

Annual Disclosure of Outside Interests

Who, what, when, where and why to disclose your outside activities

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Kennedy Krieger Institute

Agenda

- **Disclosure Requirements - Overview**
- Scenarios – What exactly must be disclosed
- Annual Disclosure Process
- Other Disclosures
- Questions

Disclosure Requirements – Why Disclose?

- **To ensure integrity in research is maintained through identifying and managing conflicts of interest and conflicts of commitment when they arise.**

“The NIH is committed to **preserving the public’s trust** that the research we support is conducted **without bias** and **with the highest scientific and ethical standards**. The regulation on promoting objectivity in research establishes the standards to provide a **reasonable expectation** that **the design, conduct, and reporting** of NIH research will be **free from bias** resulting from investigators’ financial conflicts of interest.”

- Other sponsors follow the NIH policy, too.
- KKI has a duty to know about and proactively manage any real and perceive conflicts that may arise from a researchers outside activities, particularly as they relate to outside sponsors and KKI’s mission.

Who, Where & When to Disclose?

- **Who:** All KKI faculty, staff, and others involved in the design, conduct, or reporting of research (“Covered Individuals”) are covered under the policy including the reporting requirements, including KKI employees with faculty appointments at JHU.
 - **For example,** Institute PIs, Co-PIs, all team members on an IRB study, and researchers expected to be named as a co-author on a publication.
- **Where:** Disclosures must be made **through eDisclose**
- **When:** New annual disclosure process begins **March 1, 2023, and closes on March 31, 2023**
 - Contact coi@kennedykrieger.org if you need a new eDisclose account (JHED account).

What Must I Disclose – Financial Relationships

- **Disclose all financial interests and outside activities for you, your spouse and dependent children that could reasonably appear to be related to your KKI responsibilities or professional expertise.**
 - “**KKI responsibilities or professional expertise**” means any activities you undertake on behalf of KKI or that pertain to your area of professional knowledge.
- **Financial interests** – equity, stock or stock options, royalties or other distributions, the right to future royalties or other distributions, proprietary interests in intellectual property other than those licensed by the Institute or an Institute affiliate like Johns Hopkins Technology Venture. Disclose even if an amount/value is not readily available.

What Must I Disclose – Financial Relationships

- **Financial Interests include:**

- **Publicly traded company**

- \$5,000+ in compensation and/or equity interest

- **Non-publicly traded company**

- \$5,000+ in compensation
- **Any** equity interest

- **Intellectual Property**

- Any income related to rights or interest, other than KKI or JHU licensed technology

- **Appointment to another entity** (regardless of compensation)

- **Reimbursed or sponsored travel**

- \$5,000+ reimbursed/sponsored travel by US entity
- **Any** reimbursed/sponsored travel by non-US entity

- **Payments from Foreign Governments and Institutions of Higher Education**

- **All** financial interests received

What Must I Disclose – Financial Relationships

- **You do not need to disclose:**

- Income paid by KKI during your employment
 - Intellectual property rights, royalties, etc.
- Income from investment vehicles
 - Mutual funds or retirement accounts that the researcher does not directly control
- Income from service on advisory committee or review panel for US government or institution of higher learning
 - Includes associated teaching hospitals and research institutes
- Income from engagements sponsored by US government or US institution of higher learning
- **Remember to disclose** all income engagements sponsored by non-US entities (i.e., governments, institutions of higher learning, hospitals, medical centers, companies, etc.)

What Must I Disclose – Outside Activities

- **Disclose all financial interests and outside activities for you, your spouse and dependent children that could reasonably appear to be related to your KKI responsibilities or professional expertise.**
- **Outside activities** – A services or time commitments for non-Institute activities that: (i) is based on your KKI responsibilities or professional expertise; or (ii) could reasonably appear to significantly impact your ability to satisfy your Institute responsibilities and activities.
 - Examples of include consulting, board appointments, clinical services, and teaching.
- Report both paid and unpaid outside activities.

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Scenario 1 – Question

A researcher is giving a talk at a US institution of higher education that provides you with an honorarium of \$800. Does this need to be disclosed?

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A researcher is giving a talk at a US institution of higher education, and they are providing an honoraria of \$800. Do this need to be disclosed?

NO. Compensation for activities part of your KKI duties (academic talks, peer review committees) do not need to be disclosed when the activity is with a US institution of higher ed, or a hospital, even if the amount exceeds the \$5,000 threshold.

Scenario 2 – Question

A researcher receives \$8,000/year in compensation for their role as editor of a scientific journal associated with a professional society. Is this reportable?

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A researcher receives \$8,000/year in compensation for their role as editor of a scientific journal associated with a professional society. Is this reportable?

YES. Compensation received from a private entity (including non-profits) related to the researcher's professional expertise must be disclosed.

Scenario 3 – Question

A researcher has a consulting agreement with Thermo Fisher for \$3,000. Their wife holds \$3,000 in Thermo Fisher stock. Are these interests reportable as financial interests?

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A researcher has a consulting agreement with Thermo Fisher for \$3,000. Their wife holds \$3,000 in Thermo Fisher stock. Are these interests reportable as financial interests?

YES. In aggregate, Dr. X's consulting agreement and family's stock in Thermo Fisher exceeds \$5,000, and therefore the relationship must be reported.

Scenario 4 – Question

A researcher founded a company last year, but it does not yet have employees, a website, or even a product. It is worth nothing. Must the researcher report the company?

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A researcher founded a company last year, but it does not yet have employees, a website, or even a product. It is worth nothing. Must the researcher report the company?

YES. Any ownership interest in a privately held company is reportable, regardless of value.

Scenario 5 – Question

A researcher travels to the University of Melbourne to deliver a lecture and was reimbursed \$2,000 for their travel expenses. Must they report this?

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A NIH-funded researcher travels to the University of Melbourne to deliver a lecture and was reimbursed \$2,000 for their travel expenses. Must they report this?

YES. Any reimbursed travel from a foreign entity must be reported, regardless of value.

Scenario 6 – Question

A researcher won a Nobel Prize for their work. Are they required to report the prize earnings?

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Yes. The Nobel Foundation is a non-US entity, and therefore the prize must be reported. Also, the prize amount is over \$5,000 and must be reported.

Scenario 7 – Question

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Maybe. It depends on the researcher's institutional responsibilities or professional expertise. For example, if the research studies the effect of eating chocolate on people with anxiety, then it would be related, and therefore reportable.

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Annual Disclosure Process – Who Reviews

What happens to my disclosure once I submit it?

- The Research Administration Department (RAD) will review and triage all disclosures and make determinations regarding identification and disposition, in consultation with Chairs and the Chief Science Officer (or delegate), as appropriate.
- The KKI Outside Interests Committee may be consulted and the General Counsel may advise the Outside Interests Committee and the RAD.
- If necessary, RAD will take the lead in developing a COI management plans or adding “conditions” to the relationship through eDisclose, as needed.

Contact the Christy Collins (CollinsC@kennedykrieger.org)

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Disclosure Requirements – Other Disclosures

Reminder:

Disclose financial interests and outside activities throughout the year, including:

- Before engaging in a new outside activity
- At the time of proposal (proposal screening question)
- Before a new NIH/NSF award is set up
- Within 30 days of completion of a trip sponsored by an outside entity
- Within 30 days of acquiring a new significant financial interest (e.g., inheritance)



Disclosure Requirements – Other Disclosures

- **Reminder:**

- Report **all in-kind research support** and **all sponsored funding for your lab**, regardless of who is providing the support, including awards made to institutions other than KKI.
- In-kind support
 - At time of proposal (NSF, DOE, DOD, etc.)
 - At time of award (NIH, NSF, etc.)
 - In annual reports – updated other support / current & pending – federal sponsors
- Includes research activities at institutions other than KKI
- Regardless of monetary value
- All forms of support (US-based and non-US)

Disclosure Requirements – Other Disclosures

- **Changes coming soon:**
 - **Federal funding agencies are working on their forms in 2023**
 - More changes likely coming for both other support / biosketches
 - **New certification** of other support and biosketch for federal sponsors are coming soon; **PIs will need to sign both forms** and provide assurance that the information is complete and accurate of the information
 - More information will be made available when we know more
 - NSF moving to SciENcv effective October 2023 – required
 - All researchers are encouraged to get an ORCID

Questions?

Please email us at coi@kennedykrieger.org or contact collinsc@kennedykrieger.org