



Kennedy Krieger Institute
Research Administration
Policies and Procedures

Policy: Conflicts of Interest and Commitment in Research

Issue Date:
January 10, 2022

Purpose:

Kennedy Krieger Institute is committed to conducting research with the highest ethical standards, protecting the interests of human research participants, and maintaining objectivity in the design, conduct, and reporting of research. Members of the Kennedy Krieger community are expected to conduct their relationships with each other, the Institute, and outside organizations with honesty and in a manner that supports the Institute’s mission.

This Policy establishes standards to ensure that research is conducted with integrity and openness, and that the rights and welfare of human research participants are protected. Any conflicts between an individual’s professional obligations to the Institute and personal, private interests must be identified, effectively managed, and reduced or, when necessary, eliminated for research conducted at the Institute.

Kennedy Krieger Institute employees who hold faculty appointments at the Johns Hopkins Institute are also required to comply with applicable Johns Hopkins Institute policies,¹ and employees with faculty appointments at other institutions may be required to satisfy policies and conditions of those institutions also.

Policy:

Kennedy Krieger employees owe their primary professional allegiance to the Institute, and their primary commitment of time and intellectual energy should be to the education, patient care, research, and scholarship programs of the Institute. At the same time, the Institute recognizes that engagement with outside parties such as governments, other non-profit organizations, for-profit entities, and the public is important for advancing the Institute’s non-profit mission. The Institute encourages these independent activities and seeks to support employees to engage in them, consistent with satisfying high ethical standards and applicable regulatory requirements and with producing the best research, education and clinical care.

Conflicts of interest may arise when an individual’s financial or other interests could influence, or appear to influence, the conduct of their activities for Kennedy Krieger. Conflicts of commitment are similar, and arise when an individual accepts or incurs conflicting obligations between or among multiple employers or other entities.

It is the policy of Kennedy Krieger Institute (“Institute”) that all Institute faculty, staff and others involved in the design, conduct, or reporting of research (“Covered Individuals”) must identify

¹ For example, the School of Medicine policies may be found here:
https://www.hopkinsmedicine.org/research/resources/offices-policies/OPC/Policies_Regulations/



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and disclose all Significant Financial Interests and Outside Activities (defined below) so that potential, perceived, and actual conflicts of interest or conflicts of commitment may be identified and managed. Having a conflict of interest or conflict of commitment does not necessarily imply improper conduct of research. Rather, conflicts of interest and conflicts of commitment must be identified and managed, reduced, or eliminated in accord with this Policy so that they do not threaten the integrity of research or the integrity of other Institute operations.

Presumptively Prohibited Activities

There are certain types of Significant Financial Interests and Outside Activities that create such strong appearances of or actual Conflicts of Interest and Conflicts of Commitment that management conditions are usually insufficient to protect the integrity of the Institute and, generally, are prohibited under this Policy. The most common types of prohibited activities are listed below.

- A. Outside Activities are prohibited if they involve the use of Institute proprietary information or intellectual property without a license to such Institute intellectual property that is executed with the Institute or its delegate.
- B. Outside Activities that compromise the basic scholarly independence and freedom of action that are central to the Institute's academic mission are prohibited (this includes Outside Activities that restrict a faculty member's ability to conduct Institute Research or other academic activity).
- C. Outside Activities that prevent full-time staff or faculty from fulfilling their primary responsibilities to the Institute are prohibited.
- D. Outside Activities that involve the non-incident use of Institute resources are prohibited. Non-incident use of Institute resources includes but is not limited to: (i) extensive use of Institute electronic mail for Outside Activity purposes; (ii) any use of Institute laboratory space or equipment for Outside Activity purposes, and (iii) any use of Institute administrative services for Outside Activity purposes.
- E. Covered Individuals who are full-time employed by Kennedy Krieger may not provide patient care at a facility or practice other than the Institute unless the patient care services are the subject of a contract between the Institute and the outside facility, practice, or sponsoring or funding entity.
- F. A Covered Individual may not serve as principal investigator of any human subjects research protocol or sponsor-investigator of an FDA-regulated clinical trial when a Covered Individual has a Significant Financial Interest that is related to the human subjects research.
- G. A Covered Individual may not have any involvement in an Institute business decision (including but not limited to subaward, procurement, licensing, and sponsored research decisions) when the Covered Individual has a Significant Financial Interest or Outside



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Activity that may create the appearance of a Conflict of Interest or Conflict of Commitment in that decision-making.

- H. Direction of compensation for Outside Activity to an Institute account is prohibited. Covered Individuals are not allowed to direct their personal consulting income to any Institute account, including an Institute research or discretionary account.
- I. Covered Individuals are prohibited from providing expert witness service in litigation and other contested matters where Kennedy Krieger or a constituent entity is adverse to the party who proposes to engage the Covered Individual as an expert witness.
- J. Full time employees and salaried part-time employees may not conduct Research outside of Kennedy Krieger except through an approved Institute agreement unless they have specific Department head or Chief Science Officer approval.

Definitions:

For purposes of this Policy, the terms below have the following definitions:

1. **Conflict of Commitment (COC):** An Outside Activity that may interfere with a Covered Individual's responsibilities to the Institute or that is of a nature that the activity may only be performed through the Covered Individual's Institute role.
2. **Conflict of Interest (COI):** A Significant Financial Interest or Outside Activity that could compromise or appear to compromise the integrity or objectivity of the Covered Individual's decision making. An individual need not act against the Institute's interests for a Conflict of Interest to exist; the mere fact that the individual has the Significant Financial Interest or Outside Activity is sufficient to create a Conflict of Interest.
3. **COI Management Plan:** A plan for eliminating, managing, or mitigating a Covered Individual's potential, actual or perceived COI and/or COC.
4. **COI Reporting Form:** The form that Covered Individuals complete electronically each year, and at various other points within a year, to report their Financial Interests, Outside Activities, and other interests that could affect or appear to affect their research, including reporting their Significant Financial Interests that reasonably appear to be related to their professional expertise and Institutional Responsibilities. The Significant Financial Interests of a Covered Individual's spouse and dependent children must also be reported if they are related to the Covered Individual's institutional responsibilities.
5. **Covered Individual:** Institute employees, officers, faculty, and staff who are a principal investigator or project director, co-Covered Individuals, or key personnel on Research,



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regardless of funding, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of Research.

“Design, conduct, or reporting” includes, but is not limited to:

- a. Designing, conducting, and/or directing Research;
 - b. Enrolling research subjects (including obtaining informed consent, if applicable) or making decisions related to eligibility for enrollment; and
 - c. Analyzing, reporting, presenting, or publishing research data.
6. **Financial Interest:** Income, honoraria, or other compensation including, but not limited to, equity, stock or stock options, royalties or other distributions, the right to future royalties or other distributions, proprietary interests in intellectual property that has been licensed by the Institute and/or an Institute affiliate like Johns Hopkins Technology Venture (as appropriate) or in-kind interests received by a Covered Individual or that Covered Individual’s spouse, domestic partner, or dependent children that reasonably appear to be related to the Covered Individual’s Institute responsibilities or activities. In addition, a Financial Interest exists when a Covered Individual or a Covered Individual’s spouse, domestic partner, or dependent children maintain fiduciary obligations to an outside entity when those fiduciary obligations reasonably appear to be related to the Covered Individual’s institutional responsibilities or activities.
- a. For Covered Individuals who receive funding from U.S. Public Health Service agencies, including the National Institutes of Health, Financial Interest shall also include reimbursed or sponsored travel related to the Covered Individual’s institutional duties, except when such reimbursed or sponsored travel is reimbursed or sponsored by a U.S. federal, state, or local government agency, a domestic institution of higher education as defined at 20 U.S.C. 1001(a), or a U.S. academic teaching hospital, medical center, or research institute that is affiliated with such a domestic institution of higher education (“U.S. Institutions of Higher Education”).
 - b. For Covered Individuals who engage in Research that is regulated by the U.S. Food and Drug Administration (“FDA”), Financial Interest shall also include status as an inventor of intellectual property that comprises the clinical investigational product to be studied in the Institute Research. Status as an inventor of intellectual property that is not yet covered by an issued patent shall be determined by inclusion on a report of invention to the Institute, and/or the Johns Hopkins Technology Ventures, as appropriate.



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7. **Institutional Responsibilities:** All of a Covered Individual’s professional responsibilities on behalf of the Institute, including, but not limited to, research, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as federal study sections, Institutional Review Boards (IRBs) or Data and Safety Monitoring Boards.
8. **Outside Activity:** The provision of services and time commitments for non-Institute activities that: (i) are based on the expertise and knowledge of the Covered Individual and reasonably appear to be related to the Covered Individual’s Institute responsibilities or activities; or (ii) may reasonably be deemed to significantly impact the Covered Individual’s ability to satisfy his or her Institute responsibilities and activities.
 - a. Outside Activities include, but are not limited to, consulting, service on governing boards (e.g., board of directors of for-profit and non-profit entities) or scientific advisory boards, outside speaking, professional or academic society work, outside administrative responsibility such as serving as an officer or employee of an outside entity, expert witness activity, and outside teaching.
 - b. The following activities are considered Outside Activities but are excluded from the disclosure requirements of this Policy when undertaken at, for, or on behalf of a U.S. federal, state, or local government agency, or a domestic institution of higher education as defined at 20 U.S.C. 1001(a), or a U.S. academic teaching hospital, medical center, or research institute that is affiliated with such a domestic institution of higher education (“U.S. Institutions of Higher Education”): Seminars, one-off or invited lectures, and service on an advisory committee or review panel.
 - c. The following activities are not considered Outside Activities:
 - i. Uncompensated, domestic, scholarly activities that are traditionally undertaken in the Covered Individual’s academic field, including but not limited to service on academic journals. For the avoidance of doubt, any compensation received for such traditional academic activity—including honorariums and travel reimbursement—is a Financial Interest and must be reported under this Policy.
 - ii. Services to the Institute that involve outside entities, e.g., services that are provided at another organization through a Kennedy Krieger clinical services agreement.



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9. PHS-Funded Research: PHS-Funded Research means Research funded in whole or in part by the U.S. Public Health Service.

10. Reportable Travel: Travel that is either reimbursed or sponsored by a non-Kennedy entity, and that is related to the Covered Individual's institutional responsibilities. Reimbursed travel is travel for which the Covered Individual is directly reimbursed by the sponsoring entity. Sponsored travel is travel that is paid directly by the sponsoring entity and is not reimbursed to the Covered Individual.

11. Research: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research (*e.g.*, a published article, book or book chapter) and product development (*e.g.*, a diagnostic test, drug or device), and non-research projects such as training for which external funding is received.

Research also includes any such activity for which a proposal is submitted for funding from external sources through a grant, contract or agreement, including, but not limited to, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects and research resources awards. Research also includes projects that are internally funded (*i.e.*, funded by the Institute), as well as research for which approval of an IRB (or IRB exemption) or Institutional Animal Care and Use Committee (IACUC) is required.

12. Significant Financial Interest (SFI): A Financial Interest received by a Covered Individual or their immediate family (spouse, domestic partner, or dependent child) during the 12 months preceding the disclosure or on the date of the disclosure that appears reasonably related to the Covered Individual's institutional responsibilities and meets one or more of the following thresholds:

- a. Publicly-traded entity: \$5,000 or more in aggregated remuneration (*e.g.* salary, consulting fees, honoraria, payment for services) and equity interest (stock, stock option or other ownership interests);
- b. Non-publicly traded entity: \$5,000 or more in aggregated remuneration or equity interest of any value;
- c. Any income from intellectual property rights and interests; and
- d. *For NIH-funded Covered Individuals:* reimbursed or sponsored Travel worth \$5,000 or more.

The term Significant Financial Interest excludes:



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- a. Income from seminars, lectures, teaching engagements, advisory committees, review panels or travel paid by a U.S. Federal, state, or local government agency, a U.S. institution of higher education and affiliated research institutions, U.S. academic teaching hospital, or U.S. medical center; and
 - b. Equity interests in, or income from, investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual does not directly control the investment decisions made in these vehicles.
13. **Sponsored Research:** A systemic investigation, study or experiment designed to develop or contribute to generalizable knowledge supported by a grant, cooperative agreement, sponsored research agreement, designated gift to the Institute, or internal award. The term encompasses basic and applied research, including human subject research, animal research and product development.
14. **Subrecipient:** An external entity who conducts substantive, programmatic work or an important or significant portion of a Sponsored Research project

Procedures

1. Training

All Covered Individuals who engage in Research must complete COI and COC training: (i) before engaging in Research, (ii) at least once every four years thereafter, and (iii) whenever this Policy is substantively revised. COI and COC training will be provided by or through the Research Administration Department. Whenever the Institute determines that a Covered Individual is not in compliance with this Policy, that individual will be required to complete additional COI and COC training and may face other requirements.

2. When to Disclose

Covered Individuals who engage in Research must timely disclose all Significant Financial Interest and Outside Activities, as applicable, in writing through an Institute-designated online or electronic disclosure system. Disclosures must be made:

- A. Before engaging in an Outside Activity;
- B. At least annually when Research is ongoing or anticipated;
- C. No later than the time of application for PHS-funded research; and
- D. Within 30 days of discovering or acquiring a new Significant Financial Interest, including reimbursed or sponsored travel for PHS-funded researchers.



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3. What to Disclose

The following activities must always be disclosed by Covered Individuals:

- A. Proposed Outside Activities, whether or not they are compensated;
- B. Significant Financial Interests;
- C. For Covered Individuals who engage in Public Health Service-funded research, all reimbursed or sponsored travel related to the Covered Individual's institutional responsibilities, if the value of the Covered Individual's (including his/her spouse, domestic partner, and dependent children) reimbursed travel from any third party exceeds \$5,000.00 in the previous 12 months.

4. How to Disclose

Covered Individuals who engage in Research must timely disclose all Significant Financial Interests and Outside Activities in writing through an Institute-designated online or electronic disclosure system.

5. Review of Disclosed SFIs and Outside Activities

After SFI and Outside Activities are disclosed, the Institute shall determine whether a particular SFI or Outside Activity creates a COI or COC, or appearance of COI or COC, that must be managed or eliminated.

The Research Administration Department (RAD) reviews SFI disclosures and makes determinations regarding identification and disposition, e.g., management or elimination. The RAD will assist in reviewing proposed Outside Activities also, in consultation with Department Chairs and/or the Chief Science Officer (or delegate), as appropriate.

For SFI disclosures, the Institute may conduct additional review as it deems appropriate, including consideration of the following:

- Presence of a Conflict of Interest or Conflict of Commitment.
- Risk to the rights and safety of human subjects in research.
- Impact on integrity and objectivity of academic scholarship and research data.
- Risk to Institute independence and objectivity in business transactions.
- Impact on the independence of clinical care or other professional practice judgments.



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- Impact on a Covered Individual's ability to devote professional loyalty, time, and energy to teaching, research, patient care or administrative responsibilities in accordance with the Covered Individual's responsibilities to the Institute.

RAD may be advised by the Outside Interests Committee (through individual members or as a group) in reviewing and making determinations regarding identification and resolution of actual or perceived COI or COC, consistent with applicable federal regulations, institutional policies and procedures.

Outside Interests Committee

The Outside Interests Committee meets periodically (in-person or through virtual means) and shall be comprised of at least three, multidisciplinary members selected from: (a) Chief Science Officer or designee; (b) Chief Medical Officer or designee; (c) a physician engaged in human subjects research; (d) a researcher of basic science with a PhD or a faculty member with a Doctor of Medicine (MD); (e) an administrator with familiarity with conflict of interest issues; and (f) others as identified by the RAD. The General Counsel may advise the Outside Interests Committee and the RAD.

6. Results of Review

If the Institute determines that a COI or COC exists, or a perceived COI or COC that warrants management, the Institute shall establish a Conflict Management Plan to manage the COI or COC or it will prohibit the activity if the COI or COC is deemed not manageable.

7. Review of Disclosures and Management of COI and COC

When a real or perceived COI or COC is identified and deemed manageable by the relevant Institute official, the Institute shall create a plan to manage the COI or COC in a way that allows the Covered Individual to pursue the SFI or Outside Activity while protecting the integrity of Institute activities.

Management plans may include, but are not limited to, the following conditions/requirements:

- A. Disclosure of the COI, which may include: public disclosure of the COI of the Covered Individual in, among other places, human subject research consent forms and all relevant publications and presentations, including internal Institute presentations.
- B. Limiting the Covered Individual's role in Research, which may include restrictions on the Covered Individual's ability to serve as principal investigator, serve as sponsor-investigator of a U.S. Food and Drug Administration investigational new drug



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- application or investigational device exemption, analyze data or results, participate in the conduct of the study, or obtain consent from human research subjects.
- C. Oversight, including appointment of a disinterested individual or group to monitor the Research activity.
 - D. Limitations on Institute business activity, which may require prohibiting the Covered Individual from, among other things: (i) negotiating on behalf of the Institute; (ii) receiving certain confidential or proprietary Institute information; or (iii) discussing information related to the COI with Institute officers, faculty, or staff.
 - E. Divestiture of specified Financial Interests.
 - F. Severance or limitation of Outside Activities or Financial Interests that create actual or potential COI or COC.

Once the Institute has created a management plan, that management plan shall be conveyed to the Covered Individual in writing. All arrangements may be reviewed again if circumstances change or there is new information.

As appropriate, 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 determining the role of the researcher in the human subjects research protocol and the content of the informed consent form.

The Institute will monitor compliance with management plans until the completion of related Research.

Responsibilities:

All Covered Individuals are responsible for becoming familiar with and following this Policy.

- A. *External Reporting Obligations:* In accordance with applicable regulations and research sponsors' policies and guidelines, the Institute may be obligated to report identified Financial Conflicts of Interest to the sponsor of research that could be affected by the presence of the financial Conflict of Interest. Additional special reporting and accessibility requirements apply to PHS-Funded Research
- B. *Report Violations:* All Covered Individuals have a responsibility to report violations of this policy to the institution.



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External Reporting of Conflicts of Interest:

To comply with federal regulations, prior to the expenditure of funds, the Institute will report to the PHS awarding component the following information as required for certain Financial Interests:

- A. Project number.
- B. Program director/principal investigator.
- C. Name of investigator with financial conflict of interest.
- D. Name of entity in which a Financial Interest is held.
- E. Nature of the Financial Interest.
- F. Approximate dollar value of the Financial Interest within ranges, 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.
- G. Description of how the Financial Interest relates to the federally funded research and basis for the University's determination of a Conflict of Interest.
- H. Description of the key elements of the Institute's management plan with respect to the Conflict of Interest, including: (i) role and principal duties of the conflicted investigator in the research project; (ii) conditions of the management plan; (iii) how the management plan is designed to safeguard objectivity in the research project; (iv) confirmation of the investigator's agreement to the management plan; (v) how the management plan will be monitored; and (vi) other information as needed.

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 enter into such subawards only where the subrecipient has its own policy on conflicts and certifies, through a written agreement, that 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 financial COIs 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 and applicable PHS regulations.

Consequences for Violating this Policy and Enforcement:

Failure to comply with this Policy and related policies is subject to disciplinary action, up to and including suspension without pay, or termination of employment or association with the Institute, in accordance with applicable disciplinary procedures. In the event that the Institute determines



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that a Covered Individual's undisclosed Outside Activity, relationship or interest has resulted in bias to the design, conduct, or reporting of research, the Institute will report promptly the noncompliance to research sponsors and/or funding agencies, as required.

Federal awarding agencies may also impose special conditions on a grant or contract, including suspending the award, pending corrective action, or termination.

In the case of human subjects research, failure to comply with this Policy may also be subject to responsible IRB policies on noncompliance. Potential sanctions under this Policy and related policies may range from a verbal warning to placement of a letter in the Covered Individual's employment file prior to suspension to termination.

Further, if certain compliance failures occur with respect to Conflicts of Interest related to PHS-Funded Research, an interim management plan will be implemented and a retrospective review of such research will be undertaken to determine whether bias is present in the design, conduct, or reporting of the research. Those failures include: (i) failure to timely disclose Financial Interests; (ii) failure by the Institute to review or manage a Conflict of Interest related to PHS-Funded Research; and (iii) failure of a Covered Individual to comply with a management plan. If, after a retrospective review, the Institute determines that bias in research has occurred, it will develop and implement a mitigation plan. The Institute will promptly notify the federal funding entity of the findings and corrective actions that the Institute has taken or will take.

If the Institute identifies an Outside Activity or Financial Interest that was not timely disclosed in accord with this Policy, the Institute will promptly review, determine whether a management plan is needed, and take other corrective action as appropriate. If the Institute determines that a management plan is needed, such management plan will be implemented within 60 days. The Director of Research Administration Department will promptly notify the applicable Sponsored Research funding 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.

Record Retention:

The Institute will maintain all Outside Activity and SFI records in accordance with Institute's Record Retention Policy and/or sponsor requirements, whichever is longer. For PHS-Funded Research, this means a minimum of three years from the date the final expenditures report is submitted to the PHS.

References include the following regulations or successor regulations:

PHS regulations:



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42 C.F.R. Part 50, Subpart F, *Promoting Objectivity in Research* (PHS grants)
45 CFR Part 94, *Responsible Prospective Contractors* (PHS contracts);
45 CFR Part 75, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards*

FDA regulations:

21 CFR Part 54, *Financial Disclosure by Clinical Investigators*,
21 CFR 312.53, *Selecting Investigators and Monitors* (drugs);
21 CFR 812.110, *Specific Responsibilities of Investigators* (devices)
21 CFR 812.43, *Selecting Investigators and Monitors* (devices)

National Science Foundation requirements:

Proposal and Award Policies & Procedures Guide (2021), Chapter IX, *Grantee Standards*