

<b>SOP: Conflicting Interests of IRB Members</b>			
NUMBER	VERSION	EFFECTIVE DATE	APPROVED BY
HRP-050	1.00	03/28/2023	M. Scott

## 1. PURPOSE

- 1.1. This procedure establishes the process to identify and manage [Conflicting Interests](#) of IRB members. Federal regulations prohibit any IRB member (or an IRB consultant) from participating in the IRB's initial or continuing review of any study in which the member (or IRB consultant) has a Conflicting Interest, except to provide information requested by the IRB. The use of the term IRB member in this SOP will include an IRB consultant.
- 1.2. The process begins when an IRB member is asked to review an IRB submission, or when an IRB staff person learns that an IRB member is directly involved in conducting a research study.
- 1.3. The process ends when an IRB member has either identified a Conflicting Interest and notified IRB staff, or when an IRB member has determined that no Conflicting Interest exists.

## 2. DEFINITIONS

- 2.1. **Conflicting Interest:** An IRB member is considered to have a Conflicting Interest when such individual (or the individual's spouse, domestic partner, child, or dependent) is involved in the design, conduct or reporting of the research. An IRB member is also considered to have a Conflicting Interest if such individual has any of the following interests in a company that is sponsoring the research, providing study product for the research, or has an interest in the product or service being tested in the research:
  - Ownership interest, stock options, or other ownership interest of any value that could be affected by the outcome of the research under review, excluding interests in publicly traded, diversified mutual funds.
  - Personal compensation (e.g., for employment or consulting) or receipt of reimbursement for travel or expenses in excess of \$5000 in the past year or expected in the next year.
  - Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.
  - Board service or executive position, regardless of compensation.
- 2.2. An IRB member may also be considered to have a Conflicting Interest if such individual feels that an objective or unbiased review of the research is not possible due to another reason.
- 2.3. Examples of Conflicting Interests related to a **company** sponsoring the research or whose product or service is being tested:  
The IRB member:
  - Holds stock in the company.
  - Was a consultant for the company in the past year and/or will be a paid consultant in the coming year and will receive more than \$5000 in compensation.
  - Is an inventor on a patent for a technology licensed to the company.
  - Serves as a member of the governing board of the company even if such board service is not compensated.
  - Has had travel paid for by the company in the past year or will have in the coming year.
- 2.4. Examples of Conflicting Interests involving funding (grant, cooperative agreement, or contract) from the **government**:  
The IRB member:
  - Is the direct recipient (overall PI) of a federal grant that is funding the research.

- Is not the direct recipient (overall PI) of a federal grant, but the IRB member has a project funded by the grant **and** the grant would be at risk if *this particular study* were unsuccessful.
- 2.5. Examples of interests that are generally **not** considered Conflicting Interests:

The IRB member:

- Is employed by an organization that receives funding for the conduct of *unrelated* research.
- Holds interests in publicly traded, diversified mutual funds that include the company.
- Has received less than \$5000 as a paid consultant for the company in the last year or will in the coming year.
- Serves as an officer for a foundation or scientific organization funding the research but is not in a position to influence or make funding decisions for the organization.

### 3. POLICY

- 3.1. IRB members are responsible to know the definition of Conflicting Interest and must self-identify a possible Conflicting Interests at the following times: Initial IRB membership appointment, annual certification of Conflicting Interest, when the IRB member's financial interests or activities have changed, when reviewing research via the expedited procedure, and at each IRB meeting attended.
- 3.2. Fred Hutch is committed to a policy that does not allow IRB members or IRB consultants to participate in review of studies that affect their personal financial interests, relationship to the research study, and personal or professional relationships. The integrity of the IRB review process can be compromised if such Conflicting Interests are not disclosed and mitigated.

### 4. RESPONSIBILITIES

- 4.1. IRB members (regular and alternate) and IRB staff follow these procedures.

### 5. PROCEDURE

- 5.1. Before reviewing research, IRB members must determine whether they have a Conflicting Interest with the research. The IRB member may consult with the Fred Hutch Office of General Counsel or the IRO Director (or designee) as needed.
- 5.2. If an IRB member has a Conflicting Interest for review outside a meeting (non-committee review), they are to notify the IRB staff within 24 hours of the assignment, who will remove the submission from the member's reviews and reassign it.
- 5.3. If an IRB member has a Conflicting Interest for review of a submission for which he or she has been assigned as a primary reviewer at an IRB meeting, they are to notify the IRB staff within 24 hours of the assignment so the submission can be re-assigned.
- 5.4. If an IRB member has a Conflicting Interest for review of research at a meeting, they are to notify the meeting chair, stay in the meeting room only to answer questions about the research, and leave the meeting room for discussion and voting regarding that research. IRB members with a Conflicting Interest will not be counted toward quorum.
- 5.5. Any Conflicting Interest will be documented in the IRB meeting minutes.
- 5.6. Annual Certification: Each IRB member must annually certify that they have reviewed and understand the terms of this policy and that they agree to disclose any Conflicting Interests.
- Signed annual certifications are kept in IRB member files. Annual certifications are sent to the member along with this policy and the IRB Member Annual Certification Form (068) at the time of annual IRB member evaluations.
  - If an IRB member does not sign the Annual Certification Form, they may not take part in the review process. The IRB Operations Manager will inform IRB staff that an IRB member cannot be assigned as a reviewer for any item until that IRB member provides a signed annual certification form.

5.7. At the time that research documents are submitted for IRB review, the IRB Analyst will screen the documents to determine if any IRB members are listed as key personnel (involved in the design, conduct, or reporting) for the study. If it is determined that an IRB member has a Conflicting Interest, that member will not be assigned as a reviewer. The Conflicting Interest information will be entered into Hutch IRB on the Staff Data Entry Activity.

**6. MATERIALS**

None

**7. REFERENCES**

21 CFR §56.107(e).

45 CFR §46.107(e).

AAHRPP elements I-9, II.1.D

**8. REVISIONS FROM PREVIOUS VERSION**

<b>Version History</b>	<b>Effective Date</b>	<b>Change Notes</b>
-	-	Information previously found in IRB Policy 1.6 Meeting and Meeting Records (024)