MiraVista Diagnostics Financial Conflict of Interest Policy

Purpose

The policy on Financial Conflicts of Interest in Research provides guidelines to promote objectivity in research. The policy establishes standards to ensure that the design, conduct, and reporting of research funded by extramural sponsors will not be biased by any conflicting financial interest of an investigator. MiraVista Diagnostics is engaged in research developing and producing diagnostic assays through both internal and external funding mechanisms. This includes funding through competitive grants from United States government agencies. These policies seek to ensure any research conducted, designed, or reported by MiraVista Diagnostics is held to the highest standard and not hindered by bias or the perception of bias.

Applicable Regulations and Links

Public Health Service (PHS)
https://grants.nih.gov/grants/policy/coi/index.htm

Definitions

Business: Any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes.

Financial Conflict of Interest (FCOI): A situation in which significant financial interests in a business, or other personal considerations provided by a business, may compromise, or have the appearance of compromising, an investigator's professional judgement in conducting or reporting research, the results of which could affect the aforementioned business, either directly or indirectly. An FCOI exists when MiraVista Diagnostics, through its designated official(s), reasonably determines than an Investigator's Significant Financial Interest is related to a research project, institutional responsibilities and could directly and significantly affect the design, conduct or reporting of the research.

Human Subject (PHS regulations "Protection of Human Subjects" 45 CFR Part 46): A living individual about who an Investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Immediate Family: The Investigator's spouse/domestic partner and dependent children.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of MiraVista Diagnostics, which includes research, research consultation, institutional committee memberships, publication of appropriate scientific documentation, participation in scientific conferences and activities outlines within job descriptions and agreements.

Intellectual Property: A product of the intellect that has commercial value, including copyrighted works, patents, business methods, and industrial processes.

Investigator: The principal investigator and any other person (regardless of title or position) who is responsible for the design, conduct or reporting of research. This includes research associates, assistants, scientists and consultants.

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 involved may be delegated, including the National Institutes of Health (NIH)

Research (PHS regulation 45 CFR 46.102(d)): A systematic Investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this Policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

Significant Financial Interest (SFI)

1. Significant Financial Interests mean:
    a. With regard to any publicly traded entity, an SFI 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; or
    b. With regard to any non-publicly traded entity, an SFI 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 Immediate Family) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
    c. Intellectual Property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests that when aggregated, exceeds $5,000.
    d. 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 the Investigator's MiraVista Diagnostics Institutional Responsibilities when aggregated exceeds $5,000. These requirements do not apply to travel that is reimbursed or sponsored by Federal, state or local government agency located in the United States of America (U.S.); an institution of higher education in the U.S. as defined at 20 U.S.C. 1001 (a); an academic teaching hospital; a medical center; or research institute that is affiliated with an institution of higher education located within the U.S.

SFI does not include the following:

1. Salary, royalties, or other remuneration paid by MiraVista Diagnostics (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by MiraVista Diagnostics, including that paid for intellectual property rights assigned or licensed to MiraVista Diagnostics and agreements to share in royalties related to such rights.

2. Any ownership interest in MiraVista Diagnostics (or a subrecipient as applicable) held by the investigator (e.g., Employee stock ownership plan);
3. 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 those vehicles.
4. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state or local government agency located in the U.S.; an institution of higher education in the U.S. 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 all of which must be located within the U.S.
5. Income from service on advisory committees or review panels for a Federal, state or local government agency located in the U.S., an institution of higher education as defined in 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 located within the U.S.

Sponsor: An individual company, or any entity which takes responsibility for the initiation, management, and/or financing of a research project, but which does not actually conduct the investigation.

Procedures

I. Notification

A copy of this policy will be sent to all current Investigators and will be provided to all new Investigators upon hire. The policy is also available on the MiraVista Diagnostics website.

II. Training

All PHS-funded Investigators must complete training prior to engaging in PHS funded research and at least every four years thereafter as well as under the following circumstances (in the timeframes notes in parentheses).

a. Changes in the MiraVista Diagnostics FCOI policy (within 60 days)
b. An Investigator is new to MiraVista Diagnostics (prior to engaging in PHS funded research).
c. MiraVista Diagnostics finds that an Investigator is not in compliance with the FCOI Policy or a management plan, as applicable.

III. Disclosure of SFI

Each Investigator must disclose their known SFIs (including those of the Investigator's Immediate Family) that reasonably appear to be related to the Investigators Institutional Responsibilities, or that would reasonably appear to be affected by the research for which funding is sought or are in entities whose financial interests would reasonably be affected by the research. In determining whether a financial interest has to be disclosed, the Investigator shall consult the definition of SFI within this policy and, if in doubt, resolve in favor of disclosure.

1. Disclosure for each proposal submission: At the time of submission of a new proposal, an Investigator must have completed their financial disclosure.
2. Changes in SFI: An updated disclosure shall be completed and filed within 30 days at any time when an Investigator acquires or discovers a new reportable SFI not disclosed in the last disclosure. For existing Investigators on a project, new or newly identified SFIs will be reviewed promptly to determine if an FCOI exists, create a management plan if necessary and reported the newly identified FCOI to the sponsor within 60 days if required.
3. Human Subject Research: When research involved human subjects, the Investigator must disclose SFIs to the Institutional Review Board (IRB) with every submission of protocols. If an Investigator has FCOI, but a management plan is not on file, the IRB will contact the institutional designee and hold approval of the protocol until the FCOI is resolved.
4. New Investigators: If research is ongoing and an Investigator newly participating in the project discloses an SFI related to that research, those SFIs will be reviewed promptly to determine if an FCOI exists, create a management plan if necessary and report the newly identified FCOI to the sponsor within 60 days if required.
5. Annually: If currently receiving PHS-based funding during the time of annual review by the sponsor.
6. Retrospective Review: Following a retrospective review to update a previously submitted report, if appropriate (42 CFR 50.605(a)(3)(iii)).

IV. Determination, resolution, and management of a Conflict of Interest

1. A designated official (DO) will review SFI Disclosure Forms and, if an SFI is disclosed, additional information may be requested. The DO performs an initial administrative review and refers all disclosed SFIs to the MiraVista Diagnostics Administrative Official (AO).
2. The AO will be a member of company leadership and may seek the opinions and guidance of other managers or owners as needed.
3. The AO, with the help of the DO and Investigator and based on guidelines consistent with all applicable regulations, will determine if the SFI is related to Institutional Responsibilities and/or sponsored research project and, if so related, whether the SFI constitutes a FCOI.
4. If the AO and DO identifies an FCOI, it will resolve the conflict by elimination, mitigation, or the creation of a management plan. The Investigator must agree in writing to the conditions listed in such management plan. The following are examples of conditions that may be imposed:
    - Public disclosure of SFIs, including disclosure on manuscripts submitted for publication, on abstracts and posters submitted for presentation, and on the informed consent documents;
    - Monitoring of the research by independent reviews;
    - Modification of the research;

- Disqualification from participation in all or a portion of the activities that could be affected by the FCOI;
- Divestiture or reduction of the SFI;
- Severance of relationships that create actual or potential conflicts.

5. An FCOI must be eliminated or a management plan agreed to before a related award will be set up. Neither the institution nor an investigator may expend funds unless it has been determined that no FCOI exists or that the FCOI is manageable in accordance with the terms of the management plan.

V. Notification/Reporting

If an FCOI is identified, the AO is responsible for:

1. Notification of the investigator of the management plan.
2. Provide ownership and/or management with the management plan.
3. Notification of research sponsors, as required of any FCOIs, including any measures taken to reduce, manage, or eliminate such conflicts. The elements of such a report shall include, at least, the items enumerated under the FCOI Regulations.

The AO or their delegate will notify the above individuals, offices, and sponsors. Reasonable efforts will be made to maintain the privacy of information gathered in deliberations, within the limits imposed by the applicable laws and regulations.

VI. Maintenance of records

All records related to the implementation of this policy (e.g. Individual Financial Disclosure Forms, Supplemental Information Forms, notifications to funding agencies, actions taken to resolve or mitigate FCOIs, etc.) will be maintained securely by the AO for a period of at least 3 years beyond the termination or completion of the sponsored award to which they relate, or until the resolution of any action involving those records, whichever is longer. FCOI records shall be subject to periodic review for compliance with this policy by the AO or designee.

VII. Subrecipients

If a subrecipient carries out a portion of the work, MiraVista Diagnostics shall take reasonable steps to ensure that any subrecipient and subrecipient Investigator complies with the applicable FCOI regulation.

MiraVista Diagnostics will establish this via written agreement and/or applicable Disclosure Forms, the governing FCOI policy.

1. Sub-recipient will certify that its FCOI policy complies with the respective regulations and, further, sub-recipient will report identified FCOIS for its investigators in a time frame that allows MiraVista Diagnostics to report identified FCOIs to the awarding agency.
2. Alternatively, if a sub-recipient lacks a compliant FCOI policy, the subrecipient will be governed by the MiraVista Diagnostics FCOI policy.

In the event that a sub-recipient notifies MiraVista Diagnostics of an FCOI for sub-recipient Investigators for which MiraVista Diagnostics Is the prime awardee. MiraVista Diagnostics will promptly notify the sponsor.

VIII. Public accessibility

Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the AO shall ensure public accessibility of information about the FCOI, via a written response to any requestor within 5 business days of a request, of information concerning an SFI which was disclosed and is still held by the senior/key personnel on the project, which is determined to be related to the PHS-funded research, and which is determined to be a FCOI. The information shall consist of the information required to be provided under the FCOI Regulations.

IX. Monitoring compliance/mitigation

1. The DO and AO will monitor for compliance with the policy.
2. If the DO or AO learns of an SFI that was not timely disclosed or was not timely reviewed, they, shall, in consultation with ownership and no later than the 60th day after learning of the SFI:
   - Determine whether the SFI is an FCOI; and
   - If an FCOI exists, implement an interim management plan to implement other interim measures to ensure the objectivity of the research going forward.
3. If an FCOI was not timely identified or managed or if an Investigator fails to comply with a management plan, the AO or designee shall no later than the 120th day after determining noncompliance;
   - Complete and document a retrospective review and determination as to whether research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research; and
   - Implement any measures necessary with regard to Investigator's participation in the research between the date that the noncompliance is identified and the date the retrospective review is completed.
4. For PHS-covered research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating the FCOI Report, notifying the PHS awarding component, and submitting a mitigation report as required by federal regulation.
5. MiraVista Diagnostics will notify the PHS of instances in which the failure of an Investigator to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of funded research. MiraVista Diagnostics will make information available to HHS and PHS awarding component as required by federal regulation.

X. Implementation and enforcement

The AO will be responsible for overseeing the implementation of this Policy. In consultation with ownership, all breaches of policy will be reviewed:

- Failure to comply with the process (by refusal to respond, by responding with incomplete or knowingly inaccurate information, or otherwise);
- Failure to remedy conflicts; and
- Failure to comply with a prescribed management plan.

Sanctions and penalties will be determined by the AO with advice from ownership. Sanctions include, but are not restricted to;

- Letter of reprimand
- Notification to professional and/or scientific societies, funding agencies and/or professional journals
- Removal from research project
- Suspension
- Dismissal

Contact Information

All requests for additional information should be made to nbridges@miravistalabs.com or hlargura@miravistalabs.com.

Last Updated: 18JUL2023