New: Department of Energy Interim Conflict of Interest Policy

Purdue Implementation

Office of the Executive Vice President for Research and Partnerships (EVPRP)

DOE COI Policy

- What's new: The Department of Energy (DOE) issued an interim Conflict of Interest (COI) policy for Financial Assistance on Dec. 20, 2021, <u>FAL 2022-02</u>
- Purpose of the COI policy: to establish "...standards that provide a reasonable expectation that the design, conduct, and reporting of projects ... funded under DOE financial assistance awards (e.g., a grant, cooperative agreement, or technology investment agreement) will be free from bias resulting from financial conflicts of interest or organizational conflicts of interest."
- Applicable Federal Regulations: 2 CFR 200.112.

The DOE Interim COI policy is largely aligned with the 2011 Revised Financial Conflict of Interest regulation, 42 CFR Part 50 Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought."

Applicability

Applies to -

- **Institutions** that apply for, and receive DOE funding by means of financial assistance awards such as grants, cooperative agreements, or technology investment agreements
- **Investigators** planning to participate in, or participating in, projects funded under a DOE financial assistance award
- DOE **SBIR/STTR Phase II** applicants/awardees *Phase I SBIR/STTRs are exempt*.

Implementation deadline: June, 2022.

Purdue's Responsibilities under the DOE COI policy

- **Maintain** an up-to-date, written, enforced FCOI policy that complies with the DOE Interim COI Policy for financial and organizational COI. Make the policy available via a publicly accessible website
- **Inform Investigators** on Institution's FCOI policy, Investigator's responsibilities regarding disclosure of significant financial interests (SFIs) and DOE's interim COI policy. **Train Investigators**
- Appoint a designated COI official at the institution
- Identify and manage individual and institutional FCOIs
- Report FCOIs to DOE
- Disclose any potential or actual organizational/institutional COI to DOE.

Purdue University maintains a <u>COI website</u> that is open to the public, as well as a documented and enforced <u>COI policy</u> and administrative process for identifying and managing financial conflicts of interest and ensuring compliance with all federal COI rules.

Responsibilities of Investigators*

- Complete FCOI Training prior to engaging in DOE-funded research, every four years thereafter, and/or immediately under designated circumstances.
- Disclose all Significant Financial Interests (SFIs) related to their Institutional Responsibilities** and Sponsored/Reimbursed Travel before submitting a proposal to DOE and/or DOE agencies
- Update SFI and Travel disclosures at least annually during the period of an award and within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

*Investigator: A Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the purpose, design, conduct, or reporting of a project funded by, or proposed for funding by, DOE (e.g., Co-PIs, Post-Docs, collaborators, consultants, graduate and undergraduate students, etc.)

**Institutional responsibilities: An Investigator's professional responsibilities on behalf of Purdue such as:

- Research and/or research consultation
- Teaching and professional practice
- Institutional committee memberships
- Service on panels such as Institutional Review Boards (IRB) or Data and Safety Monitoring Boards.

What is a Significant Financial Interest?

1. One or more of the following **financial interests** of the **Investigator** and those of the **Investigator's spouse and dependent children** that reasonably appears to be **related to the Investigator's institutional responsibilities** will constitute as a **Significant Financial Interest (SFI)**.

i. From a **Publicly traded entity**:

- Remuneration (e.g., consulting fees, honoraria, paid authorship etc.) received in the twelve months preceding the disclosure and the value of any equity interest (stock, stock option, or other ownership interest etc.) in the entity as of the date of disclosure, when aggregated, is > \$5,000.

ii. From a Non - publicly traded entity:

- **Remuneration** (e.g., consulting fees, honoraria, paid authorship etc.) received in the twelve months preceding the disclosure when aggregated, is > \$5,000.
- Any equity interest (stock, stock option, or other ownership interest etc.)

iii. Intellectual property (IP) rights and interests

- Receipt of income (of any value) from <u>IP rights and interests</u> (e.g., patents, copyrights).

2. <u>Reimbursed or sponsored travel</u> <u>related to institutional responsibilities</u> if paid on behalf of the Investigator must be disclosed as a <u>Significant Financial Interest</u>.

What is **NOT** a Significant Financial Interest?

Exclusions from the definition of SFI and Sponsored Reimbursed Travel:

- Salary, royalties, or other remuneration received from Purdue
- **Income from** investment vehicles, such as **mutual funds and retirement accounts (if** the Investigator does not directly control the investment decisions)
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency of the United States, a domestic Institution of Higher Education, or a domestic research institute affiliated with a domestic Institution of Higher Education; the exclusion also applies to sponsored or reimbursed travel by these institutions
- **Income from service on advisory committees or review panels** for a Federal, state, or local government agency of the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic Institution of Higher Education
- **Travel that is reimbursed or sponsored** by a US federal, state, or local government agency, an American Institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with a domestic institution of higher education.

Financial Conflict of Interest (FCOI)

An FCOI exists in circumstances where the SFIs of the Investigator or their spouse or dependent children could have a direct and significant impact on the design, conduct, reporting, or funding of a project.

- If an FCOI is identified, Purdue/EVPRP will develop and implement an FCOI management plan (MP) and monitor compliance with the plan
- The plan is accepted by electronic signatures by the Investigator, the Department/School Head (who serves as the Oversight Manager for the plan) and the Dean of the College or Unit Head
- Purdue/EVPRP must determine whether an Investigator's SFIs/FCOIs are related to the DOE-funded project(s) and submit FCOI reports to DOE.

Purdue's current definitions of "SFI" and "FCOI" align with the new DOE COI policy.

New: FCOI Training Requirement for DOE Investigators

Each DOE Investigator/Researcher must complete FCOI training:

- Prior to engaging in DOE-funded grant or contract
- At least every four years or
- Immediately under any of the following circumstances:
 - Institutional FCOI policies or procedures change in any manner that affects the Investigator responsibilities
 - An Investigator is new to the Institution
 - An Investigator is not compliant with the Institution's FCOI policy and/or their FCOI management plan.

Guidance to complete the online FCOI training in CITI can be found here.

Updated SFI Disclosures for DOE Investigators

As of June 18th, 2022, **DOE Investigators** at Purdue are required to complete a Financial Interest Statement (FIS) and SFI and/or Travel Disclosures (as needed):

- At proposal submission; watch for "Action Required: FIS for your proposal to DOE..." email messages sent by fcoi@purdue.edu
- Before participating in a DOE sponsored project

and

- Update disclosures at least annually
- Within 30 days of acquiring new SFIs.

New/updated FIS for new Proposals Submitted to DOE

Please review the definitions of <u>Significant Financial Interest</u>, <u>Institutional Responsibilities</u>, and <u>Sponsored/Reimbursed Travel</u>, and then check the appropriate boxes below: Significant Financial Interest(s):

- NO, I do not have any significant financial interests related to this proposal and/or my Institutional Responsibilities.
- YES, I do have significant financial interests related to this proposal and/or my Institutional Responsibilities.

Sponsored/Reimbursed Travel

- NO, I do not have third party sponsored/reimbursed travel related to my Institutional Responsibilities.
- YES, I do have third party sponsored/reimbursed travel related to my Institutional Responsibilities.

I hereby certify that:

- The above statement(s) concerning significant financial interests and sponsored/reimbursed travel related to my Institutional Responsibilities are accurate as of this date in compliance with applicable federal regulations (e.g., PHS, DOE); and ...
- I will complete my Research Related Significant Financial Interest and Sponsored/Reimbursed Travel Disclosure(s), as needed, now; and I will complete my FCOI Training before engaging in PHS and/or DOE funded research projects; and,
- I will update this statement and my **Research Related Significant Financial Interest** and **Travel Disclosures** whenever new significant financial interests are acquired (or current financial interests are discontinued), or new travel that requires disclosure occurs; and my **FCOI Training** as required, during the pendency of this proposal and any resulting award; and,
- I will cooperate fully with the University Responsible Official and/or the University Conflict of Interest Officer to identify any resulting real or potential conflicts of interest and to take appropriate steps to manage, reduce, or eliminate these conflicts prior to receipt of any sponsor award from this proposal.

New: Disclosure of Sponsored/Reimbursed Travel

DOE Investigators must disclose **any reimbursed or sponsored travel related to their institutional responsibilities** paid by any entity other than the ones noted below.

Travel disclosures must include the following information:

- Purpose of the trip
- Identity of the travel sponsor/organizer,
- Travel destination
- Travel duration
- Monetary value

Exemption: Travel that is reimbursed or sponsored by a federal, state, or local government agency, an American Institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with a domestic institution of higher education.

Organizational Conflicts of Interest

Organizational conflicts of interest (OCOIs) are situations where because of relationships with a parent company, affiliate, or subsidiary organization, Purdue is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization.

- Purdue/EVPRP must assess and determine OCOIs related to each DOE funded project
- Disclose in writing any potential or actual OCOIs to the DOE program office prior to using DOE funds.

Resources

 Department of Energy Interim Conflict of Interest Policy Requirements for Financial Assistance: https://www.energy.gov/sites/default/files/2021-12/Interim%20COI%20Policy%20FAL2022-02%20to%20SPEs.pdf

- Purdue Policy on Individual FCOI:
 http://www.purdue.edu/policies/ethics/iiib2.html
- Purdue Policy on Institutional FCOI:
 http://www.purdue.edu/policies/ethics/iiib6.html

Contact: fcoi@purdue.edu