Financial Conflict of Interest (FCOI) in Research – Standard Operating Procedures

Background

The Public Health Service (PHS) Policies Promoting Objectivity in Research, 42 C.F.R. 50 Subpart F and 45 C.F.R., Part 94, "Responsible Prospective Contractors ("the FCOI regulation") promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from researcher financial conflicts of interest (FCOI). The university's Outside Activities and Conflicts policy (the "Policy") and these related Standard Operating Procedures (SOPs) apply to all researchers, with special considerations noted for PHS-funded researchers throughout the Policy and these SOPs.

I. Disclosure Responsibilities

A. An electronic Conflict of Interest (eCOI) disclosure form must be filed by any individual at Ohio State, regardless of job title, who meets the definition of "researcher" under the Policy, including a project director, principal investigator or senior/key personnel (including non-university employee consultants) on a sponsored project; any individual paid under a sponsored project during the past twelve (12) months; or any investigator on Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC) or Institutional Biosafety Committee (IBC) protocols during the past twelve (12) months.

B. Researchers are required to submit eCOI forms annually to disclose their outside activities, including Significant Financial Interests (as defined by the Policy) held by the researcher (and those of the researcher's spouse and dependent children), regardless of whether they engage in outside activities;
   1. The Office of Research will notify researchers annually to complete the eCOI form.

C. Updates must be made to the eCOI form within thirty (30) days if the researcher acquires new financial interests, engages in new outside activities, or has changes regarding a previously reported activity (e.g., the updated value of a previously disclosed equity interest).

D. Researchers, including those new to the university, must complete an eCOI form no later than the time of application for PHS-funded research.

E. All researchers, including those funded by PHS in the past twelve (12) months or who reasonably expect to receive PHS funds in the coming year, must disclose any personally reimbursed or sponsored travel related to their university responsibilities. Researchers are required to disclose the purpose of the trip, the name of the sponsor/organizer, the destination, and the duration of the trip.

F. The travel disclosure requirement does not apply to the following:
   1. Travel reimbursed or sponsored by:
      a. a U.S. federal, state, or local government agency; or
      b. a U.S. academic teaching hospital, a medical center, or a research institute that is affiliated with an accredited U.S. college or university.
   2. Travel reimbursement or payment of travel made by The Ohio State University, a university college, department or unit, or travel covered by a sponsored project managed through the Office of Sponsored Programs.

II. Training Requirements

A. The FCOI regulation requires that the university provide formal conflict of interest training to researchers.

B. Deans, department chairs, and/or other supervisory officials will be responsible for ensuring that the faculty, staff, and students complete the required training in the eCOI application before engaging in research related to any PHS-funded grant and at least every four (4) years, and immediately when any of the following circumstances apply:
   1. The university substantially revises its Outside Activities and Conflicts policy in a manner that affects the requirements of researchers;
   2. A researcher is new to the university; or
   3. The university finds a researcher that is not in compliance with the Outside Activities and Conflicts policy or a conflict management plan.

III. Review of Disclosure Forms

A. Faculty disclosures of Significant Financial Interests (as defined by the policy) (SFIs) must be reviewed by the academic supervisor (Chair, Director, Dean, or designee). Following this review, the disclosure will route to the conflict administrators Office of Research Compliance for additional review.
B. Staff and student disclosures of SFIs are reviewed by the conflict administrators in the Office of Research Compliance in consultation with the employee's supervisor, as appropriate.
C. eCOI disclosure forms submitted by researchers will automatically route to the appropriate signatory. The Chair, Director, Dean, or designee will determine whether the SFI or outside activity may be related to the researcher's university responsibilities on a case-by-case basis considering whether the following applies:
    1. The Outside Activity involves an organization that provides support that is used in the research (e.g., funding, products, or services);
    2. The Outside Activity could directly and significantly affect the design, conduct, or reporting of the research; and/or
    3. The outcome of the research could affect the value of the financial interest.
D. If the Chair, Dean, designee, or the Office of Research Compliance determines that a disclosed SFI or outside activity presents a potential conflict with a specific research project, then this information will be reviewed by the Conflict Approval Committee (CAC).
E. The CAC will determine whether an SFI or outside activity is reasonably related to a researcher's university responsibilities and gives rise to a Financial Conflict of Interest (FCOI) with university research, including specific research projects or protocols, using the considerations under section III.C 1-2. An FCOI means that an SFI could directly and significantly affect the design, conduct, or reporting of research.
F. Disclosure forms will be maintained in the Office of Research Compliance.

IV. Conflict Management Plans

A. If the CAC determines that an FCOI exists, then it will recommend a conflict management plan (CMP) in order to:
    1. Promote transparency of the financial interest;
    2. Protect the integrity of the research;
    3. Protect the rights and safety of human research subjects;
    4. Protect the rights and obligations of students and trainees participating in research; and
    5. Mitigate the perception of the conflict as it could appear to collaborators, the university, the scientific community, and the public.
B. The CAC will provide its determination and recommended CMP to the researcher.
C. CMPs may include one or more of the following requirements:
    1. Disclosure of the financial interest is required in all CMPs and includes the following:
        a. disclosure of the financial interests of the researcher in all relevant publications and presentations;
        b. disclosure to the co-investigators, members of the laboratory or research group, and students or trainees;
        c. disclosure of a researcher's financial interest in the informed consent document for human subject research and veterinary clinical trials;
        d. limiting the role of the conflicted researcher in the research, including through the participation of non-conflicted study team members;
        e. restricting the researcher's role in the analysis, interpretation, and reporting of research data;
        f. prohibiting the researcher from serving as Principal Investigator of a veterinary clinical trial, per Ohio State University Rule 3335-13-07 *Rules governing faculty, staff, and student participation in companies commercializing university research*, using the considerations under section V.D-E of this FCOI SOP.
    2. Modification of the research plan.
    3. Oversight: appointment of an independent research monitor or committee.
    4. Severance of the personal relationship, e.g., relinquishing a fiduciary role, terminating a consulting agreement, or divesting equity.
    5. Other conditions, restrictions, and/or reporting requirements as recommended by the CAC.
D. Conflict Management Plans will be maintained in the Office of Research Compliance.

V. Review and management of potential conflicts of interest in human subjects research

A. Conflicts in human subject research may present real or perceived risks to the welfare and rights of human subjects, in addition to presenting risks to research integrity.
B. The CAC will review potential conflicts with human subject research studies, including projects determined to be exempt by the Office of Responsible Research Practices.
C. If the CAC finds a conflict that must be managed, it will recommend a protocol-specific CMP to the IRB. The recommended CMP may include requirements and limitations, including but not limited to the following:
    1. Requirement to disclose the financial interest to other researchers on the study and in publications and presentations resulting from the research;
    2. Requirement to disclose the financial interest in the informed consent document;
    3. Limitations around participating in recruitment and/or consenting of study subjects;
    4. Prohibition against solely determining the severity, causality, and reporting of adverse events;
    5. Restrictions against analyzing and reporting data;
    6. Other conditions or restrictions, as recommended by the CAC.
D. Principal Investigator (PI) exclusions: The CAC presumes that researchers may not serve as principal investigators in greater than minimal risk research projects involving human subjects (as determined by the IRB) while holding any of the following qualified financial interests related to the research:
    1. Greater than $25,000 in remuneration in a 12-month period;
    2. Greater than $25,000 in equity held in a publicly-traded company;
    3. Any amount of equity in a privately-held company.
E. The CAC will determine, on a case-by-case basis, whether PI exclusion is required, using the following non-exclusive considerations:
    1. Nature, depth, and status of the financial relationship;
    2. Percentage of base pay university salary in proportion to the financial interest;
    3. Possibility of financial benefit to the researcher;
    4. Potential impact on the conduct of the study and on patient safety; and
    5. Whether the conflict could be managed appropriately without a change in PI.
F. Exceptions: The CAC will consider requests for exceptions to CMP requirements, including PI exclusion, in view of a compelling justification (e.g., the conflicted researcher is the only individual at the university who possesses the expertise, know-how, or the necessary technical or procedural skills to lead the study). Researchers seeking an exception must obtain support from their Department and College, indicating agreement with the compelling justification and for providing the resources necessary to manage the conflict. Such resources may include, but are not limited to, the cost of external review boards, subject safety monitoring committees, or other independent oversight needed to ensure the integrity of the research and the protection of human subjects. The researcher will be invited to present the compelling justification to the CAC. Upon completing its review, the CAC will communicate its decision in writing, via the Office of Research Compliance, to the researcher, the unit, and Office of Responsible Research Practices within 7 days.
G. The CAC will provide its recommended CMP, via the Office of Research Compliance, to the IRB, via the Office of Responsible Research Practices. To ensure the primacy of the welfare and rights of the human subjects, the convened IRB will have the full and final authority for implementing the decision concerning the role of the conflicted researcher in the research protocol. The IRB will communicate its decision regarding the recommended CMP to the researcher in writing. The IRB's decision is final.

VI. University Reporting Requirements

A. The FCOI regulation requires the university to report FCOIs involving PHS-funded research to the PHS prior to the expenditure of federal research funding, or within sixty (60) days of the university identifying a new FCOI.
B. The FCOI regulation requires that the university submit an annual report to the PHS at the time the researcher's annual progress report is due. The annual FCOI report must address the status of the financial interest and any changes to the conflict management plan.
C. The Office of Research Compliance will be responsible for reporting FCOIs to the PHS or other sponsors as required.
D. The FCOI regulation also requires that the university provide the following information within five (5) business days to a public request concerning identified FCOIs with PHS-funded research:
    1. Researcher's name;

2. Researcher's title and role with respect to the research project;
3. Name of the entity in which the SFI is held;
4. Nature of the SFI; and
5. Value of the SFI within the following dollar ranges ($0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

VII. Non-Compliance and Sanctions

A. If an FCOI with PHS-funded research is not identified or managed in a timely manner, then the university may be required to conduct a retrospective review within 120 days of the determination of non-compliance. The purpose of the retrospective review is to determine whether the unmanaged FCOI resulted in bias in the design, conduct, or reporting of the PHS-funded research. The conditions requiring a retrospective review are when:
   1. The researcher fails to disclose an SFI that is determined to constitute an FCOI;
   2. The university fails to identify, review, or manage an FCOI; or
   3. The researcher fails to comply with a CMP.

B. Researchers failing to comply with the Outside Activities and Conflicts policy, this FCOI SOP, or with the terms of a CMP may be referred to the CAC. If non-compliance is found, the CAC may refer the matter to any of the following for corrective action, as appropriate:
   1. The researcher's unit (e.g., College, Department, Center);
   2. The Senior Vice President for Research, who may determine if a faculty member's violation of university rules should result in filing a complaint under Faculty Rule 3335-5-04 *Hearing procedures for complaints against faculty members*;
   3. The IRB (for violations of the Outside Activities and Conflicts policy, this FCOI SOP, or with the terms of a CMP relating to human subject research)
   4. Office of Human Resources
   5. Office of Student Life

VIII. Legal Obligations

A. The outside activities of employees may result in personal or institutional obligations under federal and state laws, formal contractual requirements of research sponsors, or requirements of accreditation entities. The University is also required to comply with the FCOI regulation, including maintaining and enforcing its written Outside Activities and Conflicts policy, managing, reducing or eliminating identified conflicts, and reporting identified conflicts to federal agencies within prescribed timeframes.

B. When the university carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the university must meet applicable agency requirements to ensure subrecipient compliance with the FCOI regulation.

C. The Office of Research Compliance, in consultation with the Offices of Legal Affairs and Sponsored Programs, are responsible for ensuring the university complies with sponsor and regulatory agency reporting requirements, as well as the maintenance of conflict of interest records, pursuant to applicable federal and state requirements and Ohio State University Office of Research record retention policies.

D. PHS/National Science Foundation (NSF) – Individuals who receive research funding from either the PHS or NSF must comply with agency regulations, which ensure that significant financial interests do not affect the design, conduct, or reporting of federally-funded research.
   1. The PHS regulations on "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (42 C.F.R. Part 50, Subpart F) and "Responsible Prospective Contractors" (45 C.F.R. Part 94) can be found at http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf.
   2. The NSF conflict of interest policy can be found in Chapter V, Grantee Standards, Section 510, Conflict of Interest Policies, in the NSF Grant Policy Manual at http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510.

E. Food and Drug Administration (FDA) – The FDA requires applicants to submit to FDA a list of clinical investigators who conduct covered clinical studies and to certify the absence of and/or disclose the existence of certain financial arrangements.
   1. "Financial Disclosure by Clinical Investigators" (21 C.F.R. Part 54) can be found at https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/financial-disclosures-clinical-investigators
   2. In cases where an individual researcher holds an Investigational New Drug application (IND) or an Investigational Device Exemption (IDE), the researcher may be required to personally comply with the above FDA conflict of interest reporting requirements and should consult the FDA or the Office of Legal Affairs concerning applicable rules and regulations.

F. Other sponsors – External funders may have specific requirements for the University and researchers to follow regarding conflicts of interest in research.

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) – AAHRPP accreditation requires that the university's Human Research Protection Program (HRPP) includes policies and procedures to address FCOI and institutional conflicts of interest to ensure the protection of human research participants, the integrity of the research, and the credibility of the HRPP. For more information on AAHRPP requirements, contact the Office of Responsible Research Practices (ORRP).