Financial Conflict of Interest Policy

0. Abstract

This policy encompasses the definitions and federal regulations defined in the U.S. Department of Health and Human Services Final Rule on Financial Conflicts of Interest and the associated sections of 42 CFR Part 50, Subpart F and 45 CFR Part 94, in addition to any applicable directives from other funding or government sources, including FAR Part 3: Improper Business Practices and Personal Conflicts of Interest. Individuals with employment, contractual or business relationships with Arbor Research must identify and disclose any potential financial conflict of interest as soon as the issue is anticipated or known so it can be evaluated and, if necessary, managed or eliminated.

1. Purpose

The purpose of this policy is to support Arbor Research activities including grants and contracts, regardless of funding source, by enabling Arbor Research to avoid, identify, and manage financial conflicts of interest. This policy is also intended to ensure the design, conduct, and reporting of research is not biased by financial conflicts of interest, and the rights and welfare of human research subjects are not adversely affected by potential or existing, perceived or actual, financial conflicts of interest.

This policy and all associated procedures and supplemental documents are consistent with the Statement of Values and Code of Ethics that governs all activity carried out by or on behalf of Arbor Research.

2. Scope

This policy and the associated procedures and forms apply to all Arbor Research employees, and any subcontractors, independent contractors, or other parties with a fiduciary or business relationship with Arbor Research.

3. Policy

Arbor Research employees, or subcontractors, independent contractors, or other parties with fiduciary or business relationships with Arbor Research must avoid financial conflicts of interest that may, or may appear to, compromise their objectivity in conducting research, including research that involves human subjects, regardless of funding source or sponsor. Arbor Research will comply with the financial conflict of interest and significant financial interest requirements delineated in the U.S. Department of Health and Human Services Final Rule on Financial Conflicts of Interest and the associated sections of 42 CFR Part 50, Subpart F and 45 CFR Part 94, including posting this policy to the Arbor Research website. Arbor Research will also comply with FAR Part 3: Improper Business Practices and Personal Conflicts of Interest. Arbor Research will provide a copy of this policy and any financial conflict of interest disclosures for investigators with public health service funded research upon request.
4. Procedures

4.1 Compliance Committee
The President will designate a Compliance Committee, chaired by a Compliance Officer, to oversee all reporting statements, disclosures, management plans, and significant financial interests for all individuals subject to this policy. The Compliance Committee must include at least one independent member of the Board of Directors, as well as one representative each from Human Resources and Operations, and at least one project investigator. The President may appoint additional individuals as needed.

The Compliance Committee will create, implement, and monitor financial conflict of interest management plans as required, and will make the appropriate disclosures to any necessary organizations, institutional review boards (IRBs), funders, or other parties within the timeframe designated by the organization, IRB, funder, other party, or as specified by law. The Compliance Committee may discuss any particular management plan with the President, Board of Directors, or outside counsel, and will report all disclosures, management plans, and resolutions to the Board of Directors.

4.2 Managing and Reporting Conflict of Interest

4.2.1 Statement of Values and Code of Ethics
Arbor Research maintains an open door policy as outlined in the Statement of Values and Code of Ethics. Any employee who has reason to believe another employee has an actual, or potential financial conflict of interest should direct this concern to his or her supervisor and/or the Compliance Committee. Such reports are protected by the Statement of Values and Code of Ethics, and can be made without risk of retaliation.

4.2.2 Disclosures
Arbor Research will comply with all federal requirements for disclosure of financial conflict of interest and significant financial interest issues, including any noncompliance violations, as outlined in 42 CFR 50, Subpart F. When applicable, Arbor Research will disclose all financial conflicts of interest, including potential bias in research design, to impacted parties, including funding agencies, business partners, or vendors.

Individuals subject to this policy will be required to submit disclosure statements upon hire and annually thereafter, and at any applicable time defined below:
- prior to entering an actual or potential financial conflict of interest
- prior to the application or proposal submission for funded research
- within 30 days of discovering or acquiring a new significant financial interest

Individuals acknowledge that information relating to their involvement in financial conflicts of interest may be disclosed to third parties as part of Arbor Research’s compliance with federal regulations or contractual agreements.

4.2.3 Management Plans
Upon disclosure of a financial conflict of interest, the Compliance Committee will gather information and documentation to determine whether an actual or perceived financial conflict of interest exists and whether it can be reasonably managed. The Compliance Committee may ask the individual in question or other associated individuals to provide additional information or documentation. The Compliance
Committee may determine that the financial conflict of interest cannot be reasonably managed and direct the individual to terminate the business relationship creating the financial conflict of interest.

If the financial conflict of interest can be reasonably managed, the Compliance Committee will create, implement, and monitor a management plan for the individual in question. At a minimum, the management plan should include the following elements:

1. The role and principal duties of the conflicted individual as it pertains to the conflicted area and/or research project;
2. Conditions of the management plan;
3. Procedures to safeguard objectivity in the conflicted area and/or research project;
4. Confirmation of the individual’s agreement with the management plan; and
5. Procedures for monitoring compliance.

An individual’s updated or annual conflict of interest statement must include the status of any previous management plans and a description of any changes since the last statement, including whether the financial conflict of interest is still being managed or a statement that the conflict no longer exists.

Individuals with active management plans may request that the Compliance Committee review the management plan at any time. Management plans may only be terminated when the Compliance Committee determines that the financial conflict of interest no longer exists. Decisions of the Compliance Committee are binding and may not be appealed by the individual.

### 4.2.4 Record Keeping
Arbor Research will maintain records of all disclosures and actions taken by the organization to identify, disclose, and manage financial conflicts of interest. Records will be maintained by the Human Resources department, which will make all reasonable efforts to preserve the privacy and confidentiality of personal information revealed as part of the process. All records will be kept for at least three years after the latest of final project report submission, project end date, or termination of the employment, contractual, or business relationship with Arbor Research.

### 4.3 Compliance Training
All individuals subject to this policy must review and agree to abide by this policy and participate in a financial conflict of interest training session upon hire and annually thereafter. Individuals may be required to undergo immediate financial conflict of interest training should Arbor Research make substantive changes to this policy, or find the individual in violation of this policy or the individual’s management plan, per 45 CFR Part 94.

Acceptable financial conflict of interest training includes programs sponsored by NIH, CITI, and the University of Michigan, or other programs approved by the Compliance Committee.

### 5. Definitions & Roles

#### 5.1 Definitions
1. **Arbor Research website**: presently defined as [www.ArborResearch.org](http://www.ArborResearch.org)
2. **Conflict of interest**: when an individual’s financial, personal, or business interests, obligations, or fiduciary duties might affect or reasonably appear to affect Arbor Research organizational processes including the conduct, review, or oversight of research
3. **Family member**: spouse, domestic partner, significant other, sibling, parent, child, or other member of the individual’s household

4. **Financial conflict of interest**: a conflict of interest caused by money or other significant financial interest related to an individual’s Arbor Research responsibilities that could directly and significantly affect the design, conduct, or reporting of Arbor Research projects

5. **Hire**: effective date of an individual’s employment, contractual, or business relationship with Arbor Research

6. **Investigator**: the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of public health service funded research, or proposed for such funding, which may include collaborators or consultants

7. **Organizational responsibilities**: an individual’s professional responsibilities on behalf of Arbor Research, which may include research consultation, teaching, professional practice, organization committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards

8. **Public health service funded research**: any research funded wholly or in part by a contract or grant from the Public Health Service sector of the US Department of Health and Human Services

9. **Significant financial interest**: exists when one or more of the following interests of the individual (and those of the individual’s spouse and dependent children) that reasonably appears to be related to the individual’s organizational responsibilities. The interests include the value of more than $5,000 in equity holdings or equivalent, intellectual property rights and interests, payments for events such as consulting, advisory board membership, speaker’s bureaus, honoraria, or reimbursed or sponsored travel.

5.2 Roles

1. **Compliance Officer**: an individual designated by the President to chair the Compliance Committee

2. **Compliance Committee**: a committee appointed by the President to review all financial conflict of interest and significant financial interest disclosures and oversee all management plans for Arbor Research employees, subcontractors, independent contractors, or other individuals subject to this policy

3. **President**: Arbor Research employee with responsibility to appoint the Compliance Committee and Compliance Officer in accordance with this policy

6. **Enforcement**

Any individual found to have violated this policy may be subject to disciplinary action, up to and including termination of the employment, contractual, or business relationship with Arbor Research. The Compliance Committee may require individuals who violate this policy to repeat the financial conflict of interest training or another suitable alternative.