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Next Review 01/2029

Sponsor Marcia Gonzales:
Vice President &
Chief
Compliance
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Area Compliance
Office -
Institutional

Applicability FHCC
Institutional
Policies

References Org Wide/
Institutional



Institutional Conflict of Interest

SCOPE:

This policy applies to all Fred Hutchinson Cancer Center ("Fred Hutch") [Workforce Members](#).

PURPOSE:

This policy defines an Institutional Conflict of Interest ("ICOI"), how potential ICOIs are reviewed and the manner in which ICOIs are reviewed by the Institutional Conflict of Interest for Advisory Committee ("ICOI Advisory Committee") and managed by the Compliance Office.

ICOIs differ from individual financial conflicts of interest in that they relate to institutional management, oversight and decision-making. ICOIs may arise from the External Relationships or Financial Interests of Fred Hutch or Fred Hutch Key Officials.

DEFINITIONS:

- **Business Entity:** A sole proprietorship, corporation, limited liability company, trust, joint venture, or any other form of enterprise, whether conducted for profit or not.

- **Clinical Trial:** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
- **Equity Interests:** Stocks, stock options, or other ownership interests.
- **External Relationships:** Any relationship related to the institutional responsibilities of a Key Official but falling outside the normal scope and course of their Fred Hutch employment.
- **Financial Interests:** Compensation received for service in a leadership position; ownership or Equity Interests; receipt or a right to receive compensation or other payments from intellectual property; remuneration for services such as consulting, advisory board participation; and gifts.
- **Institutional Conflict of Interest (“ICOI”):** For purposes of this Policy, an ICOI that would trigger review is defined as any of the following types of External Relationships or Financial Interests:
 - Equity Interests held by Fred Hutch or a Key Official in a Business Entity that is sponsoring a Clinical Trial at Fred Hutch or whose product or service is being tested in such Clinical Trial (excludes: i) Equity Interests which are held as part of Fred Hutch investment portfolios under management by outside parties, and ii) Equity Interests in publicly traded mutual funds);
 - Receipt by Fred Hutch or a Key Official of royalties, fees or any other one-time or periodic payments or the right to receive any such payment in the future under a patent or a copyright license, assignment or other agreement arising from the sale of a product or service that is being tested in a Clinical Trial at Fred Hutch;
 - Receipt or pledge of a gift or gifts to Fred Hutch exceeding \$500,000 in aggregate value from a Business Entity that is sponsoring a Clinical Trial at Fred Hutch or whose product or service is being tested in such Clinical Trial;
 - Appointment of a Key Official to serve as an officer, director or board member of a Business Entity sponsoring a Clinical Trial at Fred Hutch or whose product or service is being tested in a Clinical Trial (not including an appointment as a member of a scientific advisory board of the Business Entity);
 - Receipt of or the right to receive consulting fees, honoraria, gifts or other compensation exceeding \$10,000 per year by a Key Official from a Business Entity sponsoring a Clinical Trial at Fred Hutch or whose product or service is being tested in such Clinical Trial , provided that such payments are received or such rights accrue during the course of a Clinical Trial or within one year of the start or completion of a Clinical Trial ; or
 - Such other External Relationships and Financial Interests that could directly and/or significantly affect the conduct of a Clinical Trial at Fred Hutch.
- **Key Officials:** The Fred Hutch President and Director, the Executive Vice Presidents, Senior Vice Presidents, the General Counsel, and others in positions of leadership as identified by the

POLICY:

Institutional Conflicts of Interest will be disclosed, reviewed and resolved in accordance with the terms of this Policy and the procedures as established by the ICOI Advisory Committee.

Institutional Conflict of Interest Advisory Committee

The Compliance Office will review all disclosures and decide if any of the External Relationships or Financial Interests require ICOI Advisory Committee review. The ICOI Advisory Committee will review potential conflicts and recommend steps to manage, reduce or eliminate them to the Chief Compliance Officer. The Chief Compliance Officer shall be responsible for final confirmation of whether an ICOI exists, and for implementing steps to resolve the conflict in accordance with the ICOI Advisory Committee's recommendations.

The ICOI Advisory Committee will convene on an ad hoc basis. At minimum, membership will include a member of the Compliance Office and the relevant subject matter expert(s) based on the specifics of the case under review. ICOI Advisory Committee members will not hold positions that require them to exercise responsibility over the administration of Fred Hutch's human subjects protection program.

On at least an annual basis, the following information will be provided to the Compliance Office:

- COI disclosures for all Key Officials;
- Intellectual property and Equity Interests acquired or held by Fred Hutch;
- Gifts or pledges to Fred Hutch from any Business Entity that exceed \$500,000 in a fiscal year that is sponsoring a Clinical Trial at Fred Hutch or whose products or services are being tested in a Clinical Trial at Fred Hutch;
- Any other information that may assist the Compliance Office in its reviews.

If a potential Institutional Conflict of Interest involves the Chief Compliance Officer, the ICOI Advisory Committee will submit its recommendations to the Chair of the Audit and Compliance Committee. At their discretion, the Chair may escalate the matter to the full Audit and Compliance Committee for further assessment and resolution

Appeals

In the event that a clinical trial is discontinued due to an inability to effectively manage an Institutional Conflict of Interest, the stakeholder(s) involved may submit an appeal. Appeals must be directed to the Chair of the Audit and Compliance Committee, who holds discretion to either adjudicate the matter independently or convene the full Audit and Compliance Committee to assist in resolving the appeal.

Annual Reports

At least annually, a report will be provided to the Enterprise Risk Oversight Committee (EROC) and the

Audit and Compliance Committee of the Board (ACC) by the Compliance Office.

REFERENCES:

- COGR [Analyzing Personal Financial and Institutional Conflicts of Interest in Academic Research Contexts](#)
- Fred Hutch [Board of Directors, Corporate Officers and Key Employees Conflict of Interest Policy](#)
- Fred Hutch [Conflicting Interests of IRB Members \(HRP-050\)](#)
- Fred Hutch [Individual Conflict of Interest and Conflict of Commitment Policy](#)
- HHS regulation [42 CFR Part 50 Subpart F, "Promoting Objectivity in Research \(FCOI regulation\)"](#)