



Illuminating Biological Interactions

Molecular Sensing Inc. (MSI) Financial Conflict of Interest (FCOI) Policy

Responsible Executive: Scot R. Weinberger, Executive Vice President of Research and Development

Responsible Offices: MSI: 111 10th Avenue, S., Suite 110, Nashville, TN; 103 Cooper Court, Los Gatos, CA, 94035

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I. PURPOSE OF THIS POLICY

The following sections detail the content and implementation of the Policy on Financial Conflict of Interest (Objectivity in Research) at Molecular Sensing, Inc. (MSI). This policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interests.

II. APPLICABILITY

The policy applies to Staff who are responsible for the design, conduct or reporting of research funded under Public Health Service (PHS) grants or cooperative agreements. The basic principle guiding this Policy is the obligation of the Center to conduct its research and related academic activities in an ethical manner. Therefore, situations in which the general public may reasonably expect the possibility of conflict of interest shall be disclosed and managed so as to reduce or dispel any perception of lack of objectivity on the part of an Investigator. At a time when the Center research activities are becoming more complex and collaborative and relationships with the private sector are strongly encouraged, Investigators and Administrators face additional challenges in maintaining objectivity and the appearance of objectivity in research. Therefore, the primary purpose of this process is to protect Investigators and other staff, and preserve the credibility of the MSI through a transparent procedure for conflict disclosure and resolution.



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For their own protection and the protection of MSI, Investigators are expected to disclose any Significant Financial Interest (SFI) related to their organizational responsibilities for any PHS funded research project. This policy is also guided by U.S. Code of Federal Regulations (Title 42 CFR Part 50, Subpart F) that promotes “objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS (Public Health Service) grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.” Separate definitions labeled “PHS” are included for researchers and key personnel of research funded under PHS grants.

Scope: This policy applies to all MSI personnel who are Investigators on PHS funded research.

III. DEFINITIONS

1. **FINANCIAL CONFLICT OF INTEREST:** exists when the Institution/Organizational designated official(s) reasonably determines that a Significant Financial Interest (defined below) could directly and significantly affect the design, conduct, or reporting of PHS- funded research.
2. **INVESTIGATOR** is a Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.
3. **INSTITUTIONAL RESPONSIBILITIES:** An investigator’s professional responsibilities on behalf of MSI including activities such as research, teaching, clinical or other professional practice, academic/instructional activities, scholarly events, institutional committee memberships, and service on panels such as the Institutional Review Board.
4. **SENIOR/KEY PERSONNEL** means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the Organization in the grant application, progress report, or any other reports.
5. **RESEARCH** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or



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cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

6. **PHS: PUBLIC HEALTH SERVICE**, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.
7. **PHS AWARDING COMPONENT** means the organizational unit of the PHS that funds the research that is subject to 42CFR Part 50, Subpart F. This includes the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ).
8. **PHS - SIGNIFICANT FINANCIAL INTEREST** means 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:
 - 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 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;
 - 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



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- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 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 term significant financial interest does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by MSI to the Investigator if the Investigator is currently employed by MSI, including intellectual property rights assigned to MSI and agreements to share in royalties related to such rights;
- 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.

IV. PROCEDURES

ORGANIZATIONAL AND INVESTIGATOR RESPONSIBILITIES:

The following procedures will be used to comply with the expectations of 42 CFR Part 50, Subpart F, and the Visiting Nurse Service of New York's FCOI Policy.

A. Training

(1) The Center Grants Administrator shall be responsible for ensuring that each Investigator is informed about the FCOI policy, the Investigators responsibilities regarding disclosure of Significant Financial Interest, the new FCOI regulations and the process in which the new regulations are met.

(2) The Center Grants Administrator shall require each Investigator to complete training regarding items listed above prior to engaging in research related to any PHS funded grant, cooperative agreement or contract at least every four years or when any of the following apply:

- The FCOI Policy, the PHS Financial Disclosure Form or the MSI procedures are revised in any manner that affects the requirements of the investigators
- An Investigator is newly appointed
- An Investigator is not in compliance with this FCOI Policy or its management plan.

(3) The PHS Financial Disclosure Form shall be distributed to the Investigator during the training and orientation prior to any participation in a PHS-funded project.

B. Disclosure, Review and Monitoring

(1) The Center will maintain an up-to-date written, enforced policy on financial conflicts of interest that complies with this subpart and will make its policy available on its Web site Link: [<http://www.molsense.com>]

(2) MSI's Executive Vice President of Research and Development shall develop and administer an efficient and effective method for reviewing timely disclosures from Investigators planning to participate in, or participating in, PHS funded research. Investigators are required to disclose their Significant Financial Interests (SFI):



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- No later than at the time of application for PHS–funded research;
 - An Investigator participating in PHS funded research shall submit an updated PHS Financial Disclosure Form within thirty days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new Significant Financial Interest ; and
 - At least annually, in accordance with the specific time period prescribed by the institution, during the period of award.
- (3) The Grants Administrator is responsible for soliciting and tracking the PHS Financial Disclosure Form for all participating Investigators when a proposal is submitted for central review and approval (prior to submission to the agency).
- (4) On the Financial Disclosure Form, the Investigator shall list all of the Investigator’s Significant Financial Interests (and those of the Investigator’s spouse, domestic partner and dependent children) that reasonably appear to be related to the Investigator’s Institutional Responsibilities. The form will include a link to the PHS FCOI regulations and the NIH FCOI Web site.
- (5) An Investigator who is new to participating in PHS- funded activities shall submit a PHS Financial Disclosure Form at the time the Investigator is identified by the PI/PD as a participant in a PHS funded research project. Training must be completed immediately and Significant Financial Interest disclosed within 30 days to ensure reporting of an FCOI (if applicable) can be made to the respective funding agency. The Principal Investigator will provide to the Grants Administrator the information necessary to begin the process.

C. Management of Financial Conflicts of Interests

(1) The Executive Vice President of Research and Development with the assistance of the Grants Manager will review the Financial Disclosure Forms from each Investigator planning to participate, or participating, in PHS funded research activities prior to the expenditure of funds.

(2) The Executive Vice President for Research and Development will determine whether an Investigator’s Significant Financial Interest is related to the specific PHS funded research project and, if so related, whether the Significant Financial Interest is a Financial Conflict of Interest (FCOI). In the event the Ex. Vice President is an



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Investigator for a study, the SFI disclosure review will be referred to the MSI Compliance Officer.

A. This determination should include the following criteria for a Significant Financial Interest:

- An Investigator's Significant Financial Interest is related to PHS-funded research when the organization official(s) reasonably determine that the Significant Financial Interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the PHS-funded research.
- A Financial Conflict of Interest (FCOI) exists when the organization official(s) reasonably determine that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

B. If an SFI is determined to be an FCOI, MSI's Executive Vice President for Research and Development will develop and implement a management plan. Recommendations for management, reduction or elimination of the conflict of interest may include but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institutional Review Board(s);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

(3) The MSI Management Plan will include the following but is not limited to:

- The role and principal duties of the conflicted Investigator in the research project;

- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

(4) The Grants Administrator will monitor adherence to the management plan.

D. Reporting of a Financial Conflict of Interest to PHS

The MSI Ex. Vice President of Research and Development must review and report to the applicable PHS funding agency a management plan in accordance with this FCOI Policy and the FCOI Regulations;

- The Grants Administrator will submit an initial FCOI report prior to expenditure of the funds under a PHS funded grant or cooperative agreement.
- The Grants Administrator within sixty (60) days of disclosure of an FCOI for an Investigator who is participating in an existing project or for a new SFI for investigators participating on an existing project.
- The elements of the report shall include the sufficient information to enable the PHS to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the management plan.
- The Grants Administrator at least annually will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- If the Ex. Vice President for Research and Development is also an Investigator on a PHS funded research project which includes an FCOI, then the Chief Executive Officer of MSI will review the FCOI report of such a conflict

Required Elements of the Financial Conflict of Interest Report:

All FCOI reports must include sufficient information to enable the PHS to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the MSI management plan. The regulation provides key elements that must be included in the FCOI report to PHS. These include but are not necessarily limited to the following:

- i. Project number or equivalent;
- ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- iii. Name of the Investigator with the Financial Conflict of Interest;
- iv. Name of the entity with which the Investigator has a Financial Conflict of Interest;
- v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- vi. Value of the 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;
- vii. A description of how the financial interest relates to the PHS- funded research and why MSI determined that the financial interest conflicts with such research.
- viii. The Grants Administrator will provide a description of the key elements of the management plan (see section C5 for the details of the management plan to be included).
- ix. The Grants Administrator within the Center must prepare and submit all FCOI reports
- x. All other FCOI reports will be submitted to the sponsoring PHS reporting agency as specified in the notice of grant award.

E. Enforcement Mechanism, Remedies and Non- Compliance

1. Instances of noncompliance include the following:
 - Failure by the Investigator to disclose a Significant Financial Interest that
 - is determined by the Organization to constitute a Financial Conflict of Interest;
 - Failure by the Organization to review or manage such a Financial
 - Conflict of Interest; or
 - Failure by the Investigator to comply with the Financial Conflict of Interest policy or Management Plan.

- MSI will ensure compliance with the new regulations for retrospective review and prepare a mitigation report, if needed, for submission to the funding agency as required under the FCOI new regulations.
- If an Investigator violates the FCOI Policy, for example by a failure to disclose, the MSI Ex. Vice President for Research and Development may refer the matter to the Office of Compliance, Risk Management for disciplinary action or other appropriate action.

Process for Reporting Non-Compliance:

- For any Significant Financial Interest MSI identifies as a Financial Conflict of Interest subsequent to MSI's initial FCOI report under the award a report shall be prepared and submitted by the Ex. Vice President of Research and Development upon **sixty (60) days** of the identification of noncompliance. Upon the determination of a noncompliance, for Significant Financial Interests not disclosed timely or previously reviewed or identified or managed in a timely manner a **Retrospective Review** must occur within **120 days** of MSI's determination and include the following key elements:
 - i. Project number;
 - ii. Project title;
 - iii. PD/PI or contact PD/PI (if a multiple PD/PI model);
 - iv. Name of the Investigator with the FCOI;
 - v. Name of the entity with which the Investigator has a financial conflict of interest
 - vi. Reason(s) for the retrospective review;
 - vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
 - viii. Findings of the review; and
 - ix. Conclusions of the review.
- If during the course of the review, a bias is determined, then a **Mitigation Report** will be required and include the following:

- - i. Key elements documented in the retrospective review
 - ii. Description of the impact of the bias on the research project
 - iii. MSI's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).
- **Risks for Non-Compliance:**
 - i. Impose special award conditions
 - ii. Suspend funding
 - iii. Impose other enforcement mechanisms until the matter is resolved.

F. Responsibilities of the Sub-recipients

If MSI carries out PHS-funded research through a sub-recipient, MSI must take reasonable steps to ensure that all sub-recipient Investigators comply with this by:

- MSI will incorporate into its written agreement that the sub-recipient's own Financial Conflict of Interest policy will apply to the sub-recipient's Investigators.
- The sub-recipient shall certify as part of the proposal and agreement with MSI that it complies with the new Financial Conflict of Interest regulations.
- Additionally MSI's sub-recipient agreement must specify the time period for sub-recipient disclosure of any financial conflict of interests to MSI to allow for MSI to report to PHS in a timely manner.

H. Public Accessibility

1. MSI is required to make its policy on Financial Conflict of Interest publicly available via a publicly accessible Web site.

2. Prior to MSI's Center for Home Care Policy and Research expenditure of any funds under a PHS-funded research project, MSI Center for Home Care Policy and Research shall ensure public accessibility. The Grants Administrator will provide a written response within five (5) business days of a request of information concerning any Significant Financial Interest disclosed to the Organization that meets the following three criteria:

- The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the PHS-funded research project identified by the

- Organization in the grant application, progress report, or any other required report submitted to the NIH;
- The Organization determines that the Significant Financial Interest is related to the PHS-funded research; and
 - The Organization determines that the Significant Financial Interest is a Financial Conflict of Interest.

3. The Significant Financial Interest information that MSI makes available via written response shall include the following:

- i. Project number or equivalent;
- ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- iii. Name of the Investigator with the Financial Conflict of Interest;
- iv. Name of the entity with which the Investigator has a Financial Conflict of Interest;
- v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- vi. Value of the 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;
- vii. Note 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 MSI's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

I. Maintenance of Records

MSI Grants Administrator is required pursuant to the FCOI Regulations to maintain all PHS Financial Disclosure Forms and all related records of actions taken by MSI Center for Home Care Policy and Research with respect to disclosures of financial interests for a period of three (3) years from the date of submission of the final expenditures report to PHS or, for awards that are renewed quarterly or annually from the date of the submission of the quarterly or annual financial report.



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Information concerning the senior/key personnel's Significant Financial Interest must remain available for responses to written requests for at least three years from the date that the information was most recently updated.

Questions about this policy should be directed to Scot R. Weinberger, Executive Vice President of Research and Development at: sweinberger@molsense.com.

RELATED DOCUMENTS, FORMS AND TOOLS

This policy is guided by the following federal and state regulations and reports:
42 CFR Part 50, Subpart F: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding Is sought.

NIH checklist

http://grants.nih.gov/grants/policy/coi/checklist_policy_dev_20120412.pdf

MSI Web site:

<http://www.molsense.com>



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The MSI Financial Conflict of Interest Policy has been read and understood and acknowledged by the understated and undersigned below:

Director, Executive, Employee, Contractor

Signature of Director, Executive, Employee, Contractor

Date