



Missouri Breaks Industries Research, Inc.

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7.2 FINANCIAL CONFLICT OF INTEREST POLICY

Introduction:

Missouri Breaks Industries Research, Inc. (MBIRI) is committed to practicing high standards of objectivity and integrity in research. The following guidelines define MBIRI's policy and procedures in regard to financial conflict of interest in sponsored projects funded by U.S. Public Health Service (PHS) including National Institute of Health (NIH). These guidelines are designed in compliance with Title 42 CFR Part 50, Subpart F for PHS grants and cooperative agreements and 45 CFR Part 94 for contracts. These regulations promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.

The effective date of this policy is October 15, 2024. The policy review schedule is every 3 years unless there is an imminent need for an earlier review. The financial conflict interest policy review will be carried out by the Conflict-of-Interest committee, consisting of the Grants and Contracts Manager, the MBIRI Director, the Human Resource Manager, and a research staff member.

The institution's contact person regarding this policy is Marcia O'Leary, Director of MBIRI. Any questions or discussions on this policy will be addressed by the contact person.

Scope:

This policy applies to all staff, researchers affiliated to MBIRI as well as individuals involved in the conduct, design, or oversight research at the MBIRI facility. This includes subgrantee, contractor, and collaborating investigators.

This policy excludes research funded under PHS Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Definitions:

- **Conflict of Interest:**
Means any situation when an individual or individual's immediate family member may compromise the scientific integrity of a research due to the individual or individual's immediate family business dealings or other financial arrangements.
- **Conflict of Interest Committee:**
The committee consists of the Grants and Contracts Manager, the MBIRI Director, the Human Resources Manager, and a research staff. The committee is responsible for conducting policy review, reporting, and identifying potential conflict of interest in MBIRI. The committee also administers and manages the MBIRI conflict of interest policy and resolves conflict of interest matters.
- **Department of Health and Human Services (HHS):**
HHS oversees the eight agencies in the U.S. Public Health Service including the National Institute of Health (NIH).
- **Disclosure:**
Refers to Investigator's disclosures of his/her significant financial interests.
- **Financial Conflict of Interest (FCOI):**
Means that the designated officials of the institution (MBIRI) determine that an SFI could directly and significantly affect the design, conduct, or reporting of PHS funded research.
- **Immediate Family Members:**
Means the individual's spouse and dependent children.
- **Institution:**
Means any domestic or foreign, public, or private, entity or organization (excluding federal agency). In this policy, the institution refers to MBIRI.
- **Investigator:**
Means the Principal Investigator and any other individuals responsible for the design, conduct, or report of research funded by PHS or proposed by such funding.
- **PHS:**
Means Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which authority involved may be delegated.
- **PHS Awarding Component:**
Means the organizational unit of the PHS that funds the research that is subject to this support.
- **Research:**
Means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.
- **Significant Financial Interest:**
Means anything monetary value including but not limited to
 1. Salary or other payments for services like consulting fees or honoraria

2. Equity Interests like stocks, stock options, or other ownership interests
3. Intellectual property like patents, copyrights, royalties from such rights
4. Gifts, gratuities, rewards, favors, perks, completion bonus

Excluding

1. Salary, royalties, or other remunerations from the applicant institution
2. Any ownership interests in the institution if the institution is an applicant under the SBIR program.
3. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
4. An equity interest that when aggregated for the investigator and investigator's immediate family members meets both the following tests: a) does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and b) does not represent more than 5% ownership interest in any single entity.
5. Salary, royalties, or other payments that when aggregated for the investigator and investigator's immediate family members over the next twelve months are not expected to exceed \$10,000.

- **Small Business Innovation Research (SBIR):**

Means the extramural research program for small business that is established by the awarding components of PHS and certain other federal agencies under the Small Business Innovation Development Act.

Institutional Responsibilities:

- MBIRI will maintain, update, and enforce the financial conflict of interest policy and make it available to any requestor within five business days of the request.
- MBIRI will inform each investigator of the MBIRI FCOI policy and the investigator's disclosure responsibilities of all foreign and domestic SFI.
- MBIRI will inform investigators of federal regulations for training and associated resources.
- MBIRI will provide investigators with FCOI training as required by 42 CFR 50.604(b). This may include https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.
- MBIRI will make the conflict information available, upon request, to the department of health and human services (HHS).
- MBIRI will report to the PHS awarding agency the existence of a conflict of interest, and how it is managed, reduced, or eliminated.
- MBIRI will maintain FCOI records for at least 3 years. These records include investigators' SFI disclosures, institution review and response to the disclosures.

Review of Disclosure Forms:

- The designated institution officials for MBIRI are Marcia O'Leary and the Grants and Contracts Manager.
- As designated institution officials, they will solicit and review disclosures of SFI from investigators and their immediate family members. They will be responsible for collecting updated SFI disclosures. If an investigator has discovered or acquired a new SFI, an updated SFI will be solicited and received within 60 days.
- The designated institution officials will provide adequate guidelines to determine whether an investigator's SFI is related to PHS/NIH funded research and, if so related, whether the SFI is an FCOI.

- The designated institution officials will review the SFI disclosures and determine if an FCOI exists and take the necessary actions to manage the FCOI. This may include but not limited to:
 - a) Public disclosure of the SFI
 - b) Monitoring of research by independent reviewers
 - c) Modification of research plan
 - d) Disqualification of investigator's participation in all or a portion of the research
 - e) Severance of relationships that create the conflicts.

Non-Compliance:

If a failure of an investigator to comply with the conflict-of-interest policy of MBIRI compromised the design, conduct, and results of the PHS research, MBIRI will promptly notify the PHS awarding agency and/or HHS for further actions and directions to manage the conflict and maintain the objectivity of the funded research.

Resources:

https://era.nih.gov/files/fcoi_user_guide.pdf

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

<https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>

[https://grants.nih.gov/grants/compliance/42 CFR 50 Subpart F.htm](https://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm)