



Kennedy Krieger Institute  
**Research Administration**  
**Policies and Procedures**

**Policy: Outside Interests and Financial Conflicts of Interest in Research**

Issue Date:  
December 1, 2020

**Purpose:**

Kennedy Krieger Institute aims to maintain objectivity in the design, conduct, or reporting of research, foster transparency, and best serve the rights and welfare of research participants. This policy helps to ensure that research is conducted with integrity and openness, and that the rights and interests of human subjects are protected.

This policy supports institutional compliance with the U.S. Department of Health and Human Services - Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F)<sup>1</sup>, and other applicable regulations.

Kennedy Krieger Institute employees who hold faculty appointments at the Johns Hopkins University School of Medicine (JHU SOM) are also required to comply with the Johns Hopkins University School of Medicine Professional Commitment and Conflict of Interest policies.<sup>2</sup>

**Policy:**

This policy is designed to identify outside activities or interests that may represent potential or actual conflicts of interest in the conduct or reporting of research. This policy applies to Institute faculty and staff responsible for the design, conduct, or reporting of research.

**Procedures:**

**Disclosure Requirements**

Faculty and staff engaged in research (collectively, researchers) are required to disclose outside financial interests via JHU SOM's online disclosure system. Researchers are required to disclose outside financial interests at least annually when research is ongoing or anticipated; no later than the time of application for Public Health Service (PHS) funded research; and within 30 days of discovering or acquiring a new Significant Financial Interest.

Per the federal regulations, a Significant Financial Interest is a financial interest consisting of one or more of the following interests of the researcher (and those of the researcher's spouse and

<sup>1</sup> [42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought"](#) (Financial Conflict of Interest Regulation)

<sup>2</sup> [https://www.hopkinsmedicine.org/research/resources/offices-policies/OPC/Policies\\_Regulations/](https://www.hopkinsmedicine.org/research/resources/offices-policies/OPC/Policies_Regulations/)



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dependent children) that reasonably appears to be related to the researcher's institutional responsibilities.

With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.

For the purposes of this definition, "remuneration" includes:

- salary
- any payment for services not otherwise identified as salary, such as:
  - consulting fees
  - honoraria
  - paid authorship
- Equity interest, which includes:
  - stocks
  - stock options
- other ownership interests as determined through reference to public prices or other reasonable measures of fair market value

With regard to any nonpublicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000 — or when the researcher (or the researcher's spouse or dependent children) holds any equity interest (e.g., stock, stock option or other ownership interest) in the entity.

In addition, intellectual property rights and interests (e.g., patents, copyrights) present a Significant Financial Interest upon receipt of income related to such rights and interests.

### **Review and Management of Disclosures**

The Office of Human Research Administration's Outside Interests Committee reviews outside interest disclosures and makes determinations regarding the resolution of actual or perceived conflicts of interest related to research, consistent with applicable federal regulations, institutional policies and procedures, and the policies of JHU SOM.

The Outside Interests Committee consists of a multidisciplinary team including the Chief Executive Officer or designee; Chief Science Officer or designee; Chief Medical Officer or designee; a physician engaged in human subjects research; a researcher of basic science with a PhD; a faculty member with a Doctor of Medicine (MD); and an administrator with familiarity



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with conflict of interest issues. Outside interests involving JHU SOM faculty may also require additional review by JHU SOM's Office of Policy Coordination.

As applicable, recommendations concerning the management of financial interests that may relate to human subjects research will be communicated to the responsible Institutional Review Board (IRB). To ensure the welfare and rights of human research participants, the responsible IRB will have the full and final authority for implementing the decision concerning the role of the researcher in the human subjects research protocol, and the content of the informed consent form.

If the Outside Interests Committee identifies an actual or perceived financial conflict of interest, the Committee will determine whether a management plan is needed. Management plans may include, but are not limited to, the following conditions/requirements:

- Disclosure - disclosure is required in most cases and generally includes:
  - public disclosure of the financial interests of the researcher and of the Institute, if applicable, in all relevant publications, presentations (whether or not academic presentations);
  - disclosure to the appropriate co-investigators, members of the laboratory or research group, and students or trainees; and
  - disclosure on human subject consent forms;
- Restriction on Equity - requirement that options, warrants, and similar instruments not be exercised without the prior permission of the Outside Interests Committee;
- Limiting the Role of the Researcher with a Financial Interest - requiring that the role of the researcher with the financial interest be limited in some way (e.g., the researcher 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;



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- 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 (e.g., 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); or
- 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.

### **Monitoring**

Whenever the Outside Interests Committee implements a management plan, the Committee will monitor the researcher's compliance with the management plan on an ongoing basis until the completion of the research project.

### **External Reporting**

To comply with federal regulations, the Institution will make available to the public within five (5) days of a request the following information with respect to financial conflicts of interest (FCOIs) with PHS-funded research:

1. Researcher's name
2. Researcher's title and role with respect to the research project
3. Name of entity in which a significant financial interest is held
4. Nature of the significant financial interest
5. 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



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To comply with federal regulations, prior to the expenditure of funds,<sup>3</sup> the Institute will report to the PHS awarding component the following information with respect to FCOIs with PHS-funded research:

1. Project number
2. Program director/principal investigator
3. Name of researcher with financial conflict of interest
4. Name of entity in which a significant financial interest is held
5. Nature of the significant financial interest
6. 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
7. 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
8. Description of key elements of the Institution's management plan, including:
9. Role and principal duties of the conflicted researcher in the research project
10. Conditions of the management plan
11. How the management plan is designed to safeguard objectivity in the research project
12. Confirmation of the researcher's agreement to the management plan
13. How the management plan will be monitored
14. Other information as needed

Researchers 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 an FCOI with research.

If the Institute identifies an outside interest or activity that was not timely disclosed by a researcher or not previously reviewed by the Outside Interests Committee, the Committee will promptly review, determine whether a management plan is needed, and take other corrective action as appropriate. If the Committee determines that a management plan is needed, such management plan will be implemented within 60 days.

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<sup>3</sup> The Institute is also required to report to the PHS awarding component (1) within 60 days of identification of the FCOI for a researcher who is newly participating in the project; (2) within 60 days for new, or newly identified FCOI of an existing researcher; (3) at least annually (at the same time as when the Institute is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and (4) following a retrospective review to update a previously submitted report, if appropriate.



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The Director of Research Administration will promptly notify the applicable awarding agency if bias is found with the design, conduct or reporting of PHS-funded research. The Director will also submit documentation of the Institute's review and a completed Mitigation Report in accordance with federal regulations.<sup>4</sup>

### **Subrecipients**

The Institute may carry out aspects of PHS-funded research through a subrecipient with which the Institute contracts through a subaward agreement or other similar contract to provide research funding. The Institute will grant such subawards where the subrecipient has its own policy on FCOIs and certifies, through the subaward agreement or other contract, its policy complies with applicable PHS regulations. The subaward agreement or other contract will specify the time period(s) for the subrecipient to report all identified FCOIs to the Institute, which will be sufficient to allow the Institute to provide timely reports to the PHS funding agency as applicable and in accordance with this Policy.

### **Training**

All researchers must complete training on:

- The applicable regulations applicable to outside interests and financial conflicts of interest in research; and
- The Institute's and Johns Hopkins University's policies and procedures governing conflicts of interest in research and the researcher disclosure responsibilities and requirements.

Training must be completed:

- Prior to engaging in research related to any PHS-funded grant;
- At least every 4 years via Johns Hopkins University's online learning management system; or
- Immediately, if:
  - The Institute revises its conflicts of interest policies and the revisions affect the disclosure requirements of researchers;
  - A researcher is new to the Institute; or
  - A researcher is not in compliance with this Policy, JHU SOM conflict of interest policies, or an imposed management plan.

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<sup>4</sup> 42 CFR 50.605(a)(3)(iii)



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## **Compliance**

Failure to comply with this policy may lead to disciplinary action(s), which may include suspension or termination of research activities or involvement in research. As noted above, the Institute will promptly notify the relevant PHS awarding component in the event that it finds that a researcher's failure to comply has biased the design, conduct, or reporting of PHS-funded research. Such notification will include the corrective action taken or to be taken in response to the identified researcher non-compliance.

Federal awarding agencies may also impose special conditions on a grant to allow the grantee to take corrective action. If a grantee has failed to materially comply with the terms and conditions of an award, a federal institution may take action to wholly or partly suspend the grant, pending corrective action, or it may terminate the grant.

## **Record Retention**

The Institute will maintain all outside interests and financial conflicts of interest in research-related records for a minimum of three years from the date the final expenditures report is submitted to the PHS and in accordance with Institute's Record Retention Policy and/or sponsor requirements.