
QUESTION 1

Because of your position at the University, you are required to complete a Conflict of Interest Disclosure Statement. Unless indicated otherwise, the requested information applies to any activities during the previous 12 months from the date of your responses here or at any time during calendar year (CY) 2023.

- For each outside activity, equity interest and/or family association, you will be asked to complete a Conflict of Interest Disclosure Statement in its entirety.
- If you are unsure whether an outside activity, equity interest or family association is covered by a question, please disclose it.
- You may also be required to complete additional disclosures per the University's [Research Conflict of Interest and Financial Disclosure Policy, AR 7:2](#), if you engage in covered research projects. Please review AR 7:2 to determine whether that policy applies to you. Outside activities may also require prior approval annually under UK's policy on Consulting and other Overload Employment, [AR 3:9 - Faculty Consulting and Other Overload Employment](#). The overload approval request form (previously Form F) can be accessed at myUK. Further, certain "University Officials" may be required to report and have approved some relationships under UK's policy on [Institutional Conflicts of Interest Involving Research, AR 7:9](#).
- This completed Statement shall constitute a part of your University personnel records and shall be entitled to the same degree of confidentiality as other such records.

Please affirm.

QUESTION 2

Are you involved in human subjects research or clinical investigations?

QUESTION 3

Does your work involve a pending or funded grant, cooperative agreement or contract from a **Public Health Service (PHS) agency**, or other federal agency, including any sub-award from another institution?

QUESTION 4**Financial Conflict of Interest Training Module for Investigators****Background**

The Public Health Service (PHS) and the National Science Foundation (NSF) issued virtually identical conflict of interest (COI) policies in 1995. Per PHS 42 CFR 50.601, regulations were established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS will be free from bias resulting from Investigator financial conflict of interest.

The University of Kentucky conflict of interest policy was established to mirror these two policies and is applicable to all research, regardless of funding source. The University of Kentucky AR 7:2 regulation sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects.

In 2011, PHS issued a revised regulation which was effective on August 24, 2012. Grantees were required to comply to remain eligible to apply for and receive PHS funding and to continue performing on active grants. UK's policy was updated to be consistent with the revised regulation.

Who must disclose

Each “investigator” on a sponsored project proposal, award, or institutionally-sponsored research must disclose. Per UK AR 7:2, “Investigator” means the project director, principal investigator/program director, co-investigator, collaborator, senior/key personnel, faculty associate, and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, or proposing of research or other sponsored activity. Individual sponsors may have more expansive requirements for whom must disclose, and may include collaborators, consultants, and graduate students.

Additionally, individuals listed as sub-investigators on human subjects research projects are required to complete a financial disclosure.

What must be disclosed

Investigators within the Health Professions Colleges (Colleges of Medicine, Nursing, Health Sciences, Pharmacy, Dentistry and Public Health) must disclose all significant financial interests (SFI), **regardless of value**. Investigators in the other Colleges throughout campus are required to disclose SFI that are related to his/her institutional responsibilities. Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.

“SFI”, for individuals outside of the Health Professions Colleges, means one or more of the following:

- For a publicly traded entity, remuneration and equity interest exceeding \$5000 in value received in the 12 months preceding your disclosure responses here. (Members of the Health Professions Colleges must disclose regardless of value).
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding your disclosure responses here. (Members of the Health Professions Colleges must disclose regardless of value).
- Any equity or ownership interest in a non-publicly traded entity.
- Intellectual property rights and interests upon receipt of income from an entity other than UK must be disclosed.

Note: Non-publicly traded entities include non-profit organizations such as associations, foundations, institutions of higher education, and federal, state, or local governments. Specifically excluded is income from seminars, lectures or teaching sponsored by United States’ federal, state, local government, United States institutions of higher education, United States academic teaching hospitals, and medical centers or research institutes affiliated with institutions of higher education in the United States. Also excluded is income from service on advisory committees or review panels for a federal, state, or local government agency.

What constitutes “remuneration”

“Remuneration” means i. all salary and wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, and payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts); ii. holding, receipt of or payment for intellectual property rights (e.g. patents, copyrights, trademarks, and licenses, royalties, or other payments for or from such rights); iii. holding or receipt of equity interests (e.g. stocks, stock options, private equity, or other ownership interests); and iv. holding or receipt of venture or other capital financing. Excluded are UK salary, royalties paid through UK, and equity interest in publicly traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member.

How do I complete a financial disclosure

Upon certifying your training today by clicking the box at the end of the training information, you will complete the online Financial Conflict of Interest Disclosure questionnaire. This questionnaire is required annually in March. If an Investigator is new and has not completed an annual disclosure, it must be completed prior to submission of a proposal. Investigators may access their disclosure history at any time.

When do I need to revise my financial disclosure

Investigators must revise the responses to their questionnaire within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage, inheritance, or otherwise; acquiring equity or ownership, by crossing the \$5,000 aggregate threshold) or when their responses to these questions change. Disclosures must be updated within 30 days of acquiring a new affiliation with a person, entity, organization, or government, either domestic or foreign.

Examples:

If you disclosed \$10,000 in consulting income from ABC company and receive an additional \$2,000 consulting payment during the year, report this on the next annual disclosure (same type of SFI).

If you disclosed \$10,000 in consulting income from ABC company and subsequently received royalty income of \$2000, you must update your disclosure to include the royalty income within 30 days (new type of SFI).

If your dependent child receives a gift of \$7,000 worth of stock in a company related to your institutional responsibilities, you must update your disclosure within 30 days.

If you create or co-create a company and register with the Secretary of State in any state, even if the company has no monetary value, you must update your disclosure within 30 days.

What happens once I submit my responses to this questionnaire or my revised responses to this questionnaire

Responses will be reviewed using a secure web-based system with restricted access. The review will be conducted by the Institutional Official (IO) or those to whom the IO has given specific written delegation. Reviewers will assess whether an SFI is related to the Investigator's research and if an SFI is a Financial Conflict of Interest (FCOI). "Related to" means the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research. An FCOI exists if the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research or may appear to do so.

If an FCOI appears to exist, the IO will notify the Investigator and may seek review and input from the dean, director or COI committees. They will determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a management plan is required.

How are FCOIs managed on extramurally funded research

If the Investigator and dean or director determine no FCOI exists, the IO may agree with the determination that there is no FCOI, disagree and ask the parties to propose a management plan, or refer the matter to the Research Conflict of Interest Committee (RCOIC) for review and comment. All management plans are referred to the RCOIC which may accept or amend the proposed plan or formulate a new plan. The RCOIC then recommends a plan to the IO, who then makes a final decision and informs the investigator and dean or director. The Investigator must submit annual reports and a final report which outline the actions taken to meet the conditions in the management plan.

How are FCOI regulations enforced for extramurally funded research

It is a violation of the regulation to intentionally provide incomplete or erroneous information on the disclosure form, fail to make any required disclosure, or fail to provide information needed for a review. Sanctions may be imposed for violation, including without limitation being prohibited from submitting proposals, having active sponsored projects suspended, suspension, termination of employment, and notification to funding agencies.

Training

Before engaging in research, each Investigator must complete the training in this section. Training must be repeated at the time of annual disclosure, if an Investigator is found to be noncompliant with the regulation, or if the regulation substantially changes.

Who must disclose sponsored travel

Faculty members in the Health Professions Colleges (Colleges of Medicine, Nursing, Dentistry, Pharmacy, and Public Health) are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are funded by a federal agency.

For federally funded investigators outside of the Health Professions Colleges, excluded from disclosure is travel reimbursed or sponsored for spouse and dependent children, travel paid from a UK account, and reimbursed or sponsored travel paid by a United States Federal, state, or local government agency, an institution of higher education within the United States [as defined at 20 U.S.C. 1001(a)], a United States academic teaching hospital, a US medical center, or a US research institute that is affiliated with an institution of higher education within the United States.

Additional regulations for federally-funded investigators:

Prior to expending funds, UK must report to the sponsor any FCOI pertaining to the project and reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with a FCOI, as well as the name of the entity, the nature of the SFI, the value of SFI in ranges and the elements of the management plan which are designed to safeguard the research.

This policy is also applicable to Subrecipients. Subrecipients may have and be subject to a policy that complies with PHS or federal sponsor regulations, OR subrecipient Investigators will be subject to UK's policy. In either case, Subrecipient Investigators must, prior to proposal submission, disclose SFI and prior to expenditure of funds, report any FCOI to UK and UK must report to the federal sponsor.

Foreign Influence and Export Control & Sanctioned Countries/Parties Information:

The current regulatory landscape informing the research enterprise includes serious growing concerns by the US Government concerning inappropriate influence by foreign entities over US research and developmental efforts. As a result, academic research institutions have a heightened responsibility for understanding the affiliations and dealings faculty members may have with foreign governments and entities.

The University of Kentucky values international collaboration and recognizes its importance in innovation and scientific and medical advancement. To safeguard these efforts, employees should be cognizant of potential risks and maintain transparency about their foreign relationships and activities. Due to current geopolitical events, the US federal government identifies "countries of concern" as China, Iran, North Korea, and the Russian Federation; investigators engaging in collaborations, research, or other professional activities associated with these countries should work with the Office of Sponsored Projects Administration (OSPA) to identify and mitigate any potential risks.

Additionally, the US government restricts the export of certain materials and information (Export Control) and enforces sanctions against foreign countries, entities, vessels, and individuals that restrict both import and export exchanges. This may include certain typical educational, research, service, and other interactions UK and its employees regularly engage in. For more information on export Controls see "OSPA Export Controls" in the COI-Smart document library. The US Office of Foreign Assets Control (OFAC; <https://ofac.treasury.gov/>) has resources related to sanctions lists. Please contact ospa@uky.edu or UKOfficeofLegalCounsel@uky.edu for additional information.

Further, federal sponsors prohibit covered personnel from participating in "malign foreign talent recruitment programs" (see "Foreign Talent Recruitment Programs" document in the COI-Smart document library) associated with China, Iran, North Korea, or Russia. In alignment with those policies, beginning August 2024 UK will also prohibit covered individuals from participating in those programs. If you think you may be involved in a foreign talent recruitment program, please contact the Office of Sponsored Projects Administration (OSPA) immediately. They can help confirm whether your program meets that definition and discuss mitigation measures that may be taken.

All investigators on sponsored projects should check the sponsor's current disclosure requirements carefully and, if in doubt, contact the University's Office of Sponsored Projects Administration (OSPA) at ospa@uky.edu for disclosure assistance or further guidance. In addition, investigators should take the following actions:

- Review and update Biosketches, Other Support and Current and Pending Support information in proposals. More information can be found at <https://www.research.uky.edu/office-sponsored-projects-administration/other-supportcurrent-and-pending-support> and in the links below.
- Update information in OSPA's Other Support Portal
- Ensure appropriate disclosure of foreign components and affiliations
- Review COI disclosure and update as necessary
- Report all reimbursed or sponsored travel related to federally supported projects
- Reach out to OSPA's Export Control Specialist for guidance related to export control regulations
- With the assistance of the University's Office of Technology Commercialization, enter into a material transfer agreement, data use agreement, or nondisclosure agreement when sharing or exchanging materials or information

More information regarding Guidance on Foreign Influence in University Research is located at <https://www.research.uky.edu/office-sponsored-projects-administration/guidance-regarding-foreign-influence-university-research>

Retrospective Review and Mitigation Plan

For some sponsors, if an Investigator does not timely disclose an SFI, the Institution does not timely review, or the Investigator does not comply with a management plan, the Institution must conduct a retrospective review of the research to determine if there was bias in the design, conduct, or reporting of the research. If bias is found, the sponsor will be notified and provided a mitigation report outlining actions taken to eliminate or mitigate the effect of bias.

The Institution must monitor the Investigator's compliance with the management plan and submit annual reports to the sponsor and the Investigator must again complete COI training. Additionally, the investigator must disclose the FCOI in related presentations/publications and request addenda to related previous presentations/publications. The sponsor may request further information and may impose additional conditions.

If you have pending or active research sponsored by a federal agency; review the agency-specific COI policies in the document library as part of this COI training.

Additional resources:

- PHS Regulation (42 CFR § Part 50) <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>
- NIH FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- NIH Pre-Award and Post-Award Disclosures <https://grants.nih.gov/grants/forms/NIH-Disclosures-Table.pdf>
- NSF Pre-Award and Post-Award Disclosures https://www.nsf.gov/bfa/dias/policy/disclosures_table/june2021.pdf
- UK Policy 7:2 <https://regs.uky.edu/administrative-regulation/ar-72>

If you are unsure about or have any questions pertaining to the material covered in this course, please contact Dr. Emily Bradford in the Office of Sponsored Projects Administration at (859) 323-2973 or emily.bradford@uky.edu.

You have completed the above training on Financial Disclosure and Conflict of Interest.

Response : I have completed the required training on Financial Disclosure and Conflict of Interest

QUESTION 5

In the next 12 months will you travel to a location outside of the US as part of your institutional responsibilities or to fulfill sponsored program obligations?

QUESTION 6

In the next 12 months will you transfer or ship materials, animals or specimens outside of the US?

QUESTION 7

Do you receive in-kind support for your research? This includes non-UK office/laboratory space, equipment, supplies, personnel (employees, students, visiting scholars, volunteers or trainees) supported by external entities or governments (foreign or domestic), and high-value or unique gifts or donations.

QUESTION 8

Have you personally engaged in activities with, agreed to, or contracted with another individual, institution or entity, foreign or domestic, to conduct activities related to your professional expertise or institutional responsibilities, conduct research, or to advise, participate, or assist in academic or other activities, that were not processed through the University of Kentucky's Office of Sponsored Projects?

QUESTION 9

The US Government has identified countries at risk. Have you personally engaged in any activity or agreed or contracted with anyone in a foreign country of concern (see [42 USC § 19237](#)) or embargoed/sanctioned region or sector (principally China, Iran, North Korea, Russia, Belarus, Cuba, Syria, and the Crimea, Donetsk and Luhansk regions of Ukraine; see US [Office of Foreign Assets Control \(OFAC\)](#) or Foreign Talent Recruitment Programs in COI-Smart Resource Library) on UK matters or personal activities under which you have used UK resources of any kind or referenced your role at UK that were not processed through OSPA?

QUESTION 10

During the past 12 months from the date of your responses here or at any time during calendar year (CY) 2023, have you or any member of your immediate family received remuneration from, owned equity interest in, or had any other financial interest in any publicly traded entity?

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QUESTION 11

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During the past 12 months from the date of your response or at any time during calendar year (CY) 2023, have you or any member of your immediate family received remuneration from, owned equity interest in, or had any other financial interest in any non-publicly traded entity?

QUESTION 12

The Office of Inspector General (OIG) for HHS defines Physician-Owned Distributorships (PODs) as entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures that the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs).

During calendar year 2023, did you maintain any financial interest in a POD, or benefit from any business transaction between UK HealthCare and a POD?

QUESTION 13

During the past 12 months from the date of your responses here, or at any time during calendar year 2023, have you or any member of your immediate family received income derived from intellectual property rights or interests (e.g., patents, copyrights), excluding royalties paid by the University?

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QUESTION 14

During the past 12 months from the date of your responses here, or at any time during the calendar year 2023, were you a member, shareholder, director, officer, employee, consultant, contractor or other form of representative of a foundation, LLC, non- or not-for-profit entity, joint venture, partnership, corporation or other form of institution or government entity, either foreign or domestic? Please identify your role in these organizations regardless of whether you received compensation, remuneration or reimbursement.

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QUESTION 15

Please identify any individuals that you directly or indirectly supervise within UK/UK HealthCare, AND with whom you have a **family or close personal relationship**.

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QUESTION 16

Do you have a third party (non-UK/UKHC) website that is related to your UK role, clinical practice, and/or research?

QUESTION 17

Do you have any appointments or hold any positions, whether paid, unpaid or voluntary, at entities outside of the United States? This could include private businesses, non-US government entities or agencies, a combination of government and private businesses, hospitals, universities, or other foreign groups.

QUESTION 18

Have you and/or your **family** received any awards, incentives, gifts, or money from any entity or agency outside of the US? An incentive could be offered by a government or another entity. It could include funds or other material reward to you and/or your family that you may keep. Incentives also could include funds given to you to support your work, your research, or to pay for your relocation expenses. It also could be an award or other promotion including, but not limited to, so-called "**talent program**" awards which may promise some financial, teaching or research position or role, or other benefit. Non-disclosure clauses associated with or included in the expectations of any such awards, incentives, gifts, or money are not acceptable exemptions from this disclosure requirement.

QUESTION 19

Have you and/or members of your **family** received or been promised anything in exchange for your work within the US from a non-US entity or agency? This could include private businesses, non-US government entities or agencies, a combination of government and private businesses, hospitals, universities, or other foreign groups.

QUESTION 20

Upload any signed documents regarding your appointments (including academic, research or honorary appointments), positions, work, or research for non-US entities or agencies, as well as any additional documentation related to awards, gifts, money, or anything else of value received from those entities or agencies. Documents may be uploaded in any language, but all non-English language documents should be provided with a translation, and any documents which have been translated to English from another language must include the original language version. Use the link below to upload documents.

QUESTION 21

Faculty members in the Health Professions Colleges (Colleges of Medicine, Nursing, Dentistry, Pharmacy, Health Sciences, and Public Health) and Advanced Practice Providers are required to report all travel that was provided by, or reimbursed by, an entity other than UK.

All other faculty members are required to report travel only if you are funded by a federal agency. Federally funded investigators can exclude travel if it was sponsored by a US government agency, whether federal, state, or local, or if sponsored by a US institute of higher education.

Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months from the date of your responses here or at any time during calendar year 2023.

QUESTION 22

Over the past 12 months from the date of your responses here or at any time during calendar year 2023, have you received remuneration from any person, entity, organization, or government outside of UK/UK HealthCare, other than those listed in the previous questions?

QUESTION 23

Please indicate whether you have ever been or are currently debarred, suspended, excluded or otherwise ineligible to participate in any Federal program; and/or whether you have ever been or are currently subject to any revocation, termination, denial or voluntary relinquishment of any professional license, permit, certification, or medical staff membership or clinical privilege.

QUESTION 24

On an ongoing basis, I agree to disclose to the Chief Compliance Officer and/or Executive Vice President for Health Affairs any potential conflicts of interest that may arise in the course of my official duties on behalf of UK HealthCare.

QUESTION 25

On an ongoing basis, I agree to update my disclosure within thirty (30) days of acquiring a new financial interest. Among other bases for updating my disclosures, I understand that my or my immediate family members' establishment of a non-publicly traded entity, such as a faculty start-up, and the formation of a non-profit entity will require an update to my disclosure regardless of the entity's value.

QUESTION 26

I agree to provide all necessary information to enable the University to determine the materiality of a potential conflict of interest. I also agree to assist the University in resolving any potential conflicts.

QUESTION 27

I certify that I am not party to a malign foreign talent recruitment program associated with China, Russia, North Korea, Iran or any other country determined to be a country of concern by the Secretary of State (see [42 USC § 19237](#) for relevant federal statutory definitions and guidance on Foreign Talent Recruitment Programs in the COI-Smart document Library). For assistance in determining if a program that you are involved in may qualify as a malign foreign talent recruitment program, contact OSPA.

MFTRP: Malign Foreign Talent Recruitment Programs are defined in the Chips & Science Act of 2022: (A) any program, position, or activity that includes compensation in the form of cash, in-kind compensation, including research funding, promised future compensation, complimentary foreign travel, things of non de minimis value, honorific titles, career advancement opportunities, or other types of remuneration or consideration directly provided by a foreign country at any level (national, provincial, or local) or their designee, or an entity based in, funded by, or affiliated with a foreign country, whether or not directly sponsored by the foreign country, to the targeted individual, whether directly or indirectly stated in the arrangement, contract, or other documentation at issue, in exchange for the individual

1. engaging in the unauthorized transfer of intellectual property, materials, data products, or other nonpublic information owned by a United States entity or developed with a Federal research and development award to the government of a foreign country or an entity based in, funded by, or affiliated with a foreign country regardless of whether that government or entity provided support for the development of the intellectual property, materials, or data products;
 2. being required to recruit trainees or researchers to enroll in such program, position, or activity;
 3. establishing a laboratory or company, accepting a faculty position, or undertaking any other employment or appointment in a foreign country or with an entity based in, funded by, or affiliated with a foreign country if such activities are in violation of the standard terms and conditions of a Federal research and development award;
 4. being unable to terminate the foreign talent recruitment program contract or agreement except in extraordinary circumstances;
 5. through funding or effort related to the foreign talent recruitment program, being limited in the capacity to carry out a research and development award or required to engage in work that would result in substantial overlap or duplication with a Federal research and development award;
 6. being required to apply for and successfully receive funding from the sponsoring foreign government's funding agencies with the sponsoring foreign organization as the recipient;
 7. being required to omit acknowledgment of the recipient institution with which the individual is affiliated, or the Federal research agency sponsoring the research and development award, contrary to the institutional policies or standard terms and conditions of the Federal research and development award;
 8. being required to not disclose to the Federal research agency or employing institution the participation of such individual in such program, position, or activity; or
 9. having a conflict of interest or conflict of commitment contrary to the standard terms and conditions of the Federal research and development award.
- And,

(B) A program that is sponsored by

1. a foreign country of concern (defined as the People's Republic of China including Hong Kong and Macau, the Democratic People's Republic of Korea, the Russian Federation, the Islamic Republic of Iran, or any other country determined to be a country of concern by the Secretary of State) or an entity based in a foreign country of concern, whether or not directly sponsored by the foreign country of concern;
2. an academic institution on the list developed under section 1286(c)(8) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 2358 note; Public Law 115 232); or
3. a foreign talent recruitment program on the list developed under section 1286(c)(9) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 2358 note; 1 Public Law 115 232).

Response :