

Answers to Frequently Asked Questions about Kennedy Krieger Conflicts of Interest and Commitment in Research Policy & Procedure

1. Who is covered under this Policy?

All Kennedy Krieger Institute faculty, staff, and others involved in the design, conduct, or reporting of research (“Covered Individuals”) are covered under this Policy and are therefore subject to the reporting requirements outlined in the Policy. This includes Kennedy Krieger Institute employees with faculty appointments at Johns Hopkins University.

2. Who must report?

All Covered Individuals must complete an annual disclosure report, regardless of whether they have a reportable interest or activity (e.g., Significant Financial Interest (SFI) or Outside Activity (OA) as defined in the Policy in a reporting year).

3. What is considered “research” under this Policy?

Research is defined as the 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 (e.g., research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants).

Research further includes projects that are internally funded (funded by the Institute), as well as research for which approval of an IRB (or IRB exemption) or IACUC is required.

4. What does it mean to be involved in the “design, conduct, or reporting of research”?

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

- Designing, conducting, and/or directing research
- Enrolling research subjects (including obtaining informed consent, if applicable) or making decisions related to eligibility for enrollment; and
- Analyzing, reporting, presenting, or publishing research data.

Generally, this may include any individual involved in the research who works independently enough to affect the objectivity of the design, collection, or analysis of research data or reporting of research results. It includes all study team members on an IRB or IACUC application.

5. What must Covered Individuals do in order to comply with this Policy?

Covered Individuals must complete:

- (1) training (Training may be accessed [here](#)).
- (2) annual disclosure reporting (even if they do not have any reportable interests/activities); and
- (3) ad hoc disclosures as required in the Policy (e.g., if a new interest arises; and they must obtain pre-approval for Outside Activities).

Note: Every principal investigator and study team member on a new or active research study is required to re-certify their Conflict of Interest and Commitment (COIC) compliance training by Monday, February 28, 2022.

You must use your JHED and jh.edu email account to access [eDisclose](#) and the [COIC Training](#). For assistance with locating you JHED, please see Question 14 below.

6. What must be reported?

All Significant Financial Interests (SFI) (for self, partner and dependent children) and Outside Activities (OA) must be reported.

7. What is a Significant Financial Interest (SFI)?

A **Significant Financial Interest (SFI)** is 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, including 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.

8. What is a Financial Interest?

A Financial Interest is defined as 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 (NIH), 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.

9. What is an Outside Activity (OA)?

An Outside Activity is defined as 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.

10. What are some examples of Outside Activities?

Outside Activities may include, but are not limited to, the following when performed outside of official duties for Kennedy Krieger: (a) consulting, (b) service on governing boards (e.g., board of directors of for-profit and non-profit entities) or scientific advisory boards, (c) speaking, professional or academic society work, (d) serving as an officer or employee of an outside entity; (f) expert witness activity, (g) clinical services (e.g., moonlighting); and (h) teaching.

11. When must reports be made?

Covered Individuals are required to report:

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

12. When are Covered Individuals required to complete annual reporting and certification?

Kennedy Krieger annual reporting and certification will begin February 1, 2022 and must be completed within that month.

Note: Covered Individuals will not be able to initiate this annual certification process until February 1, 2022.

However, the annual certification does not affect the obligation to disclose outside activities and/or financial interests as they arise and before proposing related research. Annual certification is a separate activity from creating a new disclosure or updating an existing disclosure.

13. What time period is covered for the 2022 annual report and certification?

Covered Individuals should report any outside interests or activities from the time period beginning December 2020 through the present date.

14. Where do Covered Individuals submit their reports?

Reports should be submitted through Johns Hopkins University's web-based [eDisclose](#) system. Please see link below.

<http://edisclose.jhu.edu/>

Note: You must use your JHED and jh.edu email account to access eDisclose.

How do I find my JHED Login ID (LID)?

The easiest way to find your JHED LID is to search for yourself in the JHED directory from any campus computer. Due to security and privacy concerns, there are restrictions on information (such as the Login ID) if you attempt to search from off-campus.

1. Go to <http://jhed.johnshopkins.edu/> (this link will open a new window).
2. At the top of the screen will be "Search for a person." Enter your Last Name in the text field that says "Last Name, First Name" and click on the "Go>>" button.

For assistance with eDisclose, please contact COI@kennedykrieger.org

15. What if a Covered Individual does not have an eDisclose account?

If a Covered Individual is need of an eDisclose account, please contact COI@kennedykrieger.org.

16. What activities or interests are prohibited?

Activities that involve a conflict of interest (COI) or conflict of commitment (COC) that cannot be managed.

Additionally, certain activities create such a strong conflict or appearance of conflict (either financial or commitment) that presumptively they are barred. These include:

- use of Institute property without a license from the Institute;

- non-incident use of Institute resources (e.g., use of KKI labs);
- patient care by full time employees outside of the Institute absent an agreement with the Institute;
- serving as a PI or Sponsor-Investigator (IND holder) when one has an SFI related to the research;
- directing personal, outside income to Institute accounts;
- having any involvement in an Institute business decision (including but not limited to subaward, procurement, licensing, and sponsored research decisions) when the Covered Individual has an SFI or OA that may create the appearance of a COI or COC in that decision-making; and
- full-time employees' and salaried part-time employees conducting research as an OA absent an agreement between Kennedy and the outside entity and Department head or Chief Science Officer approval.

17. What approval is required in order to participate in Outside Activities?

Generally, outside activities must be pre-approved and financial interests resulting from them must be reported in accord with the Policy.

18. Is there anything Covered Individuals *shouldn't* disclose?

You must **disclose the outside activities whether compensated or not and significant financial interest (of you, partner or dependent children) if they are related to your "institutional responsibilities."** Institutional responsibilities may include, among other things, research, teaching, clinical care/practice, and administrative responsibilities. Disclosure is required so the Kennedy Krieger can review outside interests and activities for conflict of interest and conflict of commitment.

Covered Individuals do not need to disclose the following activities if they are performed as part of their overall time and effort ("official duties") for Kennedy Krieger:

- Service on advisory committees or boards and review panels *provided to* a U.S. state, federal or local government agency, U.S. teaching hospital, U.S. medical center, or U.S. institution of higher education or related U.S. research institute.
 - **NOTE:** The same services provided to non-US entities, including foreign-based joint ventures must be disclosed; when uncertain or unclear, disclose.
- Speaking, teaching and lecturing when provided to a U.S. state, federal or local government agency, U.S. teaching hospital, U.S. medical center or institution of higher education or related U.S. research institute
 - **NOTE:** The same services provided to non-US entities, including foreign-based joint ventures must be disclosed; when uncertain or unclear, disclose.
- Payments from the Institute (e.g., salary, salary supplement, reimbursements), other than payments derived from institutional licenses of intellectual property;
- Confidentiality agreements with no services or remuneration

In addition, Covered Individuals do not need to report their participation in local

community activities (including, but not limited to, religious institutions, schools, clubs, and local charities outside the biomedical field), unless (i) you conduct research that relates to the organization, or (ii) the organization has a relationship with the Institute or seeks to do business with the Institute and you have any role in that relationship or business.

19. Does a Covered Individual have to report honoraria received for speaking engagements at U.S. universities (e.g. honoraria for speaking at an invited seminar or grand rounds)?

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 is excluded from our definition of Significant Financial Interest (SFI).

Therefore, Covered Individuals do not need to report payment for activities/services such as honoraria for grand rounds and other lectures, and honoraria for reviewing NIH grants, consultant on a NIH-funded study if (1) these services were provided to (and payment was received from) a U.S. state, federal or local government agency, U.S. teaching hospital, U.S. medical center, or U.S. institution of higher education or related U.S. research institute and (2) these activities were performed as part of your institutional responsibilities at KKI.

However, if they receive payment for similar services from any other entity, such as a U.S. based foundation, any income over \$5,000 is considered SFI and must be disclosed.

20. What happens to the reports once they are submitted in eDisclose?

The Research Administration Department (RAD) will review disclosures and make determinations regarding identification and disposition (e.g., management plan or elimination of the conflict of interest).

RAD may also consult with the Kennedy Krieger Outside Interests Committee to make determinations regarding SFI disclosures. The General Counsel may advise the Outside Interests Committee and the RAD.

RAD will also assist in reviewing proposed Outside Activities, in consultation with Chairs and/or the Chief Science Officer (or delegate), as appropriate.

21. What are some examples of COI management plans?

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

- 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.
- 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 application or investigational device exemption, analyze data or results, participate in the conduct of the study, or obtain consent from human research subjects.

- Oversight, including appointment of a disinterested individual or group to monitor the Research activity.
- 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.
- Divestiture of specified Financial Interests.
- Severance or limitation of Outside Activities or Financial Interests that create actual or potential COI or COC.

22. Can an IRB issue a more restrictive management plan?

Yes. An IRB can issue a more restrictive management plan. In such cases, the more restrictive management plan will apply.

23. If a Covered Individual already submitted a disclosure of their Other Support to Research Administration, do they still need to submit information in an annual SFI report or Outside Activity report in eDisclose?

Yes. Although the Other Support disclosure to Research Administration may contain information that is the same as or similar to information that is required to be reported under this Policy, the Other Support disclosure (typically, via Qualtrics) is separate and distinct from the disclosures required under this Policy.

All Covered Individuals must report their SFI and outside activities in accordance with this Policy, currently through eDisclose.

24. If a Covered Individual completed an annual disclosure report in eDisclose prior to February 2022 (e.g., in August 2021), do they still need to complete the KKI annual report and certification in eDisclose in February 2022?

Yes. All Covered Individuals must complete the Kennedy Krieger annual report and certification in eDisclose in February 2022, regardless of the date of their last filing. During this process, they will be asked to review any existing disclosures to ensure they are accurate and up-to-date.

While some Covered Individuals may have already completed a report as part of their routine reporting in response to a request from Johns Hopkins, Kennedy Krieger is requiring an update to that report in February 2022 so that all Kennedy Krieger Covered Individuals will be on the same annual reporting cycle.

25. What are the training requirements?

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

Since this Policy has been substantively revised, all Covered Individuals must complete this training by February 28, 2022.

Every principal investigator and study team member on a new or active research study is required to re-certify their Conflict of Interest and Commitment (COIC) compliance training by Monday, February 28, 2022.

Training can be accessed through Johns Hopkins learning management system:

Please register [here](#) or click on the link below:

<http://lms14.learnshare.com/l.aspx?CID=89&A=2&T=412863>

26. What happens if a Covered Individual does not report in accordance with this Policy?

If a Covered Individual does not comply with this Policy, the individual will be 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 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.

27. Who do I contact if I have additional questions about this Policy and/or the reporting requirements?

For additional questions, please email COI@kennedykrieger.org