



Conflict of Interest Policy for Investigators and Subrecipients on Public Health Service (Including NIH) Grants, Contracts, and Cooperative Agreements

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MD2 Biosciences, Inc. (MD2) requires that each employee, investigator, subrecipient, subgrantee and collaborator affiliated with grants or contracts funded by National Institute of Health (NIH) or other US government programs, be in compliance with 42 CFR 50, Subpart F, *"Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought"* and 45 CFR 94 regarding grants and cooperative agreements.

MD2 holds the same values as NIH regarding the criticality of preserving the public's faith that all research, including NIH-funded research, is conducted without bias and with the highest scientific and ethical standards.

Scope.

This policy applies to all individuals who are responsible for the design, conduct or reporting of research funded by the Public Health Service (PHS), which includes the National Institutes of Health (NIH), or proposals for such funding.

If a research project involves subcontractors, subgrantees, or sub-awardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest (FCOI) in research policy is in effect at that institution and compliant with all applicable federal regulations. Should PHS or NIH or other agency funds be subcontracted by MD2 to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that MD2's policy shall apply to the subrecipient.

The Institutional Official (OI) or designee is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the IO is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy, including immediate for-cause termination of employment and/or advisory/consulting agreements.

Definitions

Clinical Trial means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's spouse and/or dependent children, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration paid to the Investigator if the Investigator is currently employed or otherwise appointed by the institution;
- b) Ownership interest in the institution where the investigator is currently employed.
- c) income from the authorship of academic or scholarly works;
- d) income from seminars, lectures, or teaching engagements sponsored by a U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers;
- e) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles; or
- f) income from service on advisory committees or review panels for a federal, state or local government agency an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

For Investigators, *Financial Interest* also includes any sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education defined in 20 U.S.C. 1001(a) (Institution and Investigator), research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest (SFI) means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities (and/or those of the Investigator's spouse and/or dependent children), and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property (e.g., patents, trade secrets and copyrights) rights and interests not reimbursed through the Institution, or
- e) is reimbursed or sponsored travel related to their institutional responsibilities, such disclosures including at a minimum: the purpose of the trip, the destination, the duration, and, if known, the monetary value.
- f) financial interests received from a foreign Institution of higher education or the government of another country.

Financial Conflict of Interest (FCOI) exists if it is determined that an Investigator has a **Significant Financial Interest** (as defined above) related to a research program or project that could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Institutional Official (IO) means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as Dr. Satheesh Ravula. The IO can appoint a designee.

Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, FDA, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means any project governed by PHS regulation for funded research. While such funded research includes applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs (these are PHS regulated), reporting for Phase 1 SBIR/STTR funding is not required.

MD2's Conflict of Interest Policy

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional official.

Disclosure of Financial Interests

All Investigators are required to disclose their outside financial interests as defined above to the Institution on an annual and on an ad hoc basis, as described below. The Institutional official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

Annual Disclosures. All Investigators must disclose their Significant Financial Interests that are related to the investigator's institutional responsibilities to the Institution, through the Institutional Official, on an annual basis.

Ad hoc Disclosures. In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within thirty (30) days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual

disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional official an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

Travel. Investigators must also disclose sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

All MD2 employees that meet the definition of Investigator are required to complete the disclosure form annually, even if they have no financial interest to report.

Investigator Responsibilities

Investigators are required to disclose all Significant Financial Interests and provide updates to disclosed information as needed, complete the annual disclosure form even if they have no financial interests to report, and complete all required training and education. If acting as the PI/PD, Investigator will provide a list of individuals who meet the definition of "*Investigator*" and any other requested information within the required disclosure timeline. Reports of financial conflicts of interest shall be submitted to MD2 within the requested disclosure timeline. Any interests that arise or are eliminated subsequent to the initial report must be reported to MD2 within 30 calendar days of such an event.

Training Requirements

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education on what constitutes financial conflict of interest. This course is required for any individual meeting the definition of Investigator. As of September 2021, the course is accessible at: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html .

Upon completion of the training, the certificate of completion must be submitted to MD2's Institutional Official (or designee) for record retention.

Each Investigator must complete training on this Policy, the investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four (4) years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to the institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

Financial Conflict of Interest (FCOI) Review and Management

If a disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. An FCOI exists when MD2 reasonably determines that a SFI could directly and significantly affect the design, conduct or reporting of PHS- or NIH-funded research.

If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the financial conflict of interest, including the reduction or elimination of the conflict, as appropriate. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she will develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward. The plan must ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

The IO will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

General Reporting Requirements

MMD2's designated Institutional Official will review all disclosures and evaluate whether they contain any FCOI. If no FCOI is found, the disclosure forms will be kept on file. If an FCOI is identified, the disclosure of the FCOI will be reported through the eRA Commons FCOI module. If any interests are identified as conflicting subsequent to the initial report, they must be reported to MD2 within 30 days. MD2 will then report it to the PHS awarding component that has issued the award within 60 days. Each Investigator must submit an updated disclosure of an SFI not less than annually.

In the event of non-compliance with reporting and/or management of a financial conflict of interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

MD2 will provide to the PHS Awarding Component an FCOI report as outlined in the regulations:

Initial Report: Prior to expenditure of any funds under the NIH- or PHS-funded research project, MD2 will provide a FCOI report regarding any SFI found to be a FCOI. MD2 will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project, or when MD2 identifies a FCOI not previously disclosed. The report will include information mandated by PHS guidelines, including Grant/Contract Number and its Principal Investigator, the Name of Investigator with the FCOI, the nature of the FCOI and its value (or relevant description in cases where value cannot be readily defined), a description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research, and key elements of the FCOI action plan.

Annual updates will be submitted to the PHS Awarding Component for the duration of the research project, describing the status of the FCOI, and, as necessary, updates to the action plan or justification that an FCOI no longer exists.

Records Management and Confidentiality

MD2 policy must be followed regarding maintenance of records as long as they are in compliance with the PHS regulation. Under the regulation, the Institution is required to keep all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest), and all actions under the Institution's policy or retrospective review, if applicable, as follows:

The IO will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, or, where applicable, from other dates specified in 45 C.F.R. 75.361. In the event any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding, or to additional entities as required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

Financial and other information disclosed in compliance with this policy will be disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel.

Non-Compliance and Penalties

Disciplinary Action. In the event of an Investigator's failure to comply with this Policy, the Institutional official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.

An Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision.

Retrospective Review. If an investigator fails to comply with this FCOI policy, within 120 days, MD2 will perform a retrospective review of the Investigator's activities. If the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Institutional Official and designees will complete a retrospective review of the Investigator's activities and the PHS-sponsored research to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional official will update any previously submitted report to the PHS relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the institution will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.

Public availability of FCOI procedure and information

Prior to the expenditure of funds, MD2 will publish on a publicly accessible website, or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation.

Requests for copies of this policy document should be directed to MD2's Point of Contact (below), who will provide a copy within 5 business days of receipt of request.

Regulatory Authority

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

Point of Contact

Questions, comments and submission of forms and training records should be directed to Dr. Satheesh Ravula, MD2's Institutional Official (IO) at sravula@md2bio.com.