

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



Because you are either the recipient of an award/contract from UK or a new UK employee without a linkblue ID, you are required to complete an annual conflict of interest (COI) disclosure statement. This ensures that UK is compliant with federal, sponsor, and institutional policies. Unless indicated otherwise, the requested information applies to any activities during the previous 12 months.

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.

In addition to PHS and NSF, UK will take steps to comply with all federal sponsor policies.

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 are required to disclose Significant Financial Interests (SFI) that are related to his/her institutional responsibilities. Financial interests are aggregated for the Investigator, his/her spouse, and dependent children.

"SFI" 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.
- For a non-publicly traded entity, remuneration exceeding \$5000 in value received in the 12 months preceding your disclosure responses here.
- Any equity or ownership interest in a non-publicly traded entity.

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.

- Intellectual property rights and interests upon receipt of income.

What constitutes "remuneration"?

"Remuneration" means i. all salary and wages, including professional income, 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. 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 is excluded.

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 questionnaire or my revised questionnaire?

Questionnaires will be reviewed 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 whether 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 required. 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, or 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?

Investigators 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.

Additional regulations for PHS or 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 that 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 disclose SFI and, prior to expenditure of funds, report any FCOI to UK which UK may 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 responsibility for understanding the affiliations and dealings investigators 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 the University's Office of Sponsored Projects Administration (OSPA) at 859-257-9420 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 for NIH-supported projects
- 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>

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 or federal 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 addenda 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) <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 <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.

QUESTION 1

I have read the required training on Financial Disclosure and Conflict of Interest.

Yes No

QUESTION 2

I have read and understand the purpose of this survey, as stated below.

Yes No

Because of you are either the recipient of an award/contract from UK or a new UK employee without a linkblue ID, you are required to complete a conflict of interest disclosure statement annually. This ensures that UK is compliant with federal, sponsor, and institutional policies. Unless indicated otherwise, the requested information applies to any activities during the previous 12 months.

- 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.
- This completed Statement shall constitute a part of your University personnel records, if applicable, and shall be entitled to the same degree of confidentiality as other such records.

QUESTION 3

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 start-up company, and the formation of a non-profit entity will require an update to my financial disclosure regardless of the entity's value.

Yes No

QUESTION 4

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.

Yes No

QUESTION 5

I understand that this Disclosure is required to obtain funding from the U.S. Government.

Yes No

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.

QUESTION 6

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 assistance in determining if a program that you are involved in may qualify as a malign foreign talent recruitment program, contact OSPA.

I agree

I do not agree

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. eing 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).

QUESTION 7

Are you involved in human subjects research or clinical investigations?

Yes No

QUESTION 8

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?

Yes No

PHS Agencies

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA) Indian Health Service (IHS)
- National Institutes of Health (NIH) Office of Global Affairs (OG)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Assistant Secretary for Planning and Evaluation
- Office of the Assistant Secretary for Preparedness and Response (ASPR) Office of Public Health and Science
- Substance Abuse and Mental Health Services Administration (SAMHSA)

QUESTION 9

Are there any individuals within UK/UK HealthCare with whom you have a family or close personal relationship? If yes, please identify them.

Yes No

QUESTION 10

During the reporting period were you a member, shareholder, director, officer, employee, consultant, contractor or other form of representative of any foundations, LLCs, non- or not-for-profit entities, joint ventures, partnerships, corporations or other forms of institutions or government entities? Please identify your role(s) in these organizations regardless of whether you received compensation or remuneration.

Yes No

Names of the entities

Titles of your positions within the entities

Goals of the entities

Are these entities domestic (solely active in the U.S.), foreign, or both?

Please provide the state(s) or foreign country (or countries) in which the entities are registered or operate

QUESTION 11

During the past 12 months, 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** entities related to your institutional responsibilities? If yes, complete the sections below, listing all entities.

Yes

No

This information pertains to:
(Check all that apply)

- Self
- Spouse
- Dependent Children

Names of Outside Entities:
(Do not abbreviate)

Check all that apply:

<ul style="list-style-type: none"><input type="checkbox"/> Employee or corporate officer<input type="checkbox"/> Consultant, whether paid or unpaid<input type="checkbox"/> Scientific advisory board, or peer review panel member<input type="checkbox"/> Royalties for inventions and copyrights (i.e., licensing revenue)<input type="checkbox"/> Fees paid for authorship of books or other publications<input type="checkbox"/> Gifts or other benefits	<ul style="list-style-type: none"><input type="checkbox"/> Board of directors, governing board, or trustee<input type="checkbox"/> Speaking fees or honoraria for lectures<input type="checkbox"/> Equity interest (e.g., stock, stock options, or other ownership interest)<input type="checkbox"/> Other, Specify: <div style="border: 1px solid black; height: 40px; width: 100%; margin-top: 5px;"></div>
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Do any of these entities support your research or other sponsored activity?

Yes
 No

Briefly summarize how your involvement with these outside entities reasonably appear to be related to your institutional responsibilities.

Use for additional information if necessary.

QUESTION 12

During the past 12 months, 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** entities? If yes, complete the sections below.

Yes

No

This information pertains to:
(Check all that apply)

- Self
- Spouse
- Dependent Children

Names of Outside Entities:
(Do not abbreviate)

Indicate whether these entities are

- For-profit, not publicly traded
- Non-profit

Check all that apply:

<ul style="list-style-type: none"><input type="checkbox"/> Employee or corporate officer<input type="checkbox"/> Consultant, whether paid or unpaid<input type="checkbox"/> Scientific advisory board, or peer review panel member<input type="checkbox"/> Royalties for inventions and copyrights (i.e., licensing revenue)<input type="checkbox"/> Fees paid for authorship of books or other publications<input type="checkbox"/> Gifts or other benefits	<ul style="list-style-type: none"><input type="checkbox"/> Board of directors, governing board, or trustee<input type="checkbox"/> Speaking fees or honoraria for lectures<input type="checkbox"/> Equity interest (e.g., stock, stock options, or other ownership interest)<input type="checkbox"/> Other, Specify: <div style="border: 1px solid black; height: 40px; width: 100%; margin-top: 5px;"></div>
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Do any of these entities support your research or other sponsored activity?

Yes
 No

Briefly summarize how your involvement with these outside entities reasonably appear to be related to your institutional responsibilities.

Use for additional information if necessary.

QUESTION 13

During the last 12 months, did you maintain any financial interest in a physician-owned distributorship (POD), or benefit from any business transaction between UK HealthCare and a POD? If yes, please provide the name of the POD(s) and the device(s) distributed.

Yes No

QUESTION 14

During the past 12 months, have you or any member of your immediate family received income derived from intellectual property rights or interests (e.g., patents, copyrights)? If yes, please identify the IP(s) and whether they will be used in the current research project.

Yes No

QUESTION 15

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. If yes, please identify the entities and describe your roles.

Yes No

QUESTION 16

Have you and/or your family received any awards, incentives, gifts, or money from any entities or agencies 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 benefits. If yes, please identify the entities and describe.

Yes No

QUESTION 17

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

Yes No

QUESTION 18

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

Yes No

QUESTION 19

Are you participating in any Foreign Government Sponsored Talent Recruitment Program or Other Foreign Government Sponsored or Affiliated Activity sponsored by a foreign country of risk? Foreign countries of risk currently include Iran, North Korea, Russia and China, but are subject to change.

Yes No

A **Foreign Government-Sponsored Talent Recruitment Program** is defined as an effort directly or indirectly organized, managed, or funded by a foreign government to recruit science and technology professionals or students (regardless of citizenship or national origin, and whether having a full-time or part-time position).

Other Foreign Government Sponsored or Affiliated Activity includes the following activities directly or indirectly involving a foreign country of risk entity, as defined below:

- a) Employment.
- b) Other support, contractual or otherwise, direct and indirect, including current and pending private and public sources of funding or income, both foreign and domestic. For researchers, other support includes all foreign country of risk entity resources made available, directly or indirectly, to a researcher in support of and/or related to all of their professional R&D efforts, including resources provided directly to the individual rather than through the research institution, and regardless of whether or not they have monetary value (e.g., even if the support received is only in-kind, such as office/laboratory space, equipment, supplies, or employees). This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, gifts, financial support for laboratory personnel, and participation of student and visiting researchers supported by other sources of funding. This further includes compensation, for example, current or promises of future: grants, awards, funding, scholarship, appointment, sabbatical, travel, university directed funding, and honoraria.
- c) Current or pending participation in, or applications to programs, e.g., grant programs, sponsored by foreign governments, instrumentalities, or entities, if not a Foreign Government-Sponsored Talent Recruitment Program, as defined. Associated contracts, upon request by DOE, must be disclosed, in addition to the fact of participation.
- d) Positions and appointments, both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

If you answered yes, please provide the following information:

Names of the entities

Please provide the foreign country (or countries) in which the entities are registered or operate

QUESTION 20

Have you had any travel related to your institutional responsibilities during the past 12 months? If yes, please complete the information below.

Yes No

Investigators 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 US government agency, whether federal, state, or local, or if sponsored by a US institute of higher education.

Travel reimbursed or paid for by:
(Name all entities)

Indicate whether these entities are
 For-profit, publicly traded
 For-profit, not publicly traded
 Non-profit

Dates of travel:

Destinations:

Purpose(s) of the trips:

Estimated monetary value for each:

QUESTION 21

As a Private individual, in the past 5 years have you provided any scientific, engineering, or technical assistance, or similar support to a federal agency through a procurement contract, subcontract, grant, or cooperative agreement? This may be referred to as Systems Engineering and Technical Assistance (SETA) or Advisory and Assistance Services (A&AS) by some federal agencies.

Yes No

By signing, I acknowledge that all information that I have provided is correct and complete to the best of my knowledge and I understand that I am required to update the disclosure as changes occur.

Name (Last, First) and Date

Signature

Definitions

Close personal relationship means a financial, family, amorous, or sexual relationship, or a relationship that involves a degree of intimacy beyond that normally present between work colleagues.

Equity interest means stock, stock options, warrants, partnership, or other ownership interests. Excluded from this definition are equity interests held in publicly-traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member, including retirement programs at the University of Kentucky.

Family is defined as a person's father, mother, brother, sister, husband, wife, son, daughter, aunt, uncle, son-in-law, daughter-in-law, and step-relatives in the same relationships. **Immediate family** refers to an investigator's spouse and dependent children.

Financial interest means anything of monetary value or potential monetary value, whether or not the value is readily ascertainable.

A **Foreign Government-Sponsored Talent Recruitment Program** is an effort directly or indirectly organized, managed, or funded by a foreign government to recruit science and technology professionals or students (regardless of citizenship or national origin, and whether having a full-time or part-time position).

Human subjects research and **clinical investigations** mean any activity that meets either (a) the Department of Health & Human Services definitions of both "research" and "human subjects" or (b) the Food & Drug Administration (FDA) definitions of both "clinical investigation" and "human subjects." These activities require review and approval of the activity by the Institutional Review Board (IRB).

Immediate family means an Investigator's spouse and dependent children.

An **institution of higher education** is defined at 20 U.S.C. 1001(a). Paraphrasing, it means an educational institution in any State that (1) admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, .; (2) is legally authorized to provide a program of education beyond secondary education; (3) provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree,.; (4) is a public or other nonprofit institution; and (5) is accredited by a nationally recognized accrediting agency or association or has been granted preaccreditation status...

Institutional responsibilities is defined as activities within a staff or faculty member's field of scientific expertise or medicine for which the University or UKHC has hired or contracted with the staff or faculty member to perform and for which the staff or faculty member is paid by the University or UKHC. This may include activities such as research, research consultation, teaching, professional practice, administrative, purchasing, institutional committee memberships and service on panels such as the IRB or Data Safety Monitoring Boards.

Investigator means the project director or 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 activity that is sponsored by an extramural agency. For the purposes of this regulation, postdoctoral scholars and postdoctoral fellows are considered investigators. Graduate and undergraduate students are not considered investigators.

A **non-publicly traded entity** or privately held company is a business owned either by a non-governmental organization or by a small number of shareholders or company members/owners, which does not offer or trade its equity interest (e.g., stock or shares) to the general public, but rather the company's stock or equity interest is offered, owned and traded or exchanged privately. This category includes most start-up companies derived from university intellectual property. This category includes remuneration from not-for-profit organizations (including associations, foundations, institutions of higher education as defined in 20 U.S.C.1001(a), etc.) or a Federal, state, or local government agency.

Outside entity means any entity recognized by law through which business for profit is conducted (including sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership, or trust), or not-for-profit organization (including association, foundation, charitable organization, etc.).

Public Health Service (PHS) is defined as an operating unit of the US Department of Health and Human Services that includes PHS Awarding Components. Public Health Service Agencies, offices, and divisions include, but may not be limited to: i. Agency for Healthcare Research and Quality (AHRQ); ii. Agency for Toxic Substances and Disease Registry (ATSDR); iii. Centers for Disease Control and Prevention (CDC); iv. Food and Drug Administration (FDA); v. Health Resources and Services Administration (HRSA); vi. Indian Health Service (IHS); vii. National Institutes of Health (NIH); viii. Administration for Community Living (ACL); ix. Office of the Assistant Secretary for Health (OASH); x. Office of the Assistant Secretary for Planning and Evaluation; xi. Office of the Assistant Secretary for Preparedness and Response (ASPR); xii. Administration for Children and Families (ACF); xiii. Substance Abuse and Mental Health Services Administration (SAMHSA); and xiv. Office of National Coordinator for Health Information Technology (ONC).

A [publicly traded entity](#) is a company or business that offers its securities (stocks/shares, bonds/loans, etc.) for sale to the general public, typically through a stock exchange (e.g., the New York Stock Exchange), or through market makers operating in over-the-counter markets.

[Remuneration](#) means i. all salary and wages, including professional income, 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. 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 is excluded.

[Sponsored agreement](#) means a grant, contract, cooperative agreement, clinical studies, or clinical trial agreement, and subagreements or subcontracts thereof.

A [talent program](#) is a foreign government sponsored talent recruitment program is an effort organized, managed, or funded by a foreign government to recruit science and technology professionals or students (regardless of citizenship or national origin).

EXAMPLE DISCLOSURE

During the past 12 months or at any time during CY 2022, 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** entities related to your institutional responsibilities? If yes, complete the sections below, listing all entities.

Yes

No

This information pertains to:
(Check all that apply)

- Self
- Spouse
- Dependent Children

Names of Outside Entities:
(Do not abbreviate)

Merck & Co.	Pfizer Inc.	Novartis AG
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Check all that apply:

<input type="checkbox"/> Employee or corporate officer <input checked="" type="checkbox"/> Consultant, whether paid or unpaid <input type="checkbox"/> Scientific advisory board, or peer review panel member <input type="checkbox"/> Royalties for inventions and copyrights (i.e., licensing revenue) <input type="checkbox"/> Fees paid for authorship of books or other publications <input type="checkbox"/> Gifts or other benefits	<input type="checkbox"/> Board of directors, governing board, or trustee <input type="checkbox"/> Speaking fees or honoraria for lectures <input checked="" type="checkbox"/> Equity interest (e.g., stock, stock options, or other ownership interest) <input type="checkbox"/> Other, Specify:	
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Do any of these entities support your research or other sponsored activity?

Yes
 No

Briefly summarize how your involvement with these outside entities reasonably appear to be related to your institutional responsibilities.

Merck & Co., Pfizer Inc., and Novartis AG are all pharmaceutical companies which relates to my research in the pharmaceutical field.

Use for additional information if necessary.

Merck & Co. and Pfizer Inc. - self and spouse have equity interest in these companies

Novartis AG - I do paid consulting for this company