



# Missouri Breaks Industries Research, Inc.

118 South Willow Street  
PO Box 1824  
Eagle Butte, SD 57625  
Phone: 605-964-3418

*Rev03.25.2021*

## **7.2 FINANCIAL CONFLICT OF INTEREST POLICY**

### **Introduction:**

Missouri Breaks Industries Research, Inc. (MBIRI) is committed to practice high standards of objectivity and integrity in research. The following guidelines define MBIRI's policy and procedures in regards 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 February 1, 2019. 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 Manager, the Director of Education and Community Outreach, and a research staff member.

The institution's contact person on this policy is Marcia O'Leary, Manager 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.

## TABLE OF CONTENTS

Content	Page:
<b>Glossary of Terms:</b>	<b>3 - 4</b>
<b>Policy:</b>	
<b>1) Training:</b>	<b>5</b>
a. Institution Policy	
b. Investigator's disclosure responsibilities	
c. Federal Regulation	
d. FCOI Training	
<b>2) Disclosure, Review and Monitoring:</b>	<b>5 - 6</b>
a. Disclosure	
b. Review	
c. Monitoring	
<b>3) Reporting:</b>	<b>6 - 7</b>
a. Initial report	
b. Annual report	
c. Revised report	
d. Mitigation report	
<b>4) Maintenance of Records:</b>	<b>7</b>
<b>5) Enforcement:</b>	<b>7 - 8</b>
a. Administrative actions	
b. Retrospective reviews	
c. Remedies	
<b>6) Subrecipient Requirements:</b>	<b>8</b>
<b>7) Public Accessibility:</b>	<b>8 - 9</b>

## **GLOSSARY OF TERMS:**

- **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 consist of the Grants and Contracts Manager, the MBIRI Manager, the Director of Education and Community Outreach and a research staff. The committee is responsible to conduct policy review, report and identify potential conflict of interest in MBIRI. The committee also administer and manage the MBIRI conflict of interest policy and resolve conflict of interest matters.
- **Department of Health and Human Services (HHS):**  
HHS oversees the 8 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, 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.
- **Manage:**  
Means taking steps to reduce or eliminate the FCOI to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- **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.

## **POLICY:**

### **1) Training:**

MBIRI will inform every Investigator of the MBIRI FCOI policy, the investigator's disclosure responsibilities, and the federal regulations (42 CFR Part 50 Subpart F) prior to engaging in research related to any PHS-funded grant.

- a. MBIRI FCOI policy is posted on the MBIRI website: <https://www.missouri-breaks.com>.
- b. Investigator's disclosure responsibilities include:
  - o completing the Significant Financial Interests Disclosure (SFID) Form, *see Attachment A*, pertaining the Investigator and family (which includes spouse/domestic partner, dependent children and other dependent relatives living in your household) on anything monetary value including but not limited to salary or other payments for services like consulting fees or honoraria, equity Interests like stocks, stock options, or other ownership interests, intellectual property like patents, copyrights, royalties from such rights, and gifts, gratuities, rewards, favors, perks, completion bonus, and travel sponsored/reimbursed (excluding travel sponsored/reimbursed by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education) that are directly related to the research involved.
  - o completing the SFID form prior to the expenditure of funds, every year (prior to the renewal of the Investigator's contractual agreement), and anytime when there are changes in Investigator and family's financial interests related to the research involved.
  - o adhering to the Federal Regulation of 42 CFR Part 50 Subpart F, [https://grants.nih.gov/grants/compliance/42\\_cfr\\_50\\_subpart\\_f.htm](https://grants.nih.gov/grants/compliance/42_cfr_50_subpart_f.htm).
  - o providing documentation of completing FCOI training prior to engaging in NIH funded research and FCOI refresher training every 4 years.
- c. MBIRI adheres to the Federal Regulation of 42 CFR Part 50 Subpart F when engaging in NIH funded research.
- d. Resources for Investigators on FCOI Training are:
  - o [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)
  - o <https://about.citiprogram.org/en/series/conflicts-of-interest-coi/>

### **2) Disclosure, Review and Monitoring:**

- a. Disclosure: Investigator/Subrecipient will be required to complete the Significant Financial Interest Disclosure for Subcontractor Investigators/Consultants form, *see Attachment A*; and submit to the designated official a) prior to expending funding, b) annually (prior to the renewal of the Investigator's contractual agreement), c) anytime (within 30 days of acquiring and discovering FCOI) when there are changes in Investigator and family's financial interests related to the research involved.
- b. Review:

- i. Designated Officials: MBIRI’s designated officials include the Chief Executive Officer, Research Coordinator and the Grants and Contracts Manager. The designated officials’ responsibilities may include but not limited to:
    - o Solicitation and review disclosures of Significant Financial Interest (SFI) from investigators and their immediate family members.
    - o Collection of updated SFI disclosures. If an investigator has discovered or acquired a new SFI, an updated SFI will be solicited and received within 60 days.
    - o Public disclosure of the SFI
    - o Monitoring of research by assigning independent reviewers
    - o Modification of research plan
    - o Disqualification of investigator’s participation in all or a portion of the research
    - o Severance of relationships that create the conflicts
    - o Conduct retrospective review
  - ii. When a FCOI is disclosed, MBIRI will assess if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
  - iii. If it is determined that the FCOI directly and significantly affect the design, conduct, or reporting of the PHS-funded research, MBIRI’s designated officials will report the identified FCOI to PHS awarding agency within sixty days, and take steps necessary to manage the FCOI. This include implementing a management plan, **see Attachment B**, to eliminate or reduce the FCOI to ensure that the design, conduct, and reporting of research will be free from bias.
  - iv. In addition, within 120 days, a retrospective review will be conducted to determine if the design, conduct, or reporting was biased during the period of non-compliance. If bias was found, a mitigation report that outlines the extent of the bias affecting the research project and the plan of action taken to mitigate the impact of the bias will be sent to the PHS awarding agency.
- c. Monitoring: MBIRI will ensure that the Investigators/Subrecipients comply with the management plan. 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.

**3) Reporting:**

MBIRI will report to NIH accordingly:

Report	What to Report?	When to Report?
a. Initial report	<ul style="list-style-type: none"> <li>• Grant Number</li> <li>• Principal Investigator/Project Director Name</li> <li>• Name of Entity with FCOI</li> <li>• Value of financial interest</li> <li>• Description of how financial interest impacts the research</li> <li>• Key elements of the management plan</li> </ul>	<ol style="list-style-type: none"> <li>1. Prior to expenditure of funds</li> <li>2. Within 60 days of any subsequently identified FCOI</li> </ol>

b. Annual report	<ul style="list-style-type: none"> <li>• Status/progress on FCOI</li> <li>• Changes to management plan</li> </ul>	1. At the time when submitting annual progress report
c. Revised report	<ul style="list-style-type: none"> <li>• Updates on actions taken on previously submitted report specifying the actions that will be taken to manage the financial conflict of interest going forward</li> </ul>	1. After completion of retrospective review
d. Mitigation report	<ul style="list-style-type: none"> <li>• Grant Number</li> <li>• Project Title</li> <li>• Principal Investigator/Project Director Name</li> <li>• Name of Investigator with FCOI</li> <li>• Name of entity with FCOI</li> <li>• Reason for review</li> <li>• Detail Methodology</li> <li>• Findings and Conclusion</li> </ul>	1. When bias is found as a result of a retrospective review

**4) Maintenance of Records:**

MBIRI shall maintain all FCOI related records for 3 years from the date the final expenditures report is submitted to PHS (NIH) or where applicable, from other dates specified in 45 CFR 75.361. These records include investigators' SFI disclosures, institution review and response to the disclosures.

**5) Enforcement:**

- a. Administrative Actions: MBIRI will ensure Investigators comply with the FCOI policy by
- i. administering the significant financial interest disclosures: a) prior to expending funding, b) annually (prior to the renewal of the Investigator's contractual agreement), c) anytime (within 30 days of acquiring and discovering FCOI) when there are changes in Investigator and family's financial interests related to the research involved
  - ii. mandating FCOI training for Investigators prior to engaging in NIH funded research and FCOI refresher training every 4 years
  - iii. administering sanctions such as disqualification of investigator's participation in all or a portion of the research and severance of relationships that create the conflicts if Investigators do not comply with the FCOI policy

- b. Retrospective Reviews: If a significant interest financial interest 1) was not disclosed timely, or 2) was not timely reviewed or reported; MBIRI will carry out a retrospective review within 120 days to determine whether a financial conflict interest exists. The Retrospective Review will include the following information:

(1) Project number;

(2) Project title;

(3) PD/PI or contact PD/PI if a multiple PD/PI model is used;

- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

If the retrospective review established that a FCOI exists, MBIRI will implement a management plan that would specify the steps that have been or will be taken to manage the conflict of interest.

- c. Remedies: If a bias occurs in the design or conduct of a PHS-funded research due to the Investigator failing to comply with the management plan on FCOI policy, MBIRI will promptly notify the PHS Awarding agency of the corrective action taken or to be taken.

In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required, MBIRI shall require the Investigator involved to disclose the financial conflict of interest in 1) each public presentation of the results of the research and 2) to request an addendum to previously published presentations .

#### **6) Subrecipient Requirements:**

MBIRI will take steps to ensure that subcontractors or consortium members comply with the FCOI policy by

- i. Incorporating it in a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the MBIRI or that of the subrecipient will apply to the subrecipient's Investigators.
- ii. Ensuring that the subrecipient's Investigators comply and certify with the subrecipient's financial conflicts of interest policy. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of MBIRI, *see Attachment C*.
- iii. Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

#### **7) Public Accessibility:**

MBIRI will ensure that the Institution's FCOI policy is posted on the MBIRI website: <https://www.missouri-breaks.com>. MBIRI will maintain and update the financial conflict of interest policy annually and make it available to any requestor within 5 business days of the written request.



MBIRI will make available information to any requestor within five business days of a request, which include, the following:

- i. the Investigator's name;
- ii. the Investigator's title and role with respect to the research project;
- iii. the name of the entity in which the significant financial interest is held;
- iv. the nature of the significant financial interest; and
- v. the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

MBIRI will update a newly identified FCOI within 60 days and maintain the FCOI information for 3 years from the date the information was updated.

Attachment A



# Missouri Breaks Industries Research, Inc.

118 South Willow Street  
PO Box 1824  
Eagle Butte, SD 57625  
Phone: 605-964-3418

## Significant Financial Interest Disclosure for Subcontractor Investigators/Consultants

<b>Research Title:</b>	
<b>Site Principal Investigator/Study Staff Name:</b>	<b>Institution:</b>
<b>MBIRI Principal Investigator:</b>	<b>Grant Award:</b>

<p>1. Did you or your family receive in the past 12 months or are you currently receiving royalties for any intellectual property rights and interests (e.g. patents, copyrights), that directly related to this research? ___Yes ___No</p> <p>If Yes, please list the entity to which the intellectual property is licensed : _____ and please check the appropriate statement below:</p> <ul style="list-style-type: none"><li>• Annual Royalties less than \$5,000 ___</li><li>• Annual Royalties is more than \$5,000 ___</li></ul>		
<p>2. Did you receive in the past 12 months or are you currently receiving personal income (e.g. consulting fees, honoraria, paid authorship) from a commercial entity that may be providing a product for this research or whose product is the subject of the research? ___Yes ___No</p>		
<p>3. Did you or your family receive in the past 12 months or are you currently receiving equity interest (e.g. stock, stock options or other ownership interests) from a publicly-traded commercial entity and/or privately held commercial entity that may be providing a product for this research or whose product is the subject of this research? ___Yes ___No</p> <p>If Yes, please list the entity : _____ and please check the appropriate statement below:</p> <ul style="list-style-type: none"><li>• Equity Interest value less than \$5,000 ___</li><li>• Equity Interest value more than \$5,000 ___</li></ul>		
<p>4. Did you or your family receive in the past 12 months or are you currently receiving an unrestricted grant or gift from a commercial entity that may be providing a product for this research or whose product is the subject of this research? ___Yes ___No</p> <p>If Yes, please list the entity : _____ and please check the appropriate statement below:</p> <ul style="list-style-type: none"><li>• Amount of Grants/Gifts less than \$5,000 ___</li><li>• Amount of Grants/Gifts more than \$5,000 ___</li></ul>		
<p>5. Are you serving as a board of director or employee for a commercial entity that may be providing a product for this research or whose product is the subject of this research? ___Yes ___No</p> <p>If Yes, please list the entity : _____ and please check the appropriate statement below:</p> <ul style="list-style-type: none"><li>• Annual compensation less than \$5,000 ___</li><li>• Annual compensation more than \$5,000 ___</li></ul>		
<p>6. Has any organization sponsored or reimbursed you for any travel you have taken that is related to your work for MBIRI? ___Yes___ No (You are not required to disclose to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.</p>		
<p><b>Definition:</b> <b>Family:</b> which includes spouse/domestic partner, dependent children and other dependent relatives living in your household <b>Commercial Entity:</b> a for-profit business that exists to generate a monetary return for its owners or stakeholders</p>		
<table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;"><b>Signature:</b> _____</td><td style="width: 50%;"><b>Date:</b> _____</td></tr></table>	<b>Signature:</b> _____	<b>Date:</b> _____
<b>Signature:</b> _____	<b>Date:</b> _____	

Updated:03/25/2021

Attachment B

Conflict of Interest Management Plan

<b>Name of Investigator/Subrecipient:</b>	<b>Entity Involved in FCOI:</b>
<b>Project Name:</b>	<b>Grant/Project Number:</b>
<b>Designated Officials:</b>	<b>Case Number:</b> <b>Date:</b>
<b>Summary of Findings of FCOI:</b>	<b>Steps Taken:</b>
<b>I will be fully responsible for meeting the requirements of the Management Plan including all applicable training, compliance, and deadline requirements listed above.</b>	
_____	_____
<b>Investigator Signature</b>	<b>Date</b>
<b>Monitoring</b>	
<b>Follow-up date:</b> <b>Progress:</b>	<b>Steps Taken:</b>
<b>Follow-up date:</b> <b>Progress:</b>	<b>Steps Taken:</b>

Attachment C



# Missouri Breaks Industries Research, Inc.

118 South Willow Street  
PO Box 1824  
Eagle Butte, SD 57625  
Phone: 605-964-3418

## Sub-recipient Financial Conflict of Interest Policy Confirmation Form

<b>Project Title:</b>	<b>Proposed Sponsor:</b>
<b>Sub-recipient Principal Investigator:</b>	<b>Sub-recipient Institution:</b>
<b>MBIRI Project Director:</b>	

In accordance with U.S. Public Health Service (PHS) regulation 42 CFR 50.604; Responsibilities of Institutions regarding Investigator financial conflicts of interest; Missouri Breaks Industries Research, Inc. (MBIRI) requires disclosure of financial of conflicts of interests by its PHS-funded subrecipients.

Please check the option (A or B) that applies to your institution:

A. \_\_\_\_\_ Our Institution has a conflict of interest policy and process that complies with the PHS regulations set forth in 45 CFR Part 50, Subpart F; Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought; and 45 CFR Part 94; Responsible Prospective Contractors.

**OR**

B. \_\_\_\_\_ our Institution does not have a conflict of interest policy and process that complies with the PHS regulations set forth in 45 CFR Part 50, Subpart F; Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought; and 45 CFR Part 94; Responsible Prospective Contractors and agrees to rely on MBIRI's FCOI policy and procedures to comply with PHS Conflict of Interest regulations. Institutions checking this option are required to follow MBIRI's FCOI policies and procedures posted on <https://www.missouri-breaks.com>

C. Name(s) of individuals working on this project who are responsible for design, conduct or reporting of the research: \_\_\_\_\_

**As the Authorized Representative, I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. Furthermore, I certify that we will comply to applicable FCOI regulations, including, but not limited to those set forth in 45 CFR Part 94 and 42 CFR Part 50, Subpart F.**

**Authorized Representative Signature:** \_\_\_\_\_

**Print Name and Title:** \_\_\_\_\_

**Date:** \_\_\_\_\_