

Foundation for the National Institutes of Health
CONFLICT OF INTEREST POLICY
for
THE BIOMARKERS CONSORTIUM

For purposes of the Biomarkers Consortium, each individual who is a member of a Governance Committee, but is not affiliated with a Non-Federal Entity or a Federal agency, and each Non-Federal Entity or Federal Agency that has one or more employees participating in any manner or through any means in the activities of the Biomarkers Consortium as part of his or her official duties agrees to comply with the following, as applicable:

Non-Federal Entities

- A. Each entity participating in the activities of the Biomarkers Consortium that is not a U.S. Government agency is required to implement a conflict of interest policy applicable to all employees participating in any manner or through any means in the activities of the Biomarkers Consortium that defines, identifies, and provides for the elimination of both financial and non-financial conflicts of interest as described, without limitation, in the FNIH Conflict of Interest Policy attached at Appendix A. Such policy shall:
 - a. be in writing and be effectively communicated to all employees who are engaged in activities connected to the BC;
 - b. address non-employees working with the entity (e.g., contractors, consultants, volunteers, etc.) to ensure that they too are subject to such policy or a comparable policy; and,
 - c. include provisions for enforcement and sanctions, including the ability of the entity to mitigate or otherwise resolve any conflicts of interest.
- B. Each non-federal entity will submit to FNIH a signed Statement of Compliance attached at Appendix B.
- C. In the event any non-federal entity discovers or identifies a possible conflict of interest involving any employee who is a member of a Governance Committee, the entity shall promptly notify the FNIH Executive Director, or the Chairman of the relevant Governance Committee, who shall promptly notify the Chairman of the FNIH Board of Directors. Furthermore, the Chairman of the relevant Governance Committee will disclose any such conflict of interest to the other members of the Governance Committee before any vote on a business transaction affecting the relevant Consortium activity, and such disclosure will be recorded in the minutes of the meeting at which it is made.

Federal Agencies

- A. Each U.S. Government agency participating in the activities of the Biomarkers Consortium will implement and enforce all Federal rules governing conflicts of interest in relation to employee involvement in Biomarkers Consortium activities, including in addition to any agency-specific regulations the applicable criminal provisions of Title 18 of the *U.S. Code* (e.g., sections 208, 203, 205, 209) and Parts 2634 and 2635 of the Code of Federal Regulations.
- B. Each U.S. Government agency will, through the appropriate agency ethics official, submit to FNIH a signed Statement of Compliance attached at Appendix B.
- C. Federal employees known by their employing agency to have any apparent, or actual conflict of interest will not be assigned to participate or will not be permitted to continue participation in Biomarkers Consortium activities unless or until any apparent, or actual conflict of interest has been, waived or resolved under Federal law and regulation.
- D. In the event a conflict is waived for a Federal employee to permit that employee's participation in activities of the Biomarkers Consortium, the Federal Agency will promptly notify FNIH that a waiver is in place with respect to that employee.

Individuals

Each individual who is a member of a Governance Committee, but is not affiliated with a Non-Federal entity or a Federal agency, must

- A. Submit to FNIH a signed Statement of Compliance attached at Appendix C
- B. Promptly notify the FNIH Executive Director, or the Chairman of the relevant Governance Committee, of any apparent, or actual conflict of interest as described, without limitation, in the FNIH Conflict of Interest Policy attached at Appendix A involving the individual or any Related Person.

Appendix A

Foundation for the National Institutes of Health CONFLICT OF INTEREST POLICY FOR FNIH-MANAGED INITIATIVES

Purpose

This policy relates to conflicts of interest related to scientific research initiatives managed by the Foundation for the National Institutes of Health (the “Foundation” or “FNIH”). The purpose of this policy is 1) to encourage the recognition and disclosure of real or apparent conflicts of interest and to manage them; 2) to ensure that decisions about an Initiative and the use or disposition of the assets of or available to an Initiative are made honestly, prudently, and solely for the benefit of the Initiative; and 3) to ensure that such decisions are not influenced by any private profit or other personal benefit to “Interested Persons” who take part in a decision or whose decision may affect a “Related Person.” In addition to actual conflicts of interest, Interested Persons are also obligated to avoid actions that could be perceived or interpreted to be in conflict with the Initiative’s best interest.

The procedures below are established to avoid the possibility that members, including federal employees, consultants, advisors, and volunteers, of Governance Committees (i.e., Executive Committee, Steering Committee, Peer Review Committee, etc.) convened by the FNIH to support an FNIH-Managed Initiative (“Initiative”) do not receive an inappropriate benefit from their actions. Interested Persons should disclose their financial interest in entities doing business with or related to the Initiative and refrain from participating in decisions affecting transactions between the Initiative and those other entities without approval. Such relationships do not necessarily preclude participation in transactions so long as the relationship is clearly disclosed and the Foundation retains final approval to manage any real or perceived conflict of interest.

Definitions

1. **FNIH-Managed Initiative** – a public-private partnership of the FNIH whereby it has the responsibility to facilitate and convene the partnership, create an infrastructure for the partnership, provide support, where necessary, for the execution of the Initiative’s activities with the Initiative’s ultimate oversight provided by the FNIH Board of Directors.
2. **Interested Person** – shall mean any member of a Governance Committee (i.e., Executive Committees, Steering Committees, etc.) convened by the FNIH to support the Initiative including federal employees, consultants, advisors, and volunteers.
3. **Related Person** - shall mean with respect to any Interested Person either
 - a. (i) a natural person who is a parent, parent-in-law, spouse, brother, sister, brother-in-law, sister-in-law, child, child-in-law, grandchild or grandchild-in-law, or
 - b. (ii) any corporation, partnership, limited liability company, trust or other entity in which the Interested Person or any natural person specified in clause (i) hereof holds a position of, or similar to, director, officer, employee, partner, stockholder, trustee, or beneficiary of a trust (other than a *de minimis* ownership interest).

4. ***de minimis* ownership interest** – shall mean an ownership interest of an Interested Person that represents a beneficial ownership of less than \$15,000 of any entity or is otherwise determined by the FNIH Board of Directors on the basis of the facts and circumstances to be *de minimis*.
5. **Financial Interest** – compensation including direct or indirect remuneration as well as gifts or favors that are not insubstantial.
6. **Foundation Business Transaction** - shall mean past, present or future plans to do one or more of the following:
 - a. initiate, make the principal recommendation for, or approve a purchase, contract, or grant;
 - b. recommend or select a vendor, contractor, grantee;
 - c. draft or negotiate the terms of such a transaction; or
 - d. participate as a reviewer on Peer Review Committee.

Disclosure

Governance Committee Members. Any member of a Governance Committee convened by the FNIH to support the Initiative who may be involved in or aware of a Foundation Business Transaction in which there is a possible conflict of interest shall promptly notify the FNIH Executive Director, or the Chairman of the specific Governance Committee, who shall promptly notify the Chairman of the FNIH Board of Directors. Furthermore, the Chairman of the Committee will disclose any potential conflict of interest to the other members of the Committee before any vote on a business transaction affecting the Initiative, and such disclosure will be recorded in the minutes of the meeting at which it is made.

Determining a Conflict of Interest

After a conflict or an apparent conflict of interest has been disclosed, the FNIH Board of Directors [or an authorized committee thereof], in the absence of the Interested Person subject to such conflict or apparent conflict, shall determine if the conflict of interest or the appearance of a conflict of interest exists and is material and will decide how it is to be managed or eliminated. With the approval of the FNIH Chairman of the Board, a committee member with a conflict of interest may participate in deliberations but shall recuse him or herself from voting on any such transaction, or using personal influence in any way in the matter. The decision by the FNIH Board of Directors on these matters will rest in their sole discretion.

The Chairman of the Board shall be responsible for the application and interpretation of this Policy as it relates to Governance Committee members.

Each Interested Person has the affirmative responsibility to report to the Committee Chair any and all knowledge of any action or conduct that appears to be contrary to this Conflict of Interest Policy.

Examples of Areas where Conflict of Interest May Arise

1. Persons and firms supplying goods and services used in connection with the Initiative;
2. Persons and firms from whom property or equipment is leased for the Initiative;
3. Persons and firms who are, or who are planning to, make gifts, purchases or sales of real estate, security, or other property in connection with the Initiative;
4. Competing organizations;
5. Agencies, organizations, and associations that affect the Initiative; and
6. Related persons, friends and employees.

Potential Conflicts of Interest (Financial) include, but are not limited to:

1. Contracting to purchase goods and services or property from a participant in the Initiative or a director, officer, staff member of such participant, or a Related Person of any of the foregoing;
2. Engaging in any financial, business or other relationships with current or potential recipients of grants made in connection with the Initiative;
3. Owning stock or holding debt or other proprietary interests in any third party dealing with the Initiative;
4. Engaging in any outside activity, such as serving on the board of organizations that are current or potential recipients of grants made in connection with the Initiative;
5. A Related Person being associated with a recipient of a grant made, or the counterparty to a contract made, in connection with the Initiative;
6. Accepting in any form whatsoever, any remuneration, compensation or gift from current or potential recipients of grants made, or counterparties to contracts made, in connection with the Initiative, or providing or giving gifts or favors to others where these might appear designed to influence improperly others in their relations with the Initiative;
7. Using the time, personnel, equipment or supplies devoted to the Initiative, or the good will associated with the Initiative, for other than activities, programs and purposes approved in connection with the Initiative.

Examples

A Committee member whose personal financial interests could be positively or adversely affected by the acceptance, holding, or disposition of a particular gift from a donor in connection with the Initiative should inform the FNIH Executive Director or Chairman of the specific Governance Committee of his/her potential conflict of interest; refrain from seeking, obtaining, or reviewing non-public information about the gift; and, until a decision on the conflict is made by the FNIH Board, abstain from discussing or voting on acceptance of the gift.

Potential Conflicts of Interest (Non-Financial) include, but are not limited to:

1. An Interested Person who seeks preferential treatment in connection with the Initiative for himself, a Related Person, or business associate.
2. An Interested Person who for personal reasons makes use of confidential information obtained in connection with the Initiative for his/her own benefit, or for the benefit of a Related Person, business associate, or other organization.

Violations of Conflict of Interest Policy

If the FNIH Board of Directors has reason to believe that an Interested Person has failed to disclose an actual or potential conflict of interest, it shall inform the person of the basis for such belief and afford the person an opportunity to explain the alleged failure to disclose.

If, after hearing the response of the Interested Person and making such further investigation as may be warranted in the circumstances, the FNIH Board determines that the Interested Person has knowingly or intentionally failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and corrective action.

Annual Reporting

The Foundation requires members of Governance Committees to annually sign a statement, due on the day of the first committee meeting each year, which affirms that he/she:

1. Has received a copy of the conflict of interest policy,
2. Has received and reviewed a listing of all current funders, grantees and contractors related to the Initiative, if any at the time,
3. Has read and understands the policy, and
4. Has agreed to comply with the policy.

Federal Employees

The FNIH Board may determine, in its sole discretion, that the FNIH Conflict of Interest Policy does not apply to a Participant that is a federal employee if (i) the Participant is subject to other conflict of interest restrictions under applicable federal regulations or policies, and (ii) in the judgment of the FNIH Board, such other regulations or policies are adequate to address potential conflicts of interest that may arise in connection with the Participant's role in the Project.

Appendix B

Conflict of Interest Statement of Compliance for Entity or Agency

On behalf of my Entity or Agency, I have received and read the Foundation for the National Institutes of Health Conflict of Interest Policy for The Biomarkers Consortium, including Appendix A, (the “Policy”). By my signature below, I hereby affirm that I have authority to bind my Entity or Agency, that my Entity or Agency complies with the Policy, and that my Entity or Agency will, at all times during its participation in the Biomarkers Consortium, maintain and implement a conflicts of interest policy as described therein.

ENTITY/AGENCY SIGNATOR

Name (Please Type/Print)

Title (Please Type/Print)

Signature

Date

Entity/Agency name _____

Conflict of Interest Statement of Compliance for Individuals

I have received and read the Foundation for the National Institutes of Health **Conflict of Interest Policy Addendum for The Biomarkers Consortium** including Appendix A (the “Policy”). By my signature below, I hereby affirm that I will comply with such Policy and affirm that I have no apparent, possible, or actual conflict of interest involving myself or any Related Person and that I will promptly notify the FNIH Executive Director, or the Chairman of the relevant Governance Committee, of any apparent, possible, or actual conflict of interest involving myself or any Related Person.

INDIVIDUAL SIGNATURE

Signature

Date

Name (Please Type/Print)