

# Human Research Protection Program Policies & Procedures



## Conflicts of Interest in Human Subjects Research and IRB Member Conflict of Interest

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### Background

Institutions and individuals involved in human subjects research may establish financial relationships related to or separate from particular research projects. Those financial relationships may create financial interests of monetary value, such as payments for services, equity interests, or intellectual property rights. A financial interest related to a research study may be a conflicting financial interest. An institution must ensure that conflicting interests do not adversely affect the protection of participants or the credibility of the human research protection program.

### I. Scope

This policy defines the IRB's role in the review of potential financial conflicts of interest in human subjects research at OHSU. This policy also covers the potential conflicts of interest of IRB members.

### II. Policy

- A. All conflicting financial interests must be disclosed and reviewed according to OHSU policy 10-01-035, Conflicts of Interest in Research, PHS Regulations 42 CFR 50 Subpart F, and FDA Regulations 21 CFR 54.
- B. Any significant financial interests potentially related to a human subjects research project must be disclosed according to OHSU policy 10-01-035, by all investigators involved in the research.
- C. Potential conflicts of interest related to human subjects research projects will be reviewed and managed by the Conflict of Interest in Research Committee. Any resulting management plan that applies to a particular human subjects research project will be forwarded to the IRB.
- D. Institutional conflicts of interest related to human subjects research projects will be reviewed and managed by the Integrity Program Oversight Council. Any resulting management plan that applies to a particular human subjects research project will be forwarded to the IRB.
- E. The IRB has the final authority to determine whether the research with the financial interest and the management plan, if any, allow the research to be approved.
- F. No IRB member may participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

### III. Procedure

#### A. Investigator Responsibilities

- 1. As required under OHSU policy 10-01-035, investigators must have a current and complete conflict of interest in research (CoIR) disclosure on file in order to participate in research at OHSU.
- 2. The CoIR disclosure is submitted annually through the online Conflict of Interest in Research Management System (CoIRMS), and must be revised if there is a change that affects any of the investigators responses on the form (e.g., new financial information to disclose).

3. The CoIRMS automatically updates the eIRB.

#### **B. OHSU IRB Responsibilities**

1. Determine whether all investigators participating in a human subjects research project at OHSU have a current CoIR disclosure on file before issuing an initial, continuing, or project modification approval.
  - a. The eIRB will flag any employees whose CoIR disclosures are out of date or missing through automatic feed from the CoIRMS and will not allow approval for any found out of compliance. For non-OHSU employees, including students, compliance must be verified by the IRB analysts during the review process.
  - b. Updates to the eIRB from the CoIRMS occur at midnight and will post the next day.
2. Determine that, for any new human subjects project where a potential conflict of interest is indicated, the CoIR committee has reviewed the disclosure and issued a final or interim management plan, if applicable, prior to final approval.
3. Review any management plans forwarded by the CoIR committee or IPOC and determine if the management plan is sufficient to allow the investigator with the conflicting interest to participate in the research, or for institutional conflict of interest, to allow the research to take place at OHSU.
4. The IRB may require additional management or refer the disclosed conflict back to the CoIR or IPOC committee for further discussion.
5. For conflicts of interest of IRB members:
  - a. The IRB will not assign review of an initial, continuing, or other study item to any member with a known conflict of interest. This includes individuals who are investigators on a study.
  - b. All full board reviewers are required to declare that they do not have a conflict of interest on their reviewer sheets.
  - c. If an IRB member receives an assignment where they feel they have a potential conflict, they should immediately notify the IRB Analyst and Chair for the assigned meeting to determine if reassignment is required.
  - d. During an IRB meeting, if a member discloses a potential conflict, the IRB can assess the conflict and determine if the member must be recused from review.
  - e. During the meeting, any member with a conflict of interest must be recused and leave the meeting room for discussion and voting, except to provide information requested by the IRB.

#### **IV. Authority**

[OHSU Policy No. 10-01-035](#) addresses conflicts of interest in research for OHSU investigators.

[OHSU Policy No. 10-01-021](#) addresses OHSU institutional conflicts of interest.

**45 CFR 46.107(e) and 21 CFR 56.107(e)** state that no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

**42 CFR 50 Subpart F** sets forth regulatory requirements designed to prevent bias from financial conflicts of interest in research funded by the Public Health Service.

**21 CFR 54** details the financial disclosure requirements for clinical investigators in FDA-regulated studies.

**AAHRPP Accreditation Elements:**

**Elements I.6.A and 1.6.B** require that the organization have and follow written policies and procedures to identify, manage, and minimize or eliminate financial conflicts of both the organization and individual researchers and research staff that could influence the conduct of research or the integrity of the Human Research Protection Program.

**Element II.1.C** requires that the organization have and follow written policies and procedures to separate competing business interests from ethics review functions.

**Element II.1.D** requires that the IRB have and follow written policies and procedures so that members and consultants do not participate in the review of research protocols or plans in which they have a conflict of interest, except to provide information requested by the IRB.

**Element III.1.B** requires that researchers and research staff identify and disclose financial interests according to organizational policies and regulatory requirements and work with the organization to manage, minimize, or eliminate these conflicts.

## V. Definitions

**Investigator:** The principal investigator, co-investigator and other OHSU employees or volunteers, or any OHSU research collaborator, including visiting scientists, responsible for the design, conduct or reporting of research or educational activities or responsible for preparing a proposal for research funding. "Investigator" includes the Investigator's spouse and dependent children.

**Significant Financial Interest:** A Significant Financial Interest is as defined in OHSU policy 10-01-035.

**Conflict of Interest:** A conflict of interest exists when an employee's financial interests or other obligations interfere, or appear to interfere, with the employee's obligations to act in the best interest of the University and without improper bias. The mere appearance of a conflict may be as serious and potentially damaging to the public trust as an actual conflict. Therefore, potential conflicts must be disclosed, evaluated, and managed with the same thoroughness as actual conflicts.

**Conflict of Interest of an IRB member:** A conflict of interest for an IRB member can be financial or non-financial. A financial conflict is defined above. Other potential conflicts include being a listed investigator (or having an immediate family member listed as an investigator) or having any other conflict that might be perceived to inhibit a fair and unbiased review of the research.

**Participate in Research:** designing research, directing research or serving as the principal investigator, enrolling research subjects (including obtaining subjects' informed consent) or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication