



## WSU HRPP Policy Guidance Document

### Financial Conflict of Interest and the Review Process

#### RESEARCH POLICY ON INDIVIDUAL AND INSTITUTIONAL FINANCIAL CONFLICT OF INTEREST AND COMMITMENT (PENDING UPDATE)

The following policy guidance is provided to address pending updates to the **Research Policy on Individual and Institutional Financial Conflict of Interest and Commitment** (version 10.7.2021(AAHRPP submission document 172, page 508)) and provide Wayne State University's processes for identifying, managing, reviewing significant financial institutional and individual conflicts of interest.

This policy guidance includes clarification and addition of information per AAHRPP Standard I-6: The organization has and follows written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated.

The full revised policy anticipated release is March 2025. Please contact the Financial Conflict of Interest Committee for assistance with FCOI disclosures (FCOIcommittee@wayne.edu).

#### WSU POLICIES REFERENCE:

The organization has and follows written policies to ensure that research is conducted so that financial conflict of interests are identified, managed, and minimized or eliminated. The following policies address individual and institutional conflicts of interest (AAHRPP Standard I-6, Element I.6.A):

- HRPP Policy 14-01 Conflict of Interest: Principal Investigator/Key Personnel (AAHRPP Submission Document 163, page 454 )
- HRPP Policy 14-02 Conflict of Interest: Institutional Review Board Member and IRB Administration Office Staff (AAHRPP Submission Document 164, page 459 )
- University Administrative Policy 08-1 Conflict of Interest Disclosure (AAHRPP Submission Document 169, page 487),
- University Administrative Policy 08-2 Investigator Disclosure (Second Release) (AAHRPP Submission Document 170, page 488)
- University Research Policy on Individual and Institutional Conflict of Interest and Commitment (AAHRPP Submission Document 172, page 508)
- Department of Veteran Affairs Research Financial Conflict of Interest Statement (AAHRPP Submission page 2330)

#### POLICY UPDATES

WSU HRPP guidance dated 2/2025

Pending Policy Revision available 3/2025

AAHRPP-Association for the Accreditation of Human Research Protection Programs-Accreditation  
Response Information

## **The University Research Policy on Individual and Institutional Financial Conflict of Interest and Commitment updates include:**

- Addition of information for recognizing and managing organization conflicts of interest
- Addition of information for the process of disclosing organization conflicts of interest
  - Includes update to FCOI process with the FCOI manager receiving a report of the university COI disclosures managed through the Office of the Secretary to the Board of Governors (BOG)
- Addition of strategies for managing organizational conflicts of interest
- Updates to policy and executive order references

## **PROCEDURES FOR RECOGNIZING AND MANAGING ORGANIZATIONAL CONFLICT OF INTEREST**

### Addition of the following language to the Research Policy on Individual and Institutional Financial Conflict of Interest and Commitment section 3.15

*(PENDING LANGUAGE) As an institution that conducts and reviews research involving human subjects, Wayne State University recognizes its obligation to protect the rights and welfare of those subjects, and ensure the integrity of the research and the human research protection program. Toward this end, significant financial interests of Wayne State University or senior administrative officials must be identified, evaluated, managed, and minimized or eliminated in order to ensure that meeting that obligation is not jeopardized.*

*All forms of potential Significant Institutional Financial Conflicts of Interest (SFI) in human subjects' research require disclosure, evaluation, and either management or elimination under this Policy.*

*The Financial Conflict of Interest Committee/Manager will inform the IRB of any annual disclosures from these individuals in which Significant Financial Interests (SFI) relating to human research are identified. The Financial Conflict of Interest Committee will contact the affected officials to receive confirmation that they will not be involved in the scientific merit, resource review, or any other review relating to research with which they have a SFI. Such confirmation will constitute the management plan that mitigates the potential COI.*

- HRPP Policy 14-01 Conflict of Interest: Principal Investigator/Key Personnel (AAHRPP Submission Document 163, page 454 ) states “Persons with institutional responsibilities (i.e., Department Chairs, individuals acting on their behalf, faculty, supervisors) at the time that they sign off on a Protocol Summary Form are prompted whether they, their spouse or domestic partner or any dependent children have a potential conflict of interest with the sponsor of the project. If disclosures have not been made prior to the submission of the research protocol to the IRB, investigators and key personnel will be required to report these relationships to the FCOI Committee and the FCOI Management Plan must be accepted before the protocol can be approved by the IRB. The FCOI disclosure must be updated on an annual basis and more frequently when significant changes have occurred.”

## THE PROCESS TO IDENTIFY OR DISCLOSE FINANCIAL CONFLICTS OF INTEREST OF THE ORGANIZATION.

University policies and procedures provide a definition of organizational financial conflict of interest

- University Administrative Policy 08-2 Investigator Disclosure (Second Release) (AAHRPP Submission Document 170, page 488)
- University Research Policy on Individual and Institutional Conflict of Interest and Commitment (AAHRPP Submission Document 172, page 508)

that includes for example:

i.Licensing, technology transfer, patents.

ii.Investments of the organization.

iii.Gifts to the organization when the donor has an interest in the research.

iv.Other financial interest

- HRPP Policy 14-01 Conflict of Interest: Principal Investigator/Key Personnel (AAHRPP Submission Document 163, page 454 ) and HRPP Policy 14-02 Conflict of Interest: Institutional Review Board Member and IRB Administration Office Staff (AAHRPP Submission Document 164, page 459 ) states “Institutional Conflict of Interest consist of two major types: (1) Conflict of Interest involving University equity holdings or a royalty arrangement related to sponsored programs, and (2) Conflict of Interest involving University officials who make decisions with institutional-wide implications, which can include department heads and center and institute directors, in addition to senior management.

Addition of the following language to the Research Policy on Individual and Institutional Financial Conflict of Interest and Commitment section 7.1 Disclosure and Review Process:

**(PENDING LANGUAGE):**

**(1) *University Conflict of Interest Reporting:*** *Wayne State University requires all management personnel (see policy 08-1 AAHRPP submission page 486) to complete an annual conflict of interest disclosure report (available at <http://policies.wayne.edu/bog-conflict-of-interest.pdf>). This questionnaire is to be completed no later than January 31 of each year and submitted to the respective division head (dean and/or vice president, supervisor) for review and signature.*

*A report of the university's conflict of interest disclosures are provided to the FCOI manager, if a disclosure is identified that could directly and/or significantly affect research activities, (e.g. review, design, conduct, or reporting of externally funded research), the FCOI Manager shall instruct submission of an eFCOI submission to evaluate and manage the conflict.*

(2) **Sponsored Program Administration Submission: Sponsored Program Administration Conflict of Interest reporting:** *When a researcher completes a SPA proposal, key personnel listed on the submission are asked whether they have a SFI that needs to be disclosed. If a FCOI is disclosed the FCOI Manager shall instruct submission of an eFCOI submission to evaluate and manage the conflict.*

(3) **Institutional Review Board (IRB) Conflict of Interest reporting:** *When the IRB receives a submission for a new study (or an amendment/continuation of an existing study), all key personnel are required to answer a question regarding whether or not they have a conflict of interest that they need to disclose. If someone answers YES, a management plan is created by the FCOI Committee and submitted to the IRB. The IRB will review the management plan for acceptance and add any additional management provisions, if needed.*

This process is also described for the (Conflict of Interest: Principal Investigator/Key Personnel Policy AAHRPP submission document 173 , page 454).

### **THE COMMITTEE OR INDIVIDUAL(S) AND PROCESS THAT THE ORGANIZATION USES TO EVALUATE AND MANAGE ORGANIZATIONAL FINANCIAL CONFLICT OF INTEREST. INCLUDE EXAMPLES OF MANAGEMENT STRATEGIES.**

#### **FCOI committee/FCOI reviewer process to evaluate and manage organization financial conflict of interest :**

- An expedited review is done for disclosures that fall into categories 1 through 4 (this range is between \$0 and \$100,000 value). The Financial Conflict of Interest Expedited Review (FCOI-ER) includes the Associated Vice for Research Integrity, FCOI Chair, and Conflict of Interest Coordinator/Manager. University Research Policy on Individual and Institutional Conflict of Interest and Commitment (AAHRPP Submission Document 172, page 508)
- Disclosures in the amount of greater than \$100,000 (category 5) will be reviewed by the FCOI Committee University Research Policy on Individual and Institutional Conflict of Interest and Commitment (AAHRPP Submission Document 172, page 508)
- If an organizational COI is identified, it is reviewed by the Vice President for Research and/or the FCOI Committee University Administrative Policy 08-2 Investigator Disclosure (Second Release) (AAHRPP Submission Document 170, page 488)

#### **FCOI Committee Management Plan Review Steps:**

1. A “potential” management plan is created based on the information received on the disclosure.
2. The disclosure is assigned to a pre-reviewer. A pre-review is done and the reviewer provides a summary of the disclosure.
3. Organizational conflicts of interest are reviewed by the full FCOI committee/FCOI Reviewer. A meeting is scheduled to discuss the disclosure and related documents.

4. The documentation (pre-review summary, disclosure, “potential” management plan, and any other related documents) are provided to committee members for review prior to a meeting.
5. The documents along with the “potential” management plan is discussed and a determination is made as to whether or not the “potential” management plan is appropriate.
  - a. A vote will be taken to determine if the “potential” management plan is acceptable. If acceptable, the proposed management plan is created, attached to the eCOI module and sent back to the disclosing individual. That individual then either accepts or declines the proposed management plan. If accepted, the disclosure is finalized in eCOI.
  - b. If the “potential” management plan is not found to be acceptable, discussions between the committee members takes place to make the necessary changes. The changes are made after the meeting and provided to the committee members to vote on. If acceptable, go through step 5a above.

### **Strategies for managing significant conflicts of interest (SFI)**

Strategies are indicated per policy 08-2 Investigator Disclosure (section 3.4, AAHRPP submission page 513). as well as the pending update to the to expand on the strategies to address significant financial conflicts that can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at institution.

The policy updates include addition of the following language to the Research Policy on Individual and Institutional Financial Conflict of Interest and Commitment, section 3.16:

***(PENDING LANGUAGE):***

*The Financial Conflict of Interest Committee/FCOI Expedited Reviewer shall take appropriate steps to manage the SFI. These steps may include but are not limited to requiring the following:*

1. *Public disclosure of Significant Financial Interests.*
  - *Disclosing the institutional conflict of interest to research subjects in the consent process and documents*
  - *Disclosing the institutional conflict of interest to any journals or other publications for which the results of the research will be submitted*
2. *Monitoring of research by independent reviewers.*
3. *Modification of the research plan.*
4. *Disqualification from participation in all or a portion of the research.*
5. *Recusing of conflicted senior administrative officials from scientific merit, resource, or any other review of human research*

6. *Divestiture of significant financial interests.*
7. *Severance of relationships that create actual or potential conflicts.*
8. *Having an external, independent IRB review the research in question (AAHRPP submission page 2388 WCG Master Services Agreement).*
9. *Prohibition of the conduct of the research at Wayne State University or WSU affiliate institutions.*
  - Current HRPP Policy 14-01 Conflict of Interest: Principal Investigator/Key Personnel (AAHRPP Submission Document 163, page 454 ) indicates “When it is determined that the integrity of the institution and the well-being of the research participants may be in question, the research may need to be conducted outside Wayne State University by independent investigators at sites that do not have a financial stake in the outcome.”