



Financial Conflict Of Interest (FCOI) Policy

As an employee of VM Discovery, Inc., you are expected to act at all times in the VM Discovery's best interests and to exercise sound judgment unclouded by personal interests or divided loyalties. Both in performing your duties at VM Discovery and in your outside activities, you should avoid the appearance as well as the reality of a conflict of interest.

Federal regulations require all institutions applying for or receiving research funding from a federal agency to maintain a financial conflict of interest policy. The goal of this policy is to "promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under federal grants will be biased by any conflicting financial interest of an Investigator (defined below)". This policy has been drafted and further revised in accordance with the code of federal regulations 45 CFR § 50.F 2011 revisions.

DEFINITIONS

The following definitions apply to this policy:

Employee refers to any person that is employed by VM Discovery and includes part-time and full-time personnel.

Investigator means the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

Subrecipient refers to any investigator that is not considered an employee, including collaborators and consultants.

Senior/Key Personnel means the Project Director or Principal Investigator 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 under the regulation.

Institution means VM Discovery, Inc. and all wholly owned subsidiaries.

Employee's Institutional Responsibilities means an Employee's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Significant Financial Interests (SFIs) includes:

- (1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably 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
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\$5,000. For 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 includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- (ii) 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) holds any equity interest (e.g., stock, stock option, 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 also must disclose 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, a medical center, or a research institute that is affiliated with an Institution of higher education. The details of this disclosure will specify, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the VM Discovery's FCOI policy, the institutional official(s) 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.
- (3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; 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; 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.
- (4) Investigators must disclose their significant financial interests (SFIs), including reimbursed or sponsored travel, no later than at the time of application over the previous twelve-month period (initial disclosure), which is also the same disclosure requirement that applies to all other SFIs. The initial disclosure of SFIs over the previous twelve-month period provides baseline information that allows Institutions to take into account whether Investigators have an ongoing financial relationship with an entity providing a payment or reimbursement or whether the payment or reimbursement was
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limited in duration. Once Investigators have made their initial disclosure, they are required to update their disclosures within 30 days of discovering or acquiring a new SFI and annually during the period of award. Disclose requirements also apply to reimbursed or sponsored travel received by the Investigator's spouse and dependent children that is related to the Investigator's institutional responsibilities.

Financial Conflict of Interest (FCOI) exists when the VM Discovery's designated official(s) reasonably determines that an Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of NIH-funded research. The regulations set forth herein and in 45 CFR §50.F are used as guidance to determine whether a Significant Financial Interest is considered a FCOI.

EMPLOYEE OBLIGATIONS

To comply with federal law, federal regulations, and the Institution's Conflict of Interest Policy, all Employees must perform the following tasks:

- (1) Complete FCOI training within 30 days of employment commencement.
- (2) Repeat FCOI training at least every four years.
- (3) Training must be completed immediately, if:
 - a) VM Discovery revises its FCOI policy in a manner that affects investigator requirements;
 - b) Employee is not in compliance with the policy or management plan.
- (4) Disclose any Significant Financial Interest(s) using the Significant Financial Interest Disclosure form provided to you upon completion of training.
- (5) Update your Significant Financial Interest Disclosure form at the following time points:
 - a) prior to the submission of a research proposal to any federal agency;
 - b) at least every year from the date of last disclosure;
 - c) within 30 days of discovering or acquiring a new Significant Financial Interest.

All training certificates and disclosure forms should be submitted to the Institution's designated official. If there is any uncertainty about what classifies as a Significant Financial Interest or if you have questions about our Institutional FCOI policy, please contact the designated official. The designated institutional official will review and determine if there appears to be a potential conflict of interest. Then the designated FCOI committee will review the potential conflict of interest and initiate steps to manage or eliminate the conflict(s) if appropriate.

All Employees must comply with the Institution's FCOI policy to reduce, manage, and eliminate all potential financial conflicts of interest. In the event an FCOI is present or there has been noncompliance of the FCOI policy, the Employee must cooperate with the management plan set forth to remedy the FCOI or noncompliance.

Except to the extent required by law and federal regulations, the information disclosed will be kept confidential. You should know, however, that the Institution is required to report the existence of real or potential conflicts of interest to certain federal agencies. Specifically, the NIH (PHS) requires institutions to report to the PHS the existence of any conflicting interests and to assure that the interest has been managed, reduced or eliminated. NSF requires that only conflicts that have not been managed, reduced or eliminated prior to the expenditure of funds under an award be reported to NSF.



INSTITUTION'S OBLIGATIONS

Policy Creation

Federal Regulations require that VM Discovery develops, maintains, and enforces a financial conflicts of interest policy in order to discover and eliminate any conflicts of interest in ongoing research programs. VM Discovery is required to inform all Employees of this policy and appropriately train and enforce this foregoing FCOI policy for all Employees.

Prior to the Institution's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall, consistent with § 50.604(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

Training

Every new employee must be provided a copy of this policy and training materials within 5 business days of start date. The employee must complete training and submit the training certificate to the designated institutional official within 30 days. This certificate must be filed in the employee's record until an updated certificate is received. Training must be completed and a new training certificate must be filed at the following times:

- (1) If the Institution revises its FCOI policy that affects requirements of Employees;
- (2) If the Employee is not in compliance with the policy or management plan;
- (3) At least every four years.

The training presentation can be found at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Disclosures, Review, and Monitoring Significant Financial Interest

VM Discovery must collect Significant Financial Interest disclosure form(s) from every employee after completion of training and within 30 days of employment commencement. A separate disclosure form is required for each entity in/with which the employee holds a Significant Financial Interest. It is the responsibility of the designated institutional official to ensure he/she receives the disclosure forms from each employee upon the respective due dates as designated above.

The disclosure forms should be collected by the designated institutional official and reviewed for potential conflict of interest within five (5) business days of receipt. The designated official must complete the Significant Financial Interest review form and attach it to the original Significant Financial Interest disclosure form. If the designated institutional official suspects a potential conflict of interest, he or she will bring it to the attention of the CEO. At that time, a review committee will be selected by the designated official and CEO to consist of at least 2 unbiased personnel to review the Significant Financial Interest. The review committee will meet to discuss and determine whether or not they feel the Significant Financial Interest is a conflict of interest.

If it is determined that an FCOI exists, a management plan must be developed by the review committee to report, manage and eliminate the conflict of interest within sixty (60) days. This management plan must be shared with the employee along with a list of tasks and/or sanctions to resolve the conflict of interest.



The review committee must meet at least monthly to ensure the management plan has been appropriately executed until the conflict has been sufficiently resolved.

VM Discovery will comply with federal agency requests to make information available about any conflicts of interest and how they have been managed, reduced, or eliminated.

Reporting

VM Discovery is required to certify in each application for research funding from federal agencies the existence of this policy and to identify any existing conflicts of interest and assure that they have been managed, reduced or eliminated. VM Discovery also must report any conflicting interests to the appropriate federal agency at the following time points:

- (1) prior to expenditure of any grant funds;
- (2) within sixty (60) days of any new conflicts of interest that become apparent after the initial report to the relevant federal agency;
- (3) within sixty (60) days of the identification of a new employee or investigator participating in the research project;
- (4) at least annually based on the requirements for the annual progress report, multi-year report, if applicable, or at time of extension to provide status of the FCOI and updates to the management plan, if applicable, until end of the project;
- (5) following a retrospective review to make appropriate changes to the previously submitted report. If applicable, a mitigation report must be filed when bias is found as a result of a retrospective review.

VM Discovery is required to submit all FCOI reports to the NIH through the eRA Commons FCOI Module.

Maintenance of Records

VM Discovery is required to keep all FCOI-related documents including the review and response to each Significant Financial Interest disclosure on file for at least three (3) years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53 (b) and 92.42 (b) for different situations.

Enforcement Mechanisms and Remedies and Noncompliance

Federal regulations require VM Discovery to impose sanctions where appropriate. VM Discovery maintains the right to impose sanctions on Employees for failure to disclose Significant Financial Interests and for failure to abide by this policy. Sanctions may include restrictions on future submission of research proposals and other disciplinary actions up to and including dismissal.

If it has been determined that an Employee or the Institution is in noncompliance with this policy (e.g. Significant Financial Interests not disclosed, reviewed or managed in a timely or appropriate manner), then VM Discovery must complete and document a retrospective review within 120 days. The retrospective review should be conducted by the Significant Financial Interest disclosure review committee as designated by the CEO and designated institutional official. The results of the retrospective review shall be documented and attached to the disclosure documents. If bias is found, VM Discovery must immediately notify the NIH by submitting a mitigation report.



VM Discovery must enforce any sanctions or actions required by the Department of Health and Human Services pertaining to a PHS-funded research project involving clinical research. If an FCOI was not reported or managed according to regulations for a project whose purpose is to evaluate safety or effectiveness of a drug, medical device, or treatment, then VM Discovery must require the Employee or Investigator to disclose the FCOI in each public presentation of the results or research and request an addendum to previously published results or presentations.

Subrecipient Requirements

If VM Discovery carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), VM Discovery (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:

- (1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.
 - (i) If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;
 - (ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;
 - (iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.
- (2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

Public Accessibility

This FCOI policy is publicly available on our website at http://vmdiscovery.com/files/04FCOI_vmd_.pdf.

Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:



- (a) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;
- (b) The Institution determines that the significant financial interest is related to the PHS-funded research; and
- (c) The Institution determines that the significant financial interest is a financial conflict of interest.

The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and 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.

If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Institution determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the significant financial interests of an individual subject to this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

RESOURCES

<http://grants.nih.gov/grants/policy/coi/index.htm>
FCOICompliance@mail.nih.gov