

**QUESTION 1 - COI.2022.01**

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 or at any time during CY 2021.

- 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. The overload approval request form (previously Form F) can be accessed at myUK.
- 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.

**Response :** I have read and understand the purpose of the survey, stated above.

**QUESTION 2 - COI.2022.03**

Are you involved in human subjects research or clinical investigations?

**QUESTION 3 - COI.2022.04**

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?

**Response :**

I understand that this Disclosure is required to obtain funding from the U.S. Government. I certify to the best of my knowledge and belief that the information contained in this Disclosure Statement is true, complete, and accurate. I understand that any false, fictitious, or fraudulent information, misrepresentations, half-truths, or omissions of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims, or otherwise. (18 U.S.C. 1001 and 287, and 31 U.S.C. 3729-3730 and 3801-3812). I further understand and agree that (1) the statements and representations made herein are material to U.S. Government's funding decision, and (2) I have a responsibility to update the disclosures during the period of performance of the award should circumstances change which impact the responses provided above.

**Response :**

**QUESTION 4 - COI.2022.05**

**Financial Conflict of Interest Training Module for Investigators with Pending or Extramurally Funded Research**

**Background**

Public Health Service (PHS) and the National Science Foundation (NSF) issued virtually identical conflict of interest 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 24th, 2012. Grantees were 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. 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 disclosure.
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding disclosure OR any equity interest, regardless of value.
- 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, medical centers or research institutes affiliated with institutions of higher education in the United States. Intellectual property rights and interests upon receipt of income from an entity other than UK must be disclosed.
- Intellectual property rights and interests upon receipt of income from an entity other than UK must be disclosed.

### What constitutes "remuneration"

"Remuneration" means all salary & wages, including professional income from non-UK faculty practice plans, consulting fees, speaking fees, payment for services (e.g. honoraria, paid authorship, travel reimbursement, gifts), licensing revenue, royalties for books, publications or reports, or equity interests. 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 of each year. 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, or inheritance).

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 questionnaire or my revised questionnaire**

Questionnaires 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 or not 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.

If an FCOI appears to exist, the IO will notify the Investigator and dean or director and seek their review and input. The Investigator and dean or director will review the Questionnaire, determine that no FCOI exists, an FCOI exists but the SFI has been eliminated, or an FCOI exists and a proposed management plan is provided. This determination is then communicated to the IO.

**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, and fail to provide information needed for a review. Sanctions may be imposed for violation, including 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 PHS or other federal agency. Additionally, these investigators can exclude travel if it was sponsored by a United States government agency, whether federal, state, or local, or if sponsored by an institute of higher education within the United States.

PHS encompasses the following agencies:

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

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 PHS- and federally-funded investigators:**

Prior to expending funds, UK must report to the sponsor any FCOI pertaining to the project; reports are due annually for the duration of the project. Elements reported are award #, PI, Investigator with FCOI as well as the name of the entity, nature of SFI, 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 Information:

The current regulatory landscape informing the research enterprise includes serious growing concerns by the US Government concerning inappropriate influence by foreign entities over federally funded research. As a result, academic research institutions have a heightened interest in understanding the affiliations and dealings faculty members may have with foreign governments and entities. The University of Kentucky encourages international collaboration, and recognizes it is important for investigators to be transparent about their foreign relationships and activities.

All investigators on sponsored projects should check the sponsor's current disclosure requirements carefully and, if in doubt, contact OSPA at 859-257-9420 for disclosure assistance or further guidance. In addition, investigators should take the following actions:

- Review and update 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>
- Review and update biosketches
- Ensure appropriate disclosure of foreign components for NIH-supported projects
- Review COI disclosure and update as necessary
- Report all reimbursed or sponsored travel related to PHS- or federally supported projects
- Reach out to OSPA's Export Control Specialist for guidance related to export control regulations
- With the assistance of the Office of Technology Commercialization, enter into a material transfer 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>

### What happens in the event of non-compliance with PHS or other federal regulations

If an Investigator does not timely disclose an SFI or the Institution does not timely review, the IO must review to determine if it is related to PHS funding and if it is an FCOI. If it is determined to be an FCOI, a management plan will be implemented as soon as possible.

### Retrospective Review and Mitigation Plan

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 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 and request addendum to related previous publications. The sponsor may request further information and may impose additional conditions.

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

#### Additional resources:

- PHS Regulation (42 CFR § Part 50) [http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)
- NIH FAQs [http://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](http://grants.nih.gov/grants/policy/coi/coi_faqs.htm)
- NIH Tutorial <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
- UK Policy 7:2 <http://www.uky.edu/regs/Administrative/ar7.2.htm>

**Thank you for your attention to this important requirement!**

**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](mailto:emily.bradford@uky.edu).**

**Response :**

QUESTION 5 - COI.2022.06

During the past 12 months or at any time during CY2021, 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?

QUESTION 6 - COI.2022.07

During the past 12 months or at any time during CY 2021, 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 7 - COI.2022.08

The OIG 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 CY 2021, did you maintain any financial interest in a POD, or benefit from any business transaction between UK HealthCare and a POD?

QUESTION 8 - COI.2022.09

During the past 12 months, or at any time during CY 2021, 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?

QUESTION 9 - COI.2022.10

During the reporting period 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? Please identify your role in these organizations regardless of whether you received compensation or remuneration.

QUESTION 10 - COI.2022.11

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.

QUESTION 11 - COI.2022.12

Do you have any appointments or hold any positions 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 12 - COI.2022.13

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.

QUESTION 13 - COI.2022.14

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 14 - COI.2022.15

Upload any signed documents regarding your 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. Use the link below to upload documents.

QUESTION 15 - COI.2022.16

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 PHS or another federal agency. Federally funded investigators can exclude travel if it was sponsored by a government agency, whether federal, state, or local, or if sponsored by an institute of higher education.

---

Please indicate whether you have had any travel related to your institutional responsibilities during the past 12 months or at any time during CY 2021.

.....

---

**QUESTION 16 - COI.2022.17**

Over the past 12 months or at any time during CY 2021, have you received remuneration from any entity outside of UK/UK HealthCare, other than those listed in the previous questions?

---

**QUESTION 17 - COI.2022.18**

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 18 - COI.2022.19**

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 19 - COI.2022.20**

On an ongoing basis, I agree to update my financial disclosure within thirty (30) days of acquiring a new financial interest. I understand that the 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 financial disclosure regardless of the entity's value.

---

**QUESTION 20 - COI.2022.21**

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.