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Montana Cancer Consortium Financial Conflict of Interest Policy (FCOI)

Expectations and requirements within this document may change based on changing regulations, board of director recommendations, and FCOI findings. Changes will be communicated through e-mail and mail correspondence and other communication methods as necessary.

1. Objective

- a. The primary goal is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health System grants, cooperative agreements and contracts will be free from bias resulting from Investigator financial conflicts of interest.
- b. The Federal government requires that entities receiving federal funding maintain a written policy on financial conflict of interest which is consistent with 42 C.F.R. 50 entitled "Responsibility of Applicants for Promoting Objectivity in Research."
- c. This policy and procedures outlined below are intended to meet the most recent requirements published by the federal government regarding Revised Financial Conflict of Interest (FCOI) Regulation on August 25, 2011 (42 CFR Part 50 Subpart F and 45 CFR Part 94).

2. Definitions

- a. Investigator
 - i. A Montana Cancer Consortium (MCC) Investigator member shall be those who have signed membership papers for participation in the Montana Cancer Consortium NCI Community Oncology Research Program. An Investigator is an individual who has the potential to enroll clients or patients on NIH clinical trials. The participating Investigator members are not employees of MCC. The FCOI regulation defines an Investigator as an individual who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding, which may also include, for example, collaborators or consultants.
- b. PI
 - i. A principal investigator of a PHS funded research project.
- c. Senior/key Personnel
 - i. The PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.



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- d. Financial Conflict of Interest (FCOI)
 - i. A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS funded research
 - e. PHS
 - i. Public Health Service of the US Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- 3. Disclosure of FCOI**
- a. All Investigators responsible for the design, conduct, or reporting of research by any grant or sponsored trial agreement, are required to file financial disclosure form.
 - b. Financial disclosure forms need to be submitted annually by Investigators and;
 - i. Within 30 days of discovering or acquiring a new transaction or activity that might involve a potential conflict of interest.
 - ii. Whenever MCC revises its FCOI policy that affects requirements of Investigators.
- 4. Training**
- a. As per regulations (42 CFR 604(b)), all Investigators responsible for the design, conduct, or reporting of research by any grant or sponsored trial agreement, are required to undergo initial FCOI training and are required to be trained at least every 4 years. Mandatory training will consist of reviewing the following documents:
 - i. Revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research, 42 CFR Part 50, Subpart F
<https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol1/pdf/CFR-2011-title42-vol1-part50-subpartF.pdf>
 - ii. Montana Cancer Consortium FCOI policy.
<https://mtcancer.org/about-clinical-trials/>
 - b. Investigators can provide evidence of FCOI training from their individual hospitals. Other acceptable training may be determined by request on a case-by-case basis as evaluated by the MCC Director for content.
 - c. Additional optional web-based training is available and may be completed at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
 - d. Investigators will review this policy annually at the time of FCOI disclosure



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5. Significant Financial Interests

- a.** Any Investigator responsible for the design, conduct, or reporting of research activities funded or proposed for funding at MCC by external sources must reveal all current significant financial interests that would reasonably appear to be affected by the research.
- b.** Significant financial interest is defined as:
 - i.** Any current financial interest of the Investigator and his/her immediate family that could reasonably appear to be affected by the activities proposed for funding; or
 - ii.** Any interest held by the Investigator and his/her immediate family in a business entity (company, corporation, or other enterprise) whose financial interests might reasonably appear to be affected by such activities.
 - iii.** With regard to any publically traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
 - iv.** With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) hold any equity interest.
 - v.** Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their MCC responsibilities; provided, however, that this disclosure requirement does not apply 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. Disclosure of reimbursed or sponsored travel will include details of travel, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. MCC will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.



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- c. Specifically, significant financial interests might include, but are not limited to, any of the following:
 - i. Anything of significant monetary value, including salary or other payments for services such as consulting fees or honoraria;
 - ii. Direct equity interests such as stock, stock options, or ownership interests;
 - iii. Intellectual property rights owned by the Investigator such as patents, copyrights, and royalties from such rights.
- d. Significant financial interests do *not* include:
 - i. Financial interests in business enterprises or entities that, when aggregated for the Investigator and his/her immediate family, meet both of the following:
 - 1. The financial interest does not exceed \$5000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
 - 2. The financial interest does not represent more than a five percent ownership interest in any single entity;
 - ii. Salary, royalties, or other remuneration from MCC;
 - iii. Salary, royalties, or other payments that, when aggregated for the Investigator and his/her immediate family, are not expected to exceed \$5000 during the next 12 month period;
 - iv. Income from seminars, lectures, or teaching engagements 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;
 - v. Income from service on advisory committees or review panels for 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;
 - vi. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles.



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- e. An Investigator may choose to disclose any other financial or related interest that might present an actual, potential, or perceived conflict of interest. Disclosure can be a key factor in protecting an individual's reputation and career from potentially harmful allegations of misconduct.

6. Disclosure Review, Management Plans, Dispute Resolution and Appeals

a. Disclosure Review

The MCC Director will provide timely review of completed FCOI Annual Disclosure Forms and FCOI Training and will notify the Principal Investigator upon review completion. The MCC FCOI Disclosure Evaluation Checklist is used as documentation of review.

b. Management Plans for reported Conflict of Interest

Upon reviewing an individual FCOI Annual Disclosure Forms with possible conflict, the Principal Investigator, after discussion with the individual, will decide whether a management plan is needed. Should management of a potential or actual significant financial conflict of interest be required, the Investigator, the Principal Investigator, Institutional Administrator (where Investigator practices), and MCC Director will draft a "Management Plan." These written plans will manage, reduce, or eliminate the significant financial interest(s). Such plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the confidentiality of disclosed information. Final management plans are reviewed and approved by the MCC Board of Directors.

Management plans may include a single element or several elements such as:

- i. monitoring of the sponsored program by independent reviewers, the Billings Clinic Institutional Review Board, or an institution based ethics review board
- ii. modifications to the research or program plan;
- iii. appointment of an oversight panel or person to review research;
- iv. public disclosure of significant financial interests, including human research participants, researchers, publishers, and/or conference organizers;
- v. limitations on the Investigator's involvement in MCC; and/or
- vi. other arrangements that manage, reduce, or eliminate a potential financial conflict of interest.



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c. Dispute Resolution

If the Investigator, Principal Investigator, Institutional Administrator (where Investigator practices), and MCC Director cannot agree on a management plan, the matter will be referred to the MCC Board of Directors.

The MCC Board of Directors will review the written materials; consult with the Investigator, the Principal Investigator, Institutional Administrator (where Investigator practices), MCC Director, and/or others as needed. The MCC Board of Directors will make their recommendation to the MCC Principal Investigator. The Principal Investigator will make the final determination on management plans.

d. Appeal

If the Investigator does not agree with the recommendation of the MCC Board of Directors, he or she may appeal and ask to provide additional work on the draft management plan.

7. Compliance

As part of the Financial Disclosure Statement, each Investigator must certify that if the MCC Program Administrator and Principal Investigator determine a conflict exists, the Investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully with the individual(s) assigned to monitor compliance.

8. Enforcement

- a.** Failure to properly disclose relevant financial interests or to adhere to conditions or restrictions imposed by the Principal Investigator will be considered a deviation from accepted standards of conducting research at MCC.
- b.** Alleged violations of this policy will be investigated by the MCC Board of Directors, who will make recommendations for action to the Principal Investigator. Breaches of policy include failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous or misleading disclosure forms; or failure to comply with procedures prescribed by the Principal Investigator. If the Principal Investigator determines that the policy has been violated, he/she may impose sanctions including, but not limited to, notification of sponsor; formal admonition; a letter to the Investigator's personnel file; membership suspension from MCC. This will be reported to NIH through eRA Commons.



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9. Record Retention

- a.** The MCC Director will maintain records of all disclosures and associated activities securely and confidentially.
- b.** All records will be maintained for three years following termination or completion of the project or resolution of any government action involving the records.
- c.** Records will not be routinely provided to sponsors unless sponsor requirements dictate otherwise. In this case a written request must be received prior to the release of records. The MCC Director will be responsible for communications with sponsors. Disclosure statements and associated information will not be released without notification to the Investigator.

10. Public Accessibility Requirement

- a.** FCOI policy will remain posted on the MCC website at www.mtcancer.org and will not be password protected to allow full disclosure.
- b.** If the web site is not accessible due to technical reasons, the policy will be made available by MCC at request to anyone, as soon as possible but within a maximum of 5 business days after the request is received.
- c.** Any modification of the MCC FCOI policy will be posted on its website within 30 days.
- d.** Annual disclosure and update of FCOI regarding key/senior personnel (as identified in the competing grant application) will be requested and if FCOI exists, federally required elements will be posted on the website or made available within 5 calendar days of a request.
- e.** Any FCOI information held by a senior/key personnel identified will be updated on the MCC website within 60 days and will remain available for three years from the date the information was most recently updated.