



FCOI Policy and Procedures for Montana Molecular

Montana Molecular's Financial Conflict of Interest (FCOI) policy requires that each investigator, subcontractor and consultant affiliated with Montana Molecular on a project funded by NIH or NSF be in compliance with 42 CFR Part 50, Subpart F (and 45 CFR Part 94 for contracts).

Definitions

The following definitions apply to this policy:

“Funded Research” means any research funded by a Funding Agency.

“Investigator” means any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of research funded by a Funding Agency.

“Training Requirement” means training related to Financial Conflict of Interest (FCOI) and required under law.

“Significant financial interest (SFI)” means

1) financial interest consisting of one or more of the following interests of the investigator (including those of the investigator's spouse and dependent children) that reasonable appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any 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 and the value of any equity interest in the entity as of the date of disclosure, when aggregated exceeds \$5,000. For the purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;

(ii) With regard to any privately held entity, a significant financial interest exists if the value of any remunerations 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) holds any equity interests (e.g. stock, stock options, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

2) Investigators must disclose (and such disclosure shall constitute an SFI Disclosure, defined below) the occurrence of any 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 institutional 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, medical center, or research institute that is affiliated with an institution of higher education. This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Upon receipt of this disclosure, the Policy Coordinator will determine if further information is needed,

including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the Funding Agency research.

3) The term Significant Financial Interest does not include the following types of financial interests: salaries, royalties or other remuneration paid by Montana Molecular to the Investigator if the Investigator is currently employed or otherwise appointed by Montana Molecular, including intellectual property rights assigned to Montana Molecular and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the investigator; income from investment vehicles, such as mutual funds and retirements accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; 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, research institute that is affiliated with an institution of higher education; or 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.

With respect to its subcontractors, Montana Molecular shall obtain a confirmation from subcontractors and consultants working on NIH or NSF funded projects that the subcontractor's FCOI policy complies with the applicable regulation. Montana Molecular shall require the subcontractor or consultant to report identified FCOIs in a time frame that allows Montana Molecular to report identified FCOIs to the funding agency as required by the regulation.

A "Financial Conflict of Interest" or "FCOI" exists when Montana Molecular's FCOI Policy Administrator reasonably determines that a significant financial interest could directly and significantly affect the design, conduct or reporting of Funded Research.

FCOI Training for Montana Molecular Investigators

All Montana Molecular Investigators are required to complete the Training Requirement. The training must be updated no less frequently than every four years or as designated based on grant or role circumstances.

Information on training and other resources developed by NIH can be accessed through the NIH Web site: (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>).

Disclosures/Reporting/Determination Process

Each Investigator shall submit SFI Disclosures (using the Montana Molecular's SFI Disclosure Form) to the Policy Coordinator as follows: (i) annually; (ii) in the event of certain sponsored travel, as set forth in the definition of "significant financial interest"; (iii) within thirty (30) days of an Investigator discovering or acquiring any significant financial interest.

Additionally, the Policy Coordinator shall solicit SFI Disclosures from each investigator, if applicable, during a reasonable period of time preceding the commencement of any research conducted hereunder.

Montana Molecular's Policy Coordinator will review each SFI Disclosure and determine if any SFIs relate to funded research, determine if an FCOI exists, and develop and implement management plans as needed to manage FCOIs and to ensure that the design, conduct and reporting of Funded Research is free from bias.

If no FCOI is found, the SFI Disclosure will be filed with the Policy Coordinator's SFI Disclosure records. If a FCOI is identified it will be put on the FCOI report through the eRA Commons FCOI module (or, where Montana Molecular is a subcontractor, then Policy Administrator will report the FCOI as required under the applicable agreement) prior to expending any Funding Agency funds.

Montana Molecular shall make available information concerning identified FCOIs accessible prior to the expenditure of funds within five calendar days of a written request, and be updated at least annually, be updated within 60 days of a newly identified FCOI, and remain available for three years from the date the information was most recently updated.

Records Management

Montana Molecular will maintain records of all SFI disclosures, and records of resulting action, for at least three years from the date of submission of the final expenditures report for the applicable funding, or for such other periods of time as may be required under 45 CFR 75.361, if applicable.

Compliance and Penalties for Non-Performance

If an investigator fails to comply with the Montana Molecular's FCOI policy, within 120 days, Montana Molecular shall complete a retrospective review of the Investigator's activities to determine bias. If as a result of that determination, or at any other time, any bias is found, Montana Molecular shall submit a mitigation report to the applicable agency in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias. Montana Molecular will work with the Investigator to set up an FCOI management plan to mitigate the situation. Companywide, Montana Molecular is required to mandate the Investigator disclose the FCOI in each public presentation with research results, and to request an addendum disclosing the FCOI in previously published presentations, if it was not reported up front. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.

Policy Administrator: Anne Marie Quinn, President and CEO.

If you are working on an NIH or NSF research project and believe you have a conflict of interest or if you have a question to discuss, please email amq@montanamolecular to set up a time to discuss your concerns.

Affirmations

Montana Molecular has an up to date, written and enforced administrative process to identify and manage financial conflicts of interest (FCOI) with regard to all research projects for which NIH funding is sought or received by NIH.

Montana Molecular promotes and enforces investigator compliance with the regulatory requirements, including those pertaining to disclosure of significant financial interests (SFI)s

Montana Molecular will review any SFI reported, manage any FCOI and will provide initial and annual FCOI reports to NIH consistent with the regulation.

Montana Molecular agrees to make information available promptly upon request to the NIH relating to any investigator disclosure of financial interests and Montana Molecular's review of, or response to, such disclosure, whether or not the disclosure resulted an FCOI.

Montana Molecular fully complies with the regulation.