information, of the University itself as well as from the faculty member’s personal involvement. On the other hand, because consulting arrangements and publication of books involve a faculty member’s personal effort, contracts for publications and payment of related royalties, or limited consulting arrangements are not subject to sharing of income with the University, although they still must be reported.

F. Whenever an outside commitment provides for intellectual or tangible property rights in the way of patent ownership or licensing to an organization other than the University.

Faculty must report any relationship they are considering or are engaged in with another organization when the organization anticipates providing financial or other support for the faculty member’s work or when the organization anticipates utilization of intellectual property (e.g., inventions, know-how) or tangible property (e.g., research materials) or original works of authorship (e.g., computer

software but not textbooks) of that faculty member's academic work or the work of a subordinate faculty or staff member. (See The Johns Hopkins University Intellectual Property Guidelines for a full description of these matters.)

G. Whenever an agreement is being considered that restricts the faculty member's public reporting of the existence of the agreement or information developed by the faculty member under the agreement.

Occasionally it may be difficult to distinguish between academic research goals and commercial research goals. In the case of a relationship with a commercial organization, the faculty member must ascertain whether there are requirements for confidentiality that might compromise his or her fundamental rights of academic freedom or those of other faculty members or of students or of the University. Academic freedom means, in part, unhindered discussion and publication of results of research.

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

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

Consideration must be given to whether there is a perception of outside financial incentives being used to direct research activity away from avenues that might lead to more substantial scientific discoveries or to the accomplishment of academic goals. Conflicts of interest may arise when a faculty member has a relationship (e.g., as consultant, advisor, owner, or shareholder) to an outside organization that is conducting business with the University on behalf of either that faculty member or a subordinate faculty member. (See also [Section VI](#) for activities that must be reported to the Committee on Outside Interests.)

Consulting arrangements between faculty members and outside institutions are distinct from research projects. Research projects require a contract with the University. In the latter case, payment for the faculty member's effort is part of the University budget (see E) and is used as a source of an appropriate proportion of the faculty member's University salary support. The Office of Research Administration must be made aware of compensation provided under a consulting agreement which will co-exist with a research grant or contract from the same industrial sponsor.

I. 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 medicine by full-time faculty members are collected and distributed in accordance with the Medical Service Plan of The Johns Hopkins University School of Medicine.

Any faculty clinical practice occurring outside of a Johns Hopkins Medical Facility 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 director and the Associate Dean for Clinical Practice. The existence of malpractice coverage with a carrier other than through the 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. (See also Section V for prohibited activities.)

IV. REPORTING PROCEDURES

A faculty member must provide a written report, as described in the following paragraph, in any of the situations outlined above in Sections III.A - III.I. Disclosure must be made prior to any agreement to undertake the outside commitment or prior to exceeding the 26-day annual threshold. However, disclosure is a continuing obligation, as it also must be made if a possible conflict becomes evident when a faculty member's ongoing relationship with an outside party changes.

In situations covered by Sections III.A to III.H, the faculty member must submit a written statement of the activity and any proposed written agreement to the director of the faculty member's department through the division director (if applicable). Reports of activity by department directors should be submitted to the Dean. If the department director approves the reported activity, the report and notice of approval must then be forwarded to the Office of Policy Coordination. In situations covered by Section III.I, the faculty member should give copies of the statement of disclosure to both the department and division director (if applicable) and the Associate Dean for Clinical Practice. The purpose of these reviews is to ensure that the proposed agreements comply with policies of the department, the School of Medicine, and the University. After the review is completed by the Office of Policy Coordination and/or the Associate Dean for Clinical Practice, and the proposed agreement is found to comply with all relevant policies, a written statement of approval will be sent to the faculty member with a copy to the department and division directors.

V. PROHIBITED ACTIVITIES

Arrangements with outside organizations that have not received approval as indicated in [Section IV](#) above or [Section VI](#) “Policy on Conflict of Interest.”

Remuneration received for the professional care of patients may not be retained by full-time faculty regardless of where or when such services are performed. While on vacation, faculty members may be permitted, at the discretion of the department director and the Office of the Dean, to serve as camp doctor or locum tenens for a practicing physician.

VI. POLICY ON CONFLICT OF INTEREST (Adopted June 2002)

The core missions of The Johns Hopkins University School of Medicine are research, teaching, and patient care. To advance the research mission, the School needs to ensure that research is conducted with integrity and openness and that the rights and interests of human subjects are protected.⁴ The School also needs to foster creativity and facilitate the translation of discoveries into therapies that improve human welfare. Increasingly, the private, for-profit sector plays an important role in this process. Corporate and industry involvement can benefit research and its translation into useful products. However, the financial incentives that accompany such involvement may lead to conflicts of interest. Financial conflicts of interest have the potential to increase bias in research, thus affecting research integrity and placing human research subjects at additional risk. Such conflicts may also reduce public confidence in the research enterprise.

To protect against the potential risks posed by financial and fiduciary conflicts of interest, the School of Medicine has adopted a revised Policy on Conflict of Interest. This policy is designed to identify arrangements involving faculty, staff, trainees, students and others (“covered parties,” See Section I, “Definitions”) who have a financial or fiduciary interest in an outside entity where such arrangements may represent a source of conflict or an appearance of conflict in the conduct and reporting of all research; the policy specifically addresses protection of the rights and interests of human subjects in research. All arrangements involving potential conflicts of interest must be reported to and reviewed by the School of Medicine. This policy is designed to maintain the trust of the public, research volunteers, and the scientific community in the School’s research enterprise and to support institutional compliance with PHS 42 CFR Part 50, Subpart F⁵ and other applicable government regulations.

⁴ The welfare of animal subjects is also a mission of the academic research center; animal welfare is the subject of separate, related policies that are implemented by the Animal Care and Use Committee. (See Handbook on Use of Experimental Animals at Johns Hopkins University.)

⁵ “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought.”

THE POLICY ON CONFLICT OF INTEREST⁶ CONTAINS THE FOLLOWING SECTIONS:

- A. General Principles**
- B. Arrangements Requiring Review by the Committee on Outside Interests**
- C. Mechanisms for Required Reporting to the Committee on Outside Interests**
- D. Review and Management of Conflicts of Interest**
- E. Special Considerations for Review and Management of Conflicts of Interest in Human Subjects Research**
- F. Legal Obligations**
- G. Appeals**
- H. Sanctions for Failure to Comply**
- I. Definitions**

A. GENERAL PRINCIPLES

- 1. All financial and fiduciary interests that might appear to present a conflict of interest related to research activities must be reported to and reviewed by the Committee on Outside Interests (Committee).**
- 2. There is no “de minimus” level below which a financial interest is exempt from reporting.**
3. The Committee may recommend either prohibition of the proposed research activity or procedures for management of the conflict of interest.
4. It is presumed that covered parties 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. (This presumption may not apply to projects that the IRB determines to meet the definition of “no more than minimal risk” to research subjects or which the Committee considers to be low risk, such as conducting studies on tissue samples.) Exceptions may be granted if an investigator provides the Committee with a compelling justification for participating in a specific research project while maintaining certain significant financial interests.
5. Covered parties are additionally responsible for complying with the requirements set forth in the School of Medicine’s policy on conflict of commitment. This policy on conflict of interest is to be interpreted in a manner consistent with the policy on conflict of commitment.

⁶ Terms used in this policy are defined in Section I.

B. ARRANGEMENTS REQUIRING REVIEW BY THE COMMITTEE ON OUTSIDE INTERESTS

The arrangements described below must be reviewed by the Committee at the time they are proposed. The Committee will recommend to the Dean whether the Dean should approve or disapprove the proposed arrangements. If the Committee recommends approval, it will also recommend conditions for management of the conflict of interest. For additional procedures related to human subjects research proposals, see Section E. Review is required regardless of the value of the financial interest in question; there is no “de minimus” level below which review is not required. Financial interests of one’s spouse, domestic partner, and dependents must be reported as though they were one’s own. Individuals who are aware of significant relevant financial interests of other family members (e.g., parents, adult children, or siblings) that might present the appearance of a conflict of interest should report such interests, but are not expected to inquire into the detailed personal matters of others.

1. Royalty

- a) Proposals to conduct research (regardless of the source of external research support, if any) when the research will be performed by a covered party who receives, or is entitled to receive, royalty from the sale of products, the value of which may reasonably appear to be materially affected by the research. This includes arrangements involving licensing-related payments, royalty, or future royalty, whether such payments are received by Johns Hopkins and distributed to the inventor or received by the inventor from another source.⁷

- b) University proposals to license inventions to outside entities.

⁷ Royalty interests arising from post-marketing sales of approved products are an example of a financial interest that promotes translational research and may be amenable to successful management. To encourage the development of new products, the Bayh-Dole Act obligates institutions to attempt to commercialize inventions resulting from federally-funded research and to distribute a portion of the royalty income from marketed products to inventors. This public policy objective of the Act and the eventual recognition of value of the innovation to the public may, in the judgment of the Committee, constitute compelling justification to permit a potential future financial interest concurrent with human subjects research, subject to appropriate and extensive management conditions. The foregoing may not be interpreted so as to eliminate reporting obligations, limit the Committee’s ability to restrict or prohibit these arrangements, or to determine what constitutes a compelling justification. See Section E for Special Considerations for Review and Management of Conflicts of Interest in Human Subjects Research.

2. Equity^{8,9}

- a) Any proposal for licensing a covered party's invention when the covered party, either directly or through the School of Medicine, holds equity or will hold equity (e.g., stock, options) in the licensee;
- b) Any proposal to conduct research (regardless of the source of research support, if any) involving a covered party who, either directly or through the School of Medicine, holds equity (e.g., stock, options) or will hold equity in: a) a company supporting the research, or b) a company whose technology is a subject of the research. This includes equity received or to be received by any means, including but not limited to the following: for consulting or advisory services, through a School of Medicine-based or personal licensing agreement, through inheritance, or as the result of an arms-length purchase;
- c) Any proposal by a covered party to acquire equity in the sponsor of an ongoing research project or in a company that controls technology that is the subject of ongoing research, where the technology may reasonably appear to be materially affected by the research.
- d) Diversified financial holdings that are not controlled, influenced, or managed by a covered party (e.g., mutual funds) are not considered a relevant financial interest and need not be reported.

3. Income/Payments

Any proposal to conduct research that may affect the value of a company or entity from which one receives or is entitled to receive income. This includes, but is not limited to, income for consulting, advisory or lecturing services, honoraria, and in-kind support. This does not include payment to the institution to support the cost of specific research projects (e.g., grants or contracts).

4. Other

- a) Any proposal by a covered party to have a management position, board of directors seat, or other fiduciary role in any organization (non-profit or for profit) whose activities could reasonably be interpreted as related to the University role or activities of the covered party.

⁸ The term equity also applies to equity instruments such as stock options and warrants, as well as to ownership interests.

⁹ The term equity does not include ownership of diversified mutual funds.

- b) Any proposal to conduct research when one's spouse, domestic partner, or minor dependents have a financial interest that may be affected by the research.

C. MECHANISMS FOR REQUIRED REPORTING TO THE COMMITTEE ON OUTSIDE INTERESTS

Covered parties have an affirmative duty to report annually all relevant financial interests, as described in Section B above, to the appropriate institutional officials. Updated reports must be submitted as financial interests change. Reports of the arrangements also are required in connection with specific activities described below.

1. Proposals for Outside Support

Information Sheets are required by the Office of Research Administration in conjunction with applications for outside funding. Those forms include questions concerning relevant financial interests. If a covered party has a relevant financial interest, as described in Section B, above, the appropriate questions on the Information Sheet must be answered in the affirmative. All proposals with affirmative answers will be referred to the Committee for review.

2. Human Subjects Research

- a) Local IRBs: Protocol applications submitted to the Johns Hopkins Medicine Institutional Review Boards ("JHM IRBs") include a question concerning relevant financial interests. If a covered party has a relevant financial interest, as described in Section B, above, the question on the application must be answered in the affirmative. All protocol applications containing an affirmative answer to the question concerning relevant financial interests will be referred to the Committee for review.
- b) External IRBs: For proposals involving human subjects research at Johns Hopkins (or administered through Johns Hopkins) which are submitted to outside IRBs for review, the principal investigator must obtain Committee review by submitting the proposed protocol directly to the Committee. The Committee review must be completed before the principal investigator submits the protocol to the outside IRB. Procedural questions should be directed to the Office of Policy Coordination.

3. Written Agreements with Outside Entities

As outlined in the Policy on Conflict of Commitment, all proposed written agreements with outside entities must be submitted to the Office of Policy Coordination. All written agreements must be reviewed, regardless of the level of compensation to the covered party. If a covered party serving as a consultant or scientific advisor proposes to participate in research that is sponsored by the consulting client or involves a product of the consulting client, the proposed consulting activity requires Committee review.

4. Technology Transfer

When a covered party proposes to participate in a license agreement between the School of Medicine and an outside entity, Johns Hopkins Technology Transfer (JHTT) office will report the proposed financial interests of the covered parties to the Office of Policy Coordination for review by the Committee. Institutional financial interests in licensed technology are subject to review by the Committee.

5. Appointment Letters

Covered parties receiving annual appointment letters must confirm that they reported all applicable outside commitments as required. Such reports must be updated as information changes.

If a covered party has a financial interest that is potentially a source of bias or perceived bias in research and has not reported that interest through one of the mechanisms listed above, the covered party must make a report to the Dean through the Office of Policy Coordination.

D. REVIEW AND MANAGEMENT OF CONFLICTS OF INTEREST

1. Review

The Committee reviews information related to all financial and/or fiduciary arrangements in light of related research activity. In its review, the Committee considers the following factors:

- a) impact on the integrity of research data;
- b) risks to the rights and safety of human research subjects (see Section E, “Review and Management of Conflicts of Interest in Human Subjects Research”);

- 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.¹⁰

2. Determination/Management

Upon completing its review, the Committee 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 Committee, the Dean will render a final decision and will communicate that decision, with a description of any specific management conditions, to the involved covered party in writing. The Dean shall report his decision in each case to the Committee.

For proposed arrangements involving human subjects research, the Committee will make a recommendation to the Dean and to the IRB. This procedure is described more fully in Section E.

If the Committee determines that a conflict of interest may be permitted, it will recommend that management of the conflict of interest be implemented using, for example, one or more of the following:

- a) Disclosure - Disclosure is required in every case approved by the Dean, including: i) public disclosure of the financial interests of the investigator and of the School of Medicine, if applicable, in all relevant publications, presentations (whether or not academic presentations), including presentations at the level of the covered party's primary department or higher, 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) Restriction on Equity - i) placement of stock in escrow until a trigger date specified by the Committee, as outlined in The Johns Hopkins University School of Medicine Intellectual Property Guidelines and associated policies, or ii) requirement that options, warrants, and similar instruments not be exercised without the prior permission of the Committee;¹¹

¹⁰ In agreements and contracts related to the arrangements under review by the Committee, the Institution will require terms that ensure the freedom of timely academic publication, uphold the rights and responsibilities of students and trainees, and ensure appropriate reporting of inventions and assignment of intellectual property rights.

¹¹ Covered parties should be aware that separate Securities and Exchange Commission and other state and federal regulations may apply to their ownership of such equity. Obtaining the necessary information and complying with such regulations is the responsibility of the covered party.

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- c) Limiting the Role of the Investigator with a Financial Interest - requiring that the role of the investigator with the financial interest be limited in some way (e.g., the investigator may not be allowed to i) serve as principal investigator, ii) analyze data, iii) determine whether potential subjects are eligible for enrollment, iv) solicit consent, or v) determine whether an adverse event report is required;
 - d) 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;
 - e) Divestiture - allow arrangements to go forward contingent upon the sale or disposal of specified financial interests to eliminate or reduce the financial conflict of interest by a certain date;
 - f) 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 Committee may recommend other conditions or restrictions on the proposed arrangements if, in its view, such conditions or restrictions will contribute to the elimination, reduction, or management of the conflict of interest.

E. SPECIAL CONSIDERATIONS FOR REVIEW AND MANAGEMENT OF CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH¹²

Financial interests in human subjects research require additional scrutiny. Such interests may present real or perceived risks to the welfare and rights of human subjects, in addition to presenting risks to research integrity.

Covered parties are required to report all financial interests in human subjects research. It is presumed that individuals (faculty, staff, trainees, students, administrators, and researchers) may not participate in research projects involving human subjects while they have a significant financial interest in the research

¹² In preparing this Section of the Policy, the School of Medicine acknowledges the document titled "Preserving Trust, Promoting Progress: Guidelines for Developing and Implementing A Policy Concerning Individual Financial Interests in Human Subjects Research," issued in December 2001 by the Association of American Medical Colleges.

project or in a financially interested company. (This principle may not apply when the proposed research activity involves “no more than minimal risk” to research subjects.) Exceptions may be made in specific cases when, in the judgment of the Committee, individuals holding significant conflicting financial interests provide the Committee with a *compelling justification* - consistent with the rights and welfare of human research subjects - for being permitted to simultaneously hold the financial interest and participate in the human subjects research project. If a covered party proposes to conduct research which is determined by the responsible IRB (in accordance with 45CFR 46.110) to entail “no more than minimal risk” to subjects and the covered party has a significant financial interest, as defined below, the research project will be not presumed to be prohibited. Such a determination by the IRB may be judged by the Committee a “*compelling justification*” for permitting participation in a human subjects research project by covered parties with significant financial interests. Although the arrangements will not be presumptively prohibited, the research project will still be subject to review by the Committee.

1. Significant Financial Interests

Although all financial interests are subject to reporting and review, only significant financial interests are presumed to be prohibited. (N.B.: financial interests below the thresholds listed below are not exempt from reporting.) Significant financial interests include:

- a) Fees, honoraria, gifts or other emoluments, or “in kind” compensation from a financially interested company (or entitlement to the same), whether for consulting, lecturing, or any other purpose, that in the aggregate exceed \$25,000 in a given twelve month period, excluding reimbursement of expenses such as travel expenses incurred as a direct result of performing consulting services;
- b) An equity interest of any amount, including stock options or warrants, in a non-publicly-traded financially interested company (or entitlement to the same);
- c) An equity interest, including stock options or warrants, (or entitlement to the same) in a publicly-traded financially interested company that exceeds \$25,000¹³ in value as determined through reference to current prices. (Should the value of the equity interest increase to more than \$25,000 during the conduct of the research project, the covered party must notify the IRB.) This does not apply to diversified mutual funds or similar instruments in which the shareholder has no control over the equities held

¹³ This limit will be reviewed every two years, beginning in 2004, to determine whether an increase is warranted in light of any increase in the cost-of-living index.

by the fund. Equity holdings worth less than \$25,000 and rights to acquire additional equity will nevertheless be subject to restrictions;

- d) Royalty income or the right to receive future royalties from commercialization of research results, including entitlement to any “milestone” payments conditioned upon specified research-related dates or events, whether such payments are received from a financially interested company or via the Institution;¹⁴
- e) Any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the applicable research agreement). This includes any bonus or milestone payments (other than those addressed in Section E above) to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested company or from the Institution;
- f) Service as an officer, director, or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service.¹⁵
- g) Royalty income and the right to receive future royalties as a result of traditional academic publishing activity, such as the publication of textbooks, are excluded.

2. Review and Determination/Management

As described in Section E, the Committee will review reports of proposed financial interests in human subjects research projects. Recommendations concerning the covered party’s relationship to the outside entity will be communicated in writing to the Dean and to the appropriate IRB. The Dean will communicate his decision concerning the covered party’s relationship with the outside entity to the covered party

¹⁴ Royalty interests arising from post-marketing sales of approved products are an example of a financial interest that promote translational research and may be amenable to successful management. To encourage the development of new products, the Bayh-Dole Act obligates institutions to attempt to commercialize inventions resulting from federally funded research and to distribute a portion of the royalty income from marketed products to inventors. This public policy objective of the Act and the eventual recognition of value of the innovation to the public may, in the judgment of the Committee, constitute compelling justification to permit a potential future financial interest concurrent with human subjects research, subject to appropriate and extensive management conditions. The foregoing may not be interpreted so as to eliminate reporting obligations, limit the Committee’s ability to restrict or prohibit these arrangements, or determine what constitutes a compelling justification.

¹⁵ A researcher’s time-limited service as an officer or director of a company formed to obtain a grant under the federal Small Business Innovation Development Act or the Small Business Technology Transfer Program may be treated analogously to royalty interests arising from post-marketing sales of approved products, as described in Footnote 14.

in writing. Never-theless, to ensure the primacy of the welfare and rights of human subjects, the IRB will have the full and final authority for implementing the decision concerning the role of the involved covered party in the human subjects research protocol. Accordingly, the IRB will communicate its decision concerning participation in the human subjects research protocol to the covered party and will provide a copy of that communication to the Committee.

If the IRB deems a specific research project involving human subjects to be exempt from IRB review, the conflict of interest issues associated with that project will remain subject to Committee review and the Committee may review the project as if it were “human subjects research” for the purposes of this Section.

The Committee’s recommendation may involve either prohibition or management. These options are described below.

- a) **Prohibition:** If, upon reviewing specific evidence provided by the covered party with the relevant financial interest, the Committee believes that a conflict of interest is incompatible with human subjects research, it will recommend to the appropriate IRB that the involved covered party be required to eliminate the relevant financial interest before beginning the project or be barred from participation in the research.
- b) **Management:** In cases involving non-significant financial interests, the Committee will generally recommend that the covered party be permitted to participate in a given human subjects research project, subject to certain specified management conditions. In a limited number of cases involving significant financial interests, if the Committee concludes that the justification provided by the covered party is sufficiently compelling and that the conflict of interest can be managed, it will recommend specific project-related management measures to the appropriate IRB.

In all cases involving human subjects research where a research consent form is required and in which an involved covered party has a relevant financial interest of any magnitude, a financial disclosure statement including the name of the financially interested individual and describing the source and nature of the relevant financial interests must be included in the consent form.

Additional project-related management measures may include, for example, one or more of the following: the covered party may not be allowed to i) serve as principal investigator, ii) analyze data, iii) determine whether potential subjects are eligible for enrollment, iv) solicit consent, or v) determine whether an adverse event report is required. Other project-related management measures, as detailed in Section D, may also be recommended.

The Committee's recommendation, accompanied by a description of the nature and magnitude of the potential conflict of interest, will be communicated in writing to the appropriate IRB. The IRB, which is responsible for ensuring the ethical acceptability of the research, will evaluate the recommendations of the Committee and decide whether to: a) accept the recommendations, b) accept the recommendations with additional management measures prescribed by the IRB, or c) conclude that the human subjects research cannot proceed. It will then communicate its determination to the covered party in writing. Upon concluding its evaluation, the IRB will inform the Dean and the Committee of its determination, but the IRB's decision will be final.

F. LEGAL OBLIGATIONS

Covered parties should be aware that as a result of their financial interest or fiduciary role in a company they might have obligations under various federal or state laws.

1. Public Health Service (PHS)/National Science Foundation (NSF)

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.¹⁶ For a copy of the complete regulations, contact the Office of Policy Coordination.

2. U.S. Food and Drug Administration (FDA)¹⁷

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.

¹⁶ "Objectivity in Research." NIH. <http://grants.nih.gov/grants/guide/notice-files/not95-179.html>. (July 14, 1995)

¹⁷ "Financial Disclosure by Clinical Investigators." FDA. <http://www.fda.gov/oc/guidance/financialdis.html>. (March 20, 2001)

3. 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 compliance with applicable SEC regulations.

4. 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.

G. APPEALS

If a covered party believes that a determination made by the Committee in a specific case and adopted by the Dean or an IRB is not appropriate or is based on erroneous information, the covered party may request additional Committee review by submitting a written request to the Vice Dean for Research. If, after a second review by the Committee and second determination by the Dean, the covered party still wishes to appeal, the covered party may appeal to the University Provost. The decision of the Provost shall be final.

In the event the Dean decides not to adopt a Committee recommendation and the Committee wishes to appeal that decision, it may appeal to the University Provost. The decision of the Provost shall be final.

Covered parties who believe that the conflict of interest management measures adopted by an IRB are not appropriate or are based on erroneous information must follow applicable IRB procedures for requesting additional review.

H. SANCTIONS FOR FAILURE TO COMPLY

Failure to comply with the policies on conflict of commitment and conflict of interest and with Committee recommendations adopted by the Dean and IRBs is subject to review under the School of Medicine's Procedures for Dealing with Issues of Professional Misconduct and the Procedures for Dealing with Issues of Research Misconduct. Potential sanctions under these policies range from a warning from the Dean and placement of a letter in the covered party's file, to suspension for a specified period of time, to termination.

I. DEFINITIONS

1. Committee on Outside Interests (the Committee)

The Committee is a standing body consisting of senior faculty members of the School of Medicine and the University as well as senior members of the University administration, serving ex officio. The Committee includes at least one member who also is a member of a School of Medicine institutional review board (IRB) or has served on a School of Medicine IRB. In addition, the Committee includes at least one senior faculty member from outside the School of Medicine.

2. Covered Party

Those covered by the Policy on Conflict of Interest include 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. While the spouse, domestic partner, and minor dependents of those listed above are not considered covered parties, their financial and fiduciary interests must be reported in accordance with this policy.

This policy on conflict of interest also applies to the Institution itself, insofar as specific financial or fiduciary interests of the Institution may represent a source of bias or perceived bias in the conduct and reporting of research. (Such interests include, but are not limited to, income from royalty or equity interests obtained as a result of licensing technology to outside entities and income or other financial interests obtained through outside consulting. This policy will be interpreted in a manner consistent with The Johns Hopkins University's Intellectual Property Guidelines and the policies encompassed by those Guidelines.)

This policy acknowledges that potential conflicts of interest may exist, for both covered parties and the Institution, with respect to activities that, in the determination of the Committee, do not involve research. An example of such activity would be procurement. Accordingly, although conflict of interest in research is the focus of the Committee, the Dean may request that the Committee review and advise him concerning financial interests related to other activities.

The policy shall be interpreted in a manner consistent with applicable federal and state statutes and implementing regulations.

3. Fiduciary Role

A fiduciary role refers to a legal and/or ethical obligation on the part of a covered party to act in the best interests (i.e., the financial success) of another. Examples of fiduciary roles include, but are not limited to:

- Membership on a board of directors
- Management role in a company or partnership

4. Financially Interested Company

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).

5. Research/Conducting Research

“Research” shall mean any organized program of scientific inquiry. “Conducting Research” includes designing research, directing or serving as an investigator, performing laboratory experiments, having a role in soliciting consent from research subjects or making decisions related to eligibility of patients to participate in research, analyzing or reporting research data, or submitting manuscripts or abstracts concerning the research for publication. Examples include, but are not limited to, projects for which outside support is requested and projects for which approval of an IRB is required. For purposes of this policy, the determination of what constitutes research and what constitutes the conduct of research shall be made by the Committee, although such determinations shall be consistent with Section 6, below.

6. Human Subjects Research

Human subjects research includes all research meeting the definition of “research” performed with “human subjects” as defined in the Federal Common Rule (45 C.F.R. Part 46 and 21 CFR Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation. In the event that the Common Rule definitions of “human subject” or “research” are modified through rulemaking,

any such revisions shall apply for the purposes of this policy. See Section E for special considerations related to human subjects research.

7. Institution

Institution means The Johns Hopkins University School of Medicine.