

Johns Hopkins University

Policy on Individual Financial Interests and Financial Conflict of Interests^{1, 2} in Research

This policy applies to the Bloomberg School of Public Health, Krieger School of Arts and Sciences, School of Medicine, School of Nursing, and Whiting School of Engineering.³

A. Introduction

The mission of the Johns Hopkins University is to generate knowledge for the world through research, teaching, clinical practice and service. To advance the research mission, the University needs to ensure that research is conducted with integrity and openness and that the rights and interests of human subjects are protected.⁴ The University also seeks to foster creativity and facilitate the translation of discoveries into products, techniques, and processes that improve human welfare. Increasingly, the private, for-profit sector plays an important role in this process. Industry involvement can benefit research and its translation into useful products. However, the financial incentives that accompany such involvement may have the potential to create or 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 ensure the integrity of research in the setting of related financial and fiduciary interests, the University has adopted a revised Policy on Individual Financial Interests and Conflict of Interest in Research. This policy is designed to identify arrangements involving investigators and others who have a financial or fiduciary interest in an outside entity where such arrangements may create risks or the appearance of risks in the conduct and reporting of all research. The financial interests and arrangements reported in accordance with divisional policies on disclosure and professional commitment must be reviewed by the appropriate University division for financial conflict of interest with research. This policy is designed to maintain the trust of the public, research volunteers, and the research community in the University's research

¹ Terms used in this policy are defined in Section B.

² Different University policies govern other financial interest and conflict of interest issues (e.g., institutional financial conflicts of interest, financial conflicts of interest with purchasing). Policies on disclosure and professional commitment may require disclosure of additional information.

³ Faculty members at other University divisions must comply with the JHU Policy on Conflict of Interest and Conflict of Commitment.

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.)

enterprise and to support institutional compliance with PHS 42 CFR Part 50, Subpart F⁵ and other applicable government regulations.

- Separate University and divisional policies govern disclosure and professional commitment for faculty and staff.
- This policy is effective August 24, 2012.
- The JHU Schools of Arts and Sciences, Engineering, Medicine, Public Health, and Nursing must follow this policy or adopt policies that are consistent with this policy.
- This policy applies to all Covered Parties.
- Faculty members at other University divisions must comply with the JHU Policy on Conflict of Interest and Conflict of Commitment.

B. Definitions

- **Covered Party(ies)**
 - Covered parties are investigators on all research conducted under the auspices of JHU, including research that is funded by or through the University, its divisions, centers or institutes, or conducted under the aegis of any JHU IRBs (including JHM IRBs).
- **Entity**
 - Any for-profit or not-for-profit organization, whether private or governmental. This does **not** include: the Johns Hopkins University and local, state, and federal government entities; institutions of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education.
- **Institution**
 - Institution means the Johns Hopkins University, its divisions, centers, and institutes and any other constituent parts.
- **Institutional responsibilities**
 - The responsibilities and roles investigators are assigned in the course of their faculty appointment or employment by the Johns Hopkins University. This includes, for example, clinical practice, teaching, research, administrative roles, and committee service.
- **Investigator**

⁵ "Promoting Objectivity in Research"

- Project director or principal investigator and any other person responsible for the design, conduct, or reporting of research. Includes collaborators and consultants.
- All study team members on IRB applications.
- This definition is independent of whether one is appointed or employed by the Johns Hopkins University.
- **Research**
 - 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 from a PHS Awarding Component through a grant or cooperative agreement; for example, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, and research resources awards.

C. Obligations of Covered Parties

Disclosure to institution. Covered parties must make disclosures to the institution of financial interests as outlined in the policy on disclosure and professional commitment of the division in which the covered party has a primary appointment. If the division of the covered party's primary appointment does not maintain a disclosure and professional commitment policy, the disclosure requirements outlined in the University Policy on Conflict of Interest and Conflict of Commitment [insert link] must be followed.

Completion of conflict of interest training. Covered parties must complete Johns Hopkins University conflict of interest training.

- When training must be completed
 - Prior to engaging in research at Johns Hopkins and
 - At least every four years
- Training also must be completed when any of the following occur:
 - Johns Hopkins revises its policy on conflict of interest in research;
 - A covered party is new to Johns Hopkins; or
 - Johns Hopkins determines that a covered party is not in compliance with this policy or his/her assigned management plan
- How training should be completed
 - Via MyLearning⁶ or as specified

Compliance with Institutional Management and Related Requirements. (See also Compliance Section below.) Covered parties are required to comply with institutional

⁶ See <https://learning.jhu.edu>.

conflict of interest management requirements and administrative conditions associated with financial interests related to research.

D. Review of Disclosures

Review Process and Standards

- Responsibility for review of disclosures
 - Disclosures will be reviewed by designated divisional staff and/or a Committee appointed or designated by the divisional dean or vice dean for research. For purposes of this policy, “Committee” will mean the committee or individuals (e.g., staff assigned to review financial disclosures) appointed by the dean to review financial disclosures for FCOI (defined below).
 - Review generally will occur in the division of an individual’s primary appointment or employment. However, in some cases, review will occur in the division with the primary responsibility for research or other activity potentially affected by the financial interest.
- Standards for review of disclosures
 - Disclosures are reviewed in light of related research activity for the following:
 - potential of disclosed interests to directly and significantly affect the design, conduct, or reporting of research funded by a PHS Awarding Component or other sponsor (“financial conflict of interest”, or “FCOI”); and
 - risks to the rights and safety of human research subjects; and
 - impact on the integrity of research data; and
 - risks to the rights and obligations of students and trainees participating in research; and
 - impact on the availability of research results to the scientific community for use in the public interest; and
 - appearance of a conflict of interest.

Determination/Management/Administrative Conditions

- The Committee will determine whether or not the disclosed interests constitute a financial conflict of interest (FCOI). If the Committee identifies an FCOI, the Committee will recommend to the Dean that the proposed arrangements be either (a) prohibited, or (b) permitted, subject to specific management measures.
- In cases where the Committee does not judge the arrangement to be an FCOI, the arrangements nevertheless may be subject to administrative conditions. All

arrangements may be reviewed again if circumstances change or there is new information.

- After reviewing the recommendation of the Committee, the divisional Dean will render a final decision and will communicate that decision, with a description of management measures or administrative conditions, to the involved covered party in writing. The Committee will be notified of the Dean's decision if it differs from the recommendation of the Committee. For proposed arrangements involving human subject research, the Committee will make recommendations to the Dean and to the IRB. This procedure is described more fully below. If the Committee determines that a particular financial interest is not prohibited in the presence of related human subject research, it will recommend that the conflict of interest be made subject to a management plan or administrative conditions. This may consist of one or more of the following:
 - *Disclosure* - Disclosure is required in most cases and generally includes: i) public disclosure of the financial interests of the investigator and of the University, 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, 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;
 - *Restriction on Equity* - i) placement of stock in escrow until a trigger date specified by the Committee, as outlined in The Johns Hopkins University 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;⁷
 - *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);
 - *Oversight* - appointment of a disinterested individual or group to monitor the relevant research activity. Oversight might include review of abstracts and manuscripts before submission for presentation or publication to ensure that the research is conducted and reported according to scientific and ethical standards and that there is compliance with conflict of interest management plans. Oversight of human subject research might involve review of protocols, subject accrual, adverse events, and other issues as appropriate;

⁷ Covered parties should be aware that separate Securities and Exchange Committee 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.

- *Divestiture* - allow arrangements to go forward contingent upon the sale or disposal of specified financial interests to eliminate or reduce the risks associated with the financial interests by a certain date;
- *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 risks associated with the financial interest or fiduciary relationship.

Other conditions or restrictions on the proposed arrangements may be recommended if, in the view of the committee, such conditions or restrictions will contribute to the elimination or reduction of the conflict of interest or to the promotion of transparency and research integrity.

E. Special Considerations for Review of Financial Interests in Human Subjects Research⁸

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.

It is presumed that covered parties may not participate in research projects involving human subjects while they have certain specified financial interests (“presumptively prohibited” financial interests) in the research project. (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 presumptively prohibited 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 has a presumptively prohibited financial interest, as defined below, and 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 the research project will not be 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.

⁸ The University 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.

Presumptively Prohibited Financial Interests in Human Subjects Research

The financial interests that must be reported are outlined in divisional policies on disclosure and professional commitment. Presumptively prohibited financial interests include:

- Fees, honoraria, gifts or other emoluments, or "in kind" compensation from a financially interested entity (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;
- An equity interest of any amount, including stock options or warrants, in a non-publicly-traded financially interested entity (or entitlement to the same);
- An equity interest, including stock options or warrants, (or entitlement to the same) in a publicly-traded financially interested entity that exceeds \$25,000 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 by the fund. Equity holdings worth less than \$25,000 and rights to acquire additional equity will nevertheless be subject to restrictions;
- 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 entity or via the Institution;⁹
- 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 above) to the investigator in

⁹ 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 or administrative 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.

excess of reasonable costs incurred, whether such payments are received from a financially interested entity or from the Institution;

- Service as an officer, director, or in any other fiduciary role for a financially interested entity, whether or not remuneration is received for such service.¹⁰
- 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 from the presumptive prohibition.

Review and Determination/Management and Administrative Conditions in Cases Involving Human Subject Research

The Committee will review reports of proposed financial interests for potential to create FCOIs in human subject 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 in writing. Nevertheless, 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 financial interest issues associated with that project will remain subject to review by the Committee, 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 prohibition, management, or administrative conditions to achieve transparency and promote research integrity. These options are described below.

¹⁰ 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 9.

- *Prohibition:* If, upon reviewing specific evidence provided by the covered party with the relevant financial interest, the Committee believes that a financial 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.
- *Management:* In cases involving -financial interests that are not presumptively prohibited, the Committee will generally recommend that the covered party be permitted to participate in a given human subjects research project, subject to certain specified conditions. In a limited number of cases involving presumptively prohibited financial interests, if the Committee concludes that the justification provided by the covered party is sufficiently compelling and that the financial interest can be permitted, it will recommend specific project-related measures to the appropriate IRB.

In all cases involving human subjects research where a written research consent form is required and in which an involved covered party has a relevant financial interest of any magnitude, a financial interest disclosure statement must be included in the consent form.

Additional project-related 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 administrative conditions may also be recommended.

The Committee's recommendation, accompanied by a description of the nature and magnitude of the potential risks associated with the financial 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 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. 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 measures adopted by an IRB are not appropriate or are based on erroneous information must follow applicable IRB procedures for requesting additional review.

G. External Reporting

- To comply with federal regulations, the Institution will make available to the public within 5 days of a request the following information with respect to financial conflicts of interest with PHS-funded research:
 - Investigator's name
 - Investigator's title and role with respect to the research project
 - Name of entity in which a significant financial interest is held
 - Nature of the significant financial interest
 - Approximate dollar value of the significant financial interest within ranges (e.g., \$0-\$4,999; \$5,000-9,999; \$10,000-19,999; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000), or a statement that the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- To comply with federal regulations, the Institution will report to the PHS Awarding Component the following information with respect to financial conflicts of interest with PHS-funded research:
 - Project number
 - Program director/principal investigator
 - Name of investigator with financial conflict of interest
 - Name of entity in which a significant financial interest is held
 - Nature of the significant financial interest
 - Approximate dollar value of the significant financial interest within ranges (e.g., \$0-\$4,999; \$5,000-9,999; \$10,000-19,999; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000), or a statement that the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value

- Description of how the financial interest relates to the PHS-funded research and basis for the Institution's determination of a financial conflict of interest
- Description of key elements of the Institution's management plan, including:
 - Role and principal duties of the conflicted Investigator in the research project
 - Conditions of the management plan
 - How the management plan is designed to safeguard objectivity in the research project
 - Confirmation of the investigator's agreement to the management plan
 - How the management plan will be monitored
 - Other information as needed

Covered parties must abide by other disclosure requirements and standards, such as for journals and professional societies; in publications, presentations, and to colleagues, students and trainees -- even if an interest is not identified as a FCOI with research.

H. Compliance

Failure to comply with this policy and with Committee recommendations adopted by the Dean and IRBs is subject to review under the applicable division's policies and procedures on professional or 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.

In the event of any of the following, an interim management plan will be implemented and a retrospective review of ongoing research will be undertaken to determine whether bias is present in the design, conduct or reporting of the research: failure to disclose in a timely manner financial interests that are determined to constitute an FCOI with PHS-funded research; failure by the institution to review or manage an FCOI; or failure by a covered party to comply with a management plan. If bias is identified, the institution will develop and implement a mitigation plan.

If the failure of an investigator to comply with this conflict of interest policy has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, in accordance with PHS regulations, the institution must promptly notify the PHS Awarding Component of the findings and corrective action(s) taken or to be taken. The PHS Awarding Component will consider the situation and make take appropriate action or refer the matter to the Institution for further action, potentially including directions on how to maintain appropriate objectivity in the funded project.

I. Legal Obligations

Covered parties have obligations under various federal laws and regulations governing financial interests related to research. This policy is designed to comply with the federal regulations governing objectivity in research.

- **Public Health Service (PHS)/National Science Foundation (NSF)**
This policy is intended to comply with and should be interpreted in accordance with 42 CFR Part 50 Subpart F, 45 CFR Part 94, and applicable NSF regulations.
- **U.S. Food and Drug Administration (FDA)**
The FDA requires applicants, under various regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860), to submit to FDA a list of clinical investigators who conducted covered clinical studies and to certify the absence of and/or disclose the existence of certain financial arrangements. For a copy of the complete policy, contact the Office of Policy Coordination.
 - Individuals holding Investigational New Drug applications (IND) applications and Investigational Device Exemptions should consult FDA concerning applicable rules and regulations.
- **Securities and Exchange Commission (SEC)**
 - The SEC enforces regulations concerning equity ownership, including insider trading, which may affect covered parties who hold equity in a financially interested company. For additional information, covered parties should seek advice from personal counsel. It is the obligation of the financially interested individual to ensure that compliance with applicable SEC regulations.
- **Other Sponsors**
Outside sponsors may have specific requirements regarding the financial interests of covered parties. For more information, contact the sponsor or the Office of Research Administration.