



**MONELL CENTER**

ADVANCING DISCOVERY IN TASTE AND SMELL

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## **Monell Chemical Senses Center Financial Conflict of Interest Policy**

### **Background and Purpose**

Monell Chemical Senses Center (“Monell”) recognizes its responsibility to ensure that research activities are conducted in an unbiased, objective manner that preserves public trust and that of our research program sponsors.

This policy sets forth that position and provides a mechanism for ensuring the integrity of research at Monell if a financial conflict should arise. This policy meets the requirements established by The U.S. Department of Health and Human Services (HHS) final rule in the [Federal Register](#) amending the Public Health Service (PHS) regulations on Responsibility of Applicants for ***Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94)***.

This policy applies to all persons at Monell who meet the definition of Investigator and applies to all Monell federally-funded research activities. Designated provisions of this policy apply only to Investigators applying for or conducting research funded by PHS agencies (including the National Institutes of Health).

### **Policy Statement**

It is the policy of Monell that no proposed, awarded, or ongoing research project shall be biased by any significant financial interest of any Investigator responsible for the design, conduct, or reporting of that research or activity.

All Investigators who apply for external funding from any federal entity for a research project shall comply with the requirements of this policy. If research is carried out through a subcontractor or collaborator, Monell shall require the subcontractor or collaborator of federally sponsored projects to certify that all Investigators working on the project are in compliance with a conflict of interest policy that satisfies the requirements of this policy.

As Monell promotes and encourages new and varied collaboration with other institutes, corporations and agencies of state and federal governments, it is a natural by-product that agency interests can appear to become tangled, regardless of whether that is in fact the case. Monell recognizes that many potential conflicts of interest do not constitute violation of federal regulations of financial conflict of interest, or may be acceptable with proper oversight and safeguards.

Below are a few examples of potential financial conflicts of interest (FCOI) that would need to be evaluated:

- Involvement of Monell investigators in an outside organization with which the faculty member has a personal financial interest
- Reimbursements to employees paid from public funds for work motivated by private concerns of Investigators
- Involvement of employees in decisions that could result in personal financial gain for themselves
- Transfer of Monell technology or intellectual property to a business entity owned by an employee
- Use of Monell resources, facilities, or equipment to provide services to a business in which the employee has a financial interest

### **Key Definitions**

For the purposes of this policy, the following definitions shall apply:

**Financial Conflict of Interest:** A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a federally-funded research project and could directly and significantly affect the design, conduct or reporting of the federally-funded research.

**Institution:** Any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for or that receives federal research funding. In this policy, Monell is considered the Institution.

**Institutional Responsibilities:** an Investigator's professional responsibilities on behalf of the Institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**Investigator:** 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 federal sources (e.g., NIH, CDC, FDA, ARO) or proposed for such funding, which may include, for example, collaborators or consultants.

**Management Plan:** an action plan to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**Senior/Key Personnel:** the Project Director/Principal Investigator (PD/PI) 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 federal agency by the Institution under the regulation.

**Significant Financial Interest:**

(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 \$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. *Please note exception listed in ii. below.*

(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; however, 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.

(3) The term *significant financial interest* does not include the following types of financial interests:

- i. salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- ii. intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights
- iii. any ownership interests in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization
- iv. 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;
- v. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, 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;
- vi. income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.

## **Disclosure Process**

When an Investigator submits a proposal for external funding of a research project, the Investigator(s) shall complete and provide to the Administrator/Treasurer a completed "Financial Interests Disclosure Form" form (the "Disclosure"). In the Disclosure, the Investigator shall indicate the general category of any Significant Financial Interests held by the Investigator, the Investigator's spouse or domestic partner, or her or his dependent children that reasonably appear to be related to the Investigator's Institutional responsibilities in the following timeframe:

- no later than at the time of application for federally-funded research;
- within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and
- at least annually during the period of award.

For any categories marked, the Investigator shall attach to the Disclosure supplemental documentation providing additional information on the entities involved and the nature and the amount of the interest.

Disclosure of sponsored or reimbursed travel must be reported within 30 days of completion using Monell's online travel disclosure form available through the Center's intranet. These disclosures will be reviewed on an ongoing basis. If further information related to travel is needed, a member of the FCOI committee will request this from the Investigator.

If the Investigator does not disclose any Significant Financial Interests in the Disclosure submitted at the time of a research application, the proposal shall be processed in the ordinary manner.

## **Review Procedures**

If the Investigator discloses any Significant Financial Interests (SFI) in the Financial Disclosure Form, the Administrator shall review the supporting documentation and the proposal to determine if there is a potential conflict of interest and therefore a need for a thorough FCOI review by the FCOI committee to determine if the SFI could be affected or be perceived to be affected by the federally-funded research, or if the SFI is in an entity whose financial interest could be affected by the proposed research.

If there is sufficient evidence to indicate a possible conflict of interest, the Administrator shall forward the Disclosure, the supporting documentation,

and the proposal to the Financial Conflict of Interest Review Committee (the "Committee") within two (2) business days of receipt of the Disclosure. The Committee shall consist of at least three members from the faculty, staff, or administration appointed by the Director, with one member designated as Chair of the Committee. If more than three Committee members are appointed, the total number of members shall be an odd number. If members of the FCOI committee have a disclosed SFI that requires review, then the remaining member(s) of the FCOI committee will select alternate members from the faculty or senior administration to serve on the Committee so that the FCOI committee consists of at least three members.

Upon notice that the project is likely to be funded, the Committee shall meet and determine whether the Significant Financial Interest(s) disclosed could directly and significantly affect the design, conduct, or reporting of the proposed research. The Committee may require the Investigator to submit more detailed information regarding the Significant Financial Interest(s) that relates to the project proposed for funding and may require the Investigator to meet with the Committee to provide additional information.

The Committee shall take one of the following actions on each proposal referred for review: (1) allow the proposal to go forward without modification; or if determined that the SFI could directly and significantly affect the design, conduct or reporting of the federally-funded research (2) require modifications, conditions, or administrative oversight for the proposed project to manage, reduce, or eliminate such conflict of interest; or (3) in the most severe cases, recommend withdrawal of the proposed project.

Examples of conditions or restrictions that might be imposed by the FCOI Committee include, but are not limited to:

1. public disclosure of Significant Financial Interests;
2. monitoring of the research by independent reviewers;
3. modification of the research plan;
4. disqualification of the Investigator from participation in all or a portion of the research;
5. divestiture of Significant Financial Interests; or
6. severance of relationships that create actual or potential conflicts of interest.

The FCOI Committee shall notify the Investigator and Monell's Director of the Committee's decision in writing. If the Investigator does not agree with any modifications or conditions imposed by the Committee in managing the FCOI or with the Committee's recommendation that the proposed project be

withdrawn, the Investigator shall have ten (10) business days following receipt of such notice to appeal the decision to an Appeal Committee made up of the Director, Associate Director(s) and Administrator/Treasurer. If the Director or Associate Director have a Significant Financial Interest that requires Committee review, and they wish to appeal the FCOI Committee's recommendations for modifications, conditions or withdrawal of the proposed project, then the remaining member (s) of the appeal Committee will select alternate members from either the Board of Directors, senior faculty or Emeritus faculty to serve on the appeal Committee so that the appeal committee consists of at least three members. Within ten (10) business days of receipt of an appeal, the appeal Committee shall notify the Investigator, and the FCOI Committee, of their decision in writing. The decision of the Appeal Committee, (the Director, Associate Director(s) and Treasurer) shall be final. A copy of any management plan adopted by the FCOI Committee or the Appeal Committee shall be maintained in the records of the Administrator/Treasurer. Any conditions or restrictions to resolve or manage conflicts of interest must be implemented before the expenditure of any funds awarded under a federally-funded grant or contract with Monell.

### **Notifying Agencies of Conflict Issues**

Monell is responsible for notifying PHS of an identified FCOI on an initial and ongoing basis. Prior to the expenditure of any funds under a PHS award, Monell shall report to the PHS awarding component within 60 days of discovery, the existence of a conflicting interest through the eRA Commons FCOI module. Details of this report will include the name of the entity with which the Investigator has a FCOI, nature of the FCOI, value of the financial interest, a description of how financial interest relates to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research along with key elements of the Institution's management plan. For any conflicting interest identified subsequent to a PHS award, Monell shall advise the PHS awarding component of the manner in which the conflict will be managed, reduced, or eliminated, at least on an interim basis, within 60 days of such identification. For all other federal agencies, Monell will follow the established procedures according to the terms of the award agreement.

### **Public Accessibility for FCOIs related to PHS funding**

Information on identified FCOIs held by senior/key personnel will be made available to the public upon request within 5 days of receipt of the written request or through the Monell Center's website ([www.monell.org](http://www.monell.org)). Information available to the public will include the name of the Investigator, nature and value ranges of the SFI and management provisions.

## **Mandatory Training**

Monell is responsible for ensuring that each Investigator is informed about this FCOI Policy, the Investigator's responsibilities regarding disclosure of SFI relating to the Investigator's Institutional Responsibilities, and the FCOI Regulations. This will be accomplished through mandatory training. Training records will be maintained by the Research Compliance Officer.

- Each Investigator must complete training prior to engaging in research related to any federally -funded grant or contract and at least every four (4) years, and immediately under the following circumstances:
- Monell Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to Monell
- Monell finds an Investigator non-compliant with this FCOI policy or established management plan.

## **Retrospective Review/Mitigation Plan for non-compliance for PHS Awards**

Monell is required to conduct a retrospective review in those cases of non-compliance with the regulation but is not required to report the review to the PHS Awarding Component. Monell will notify the PHS Awarding Component promptly and submit a report to the PHS Awarding Component only in cases where bias is found. The report will address the impact of the bias on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias.

## **Special Requirement for Clinical Research**

The 2011 revised regulation further requires that if funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

## **Records Retention**

The Administrator/Treasurer shall maintain records of all financial disclosures and of all actions taken to resolve actual or potential conflicts of interest until the later of: (1) a minimum of three years after the termination or completion of the award to which they relate; (2) the resolution of any



governmental action involving those records; (3) the date specified by applicable federal or state law; or (4) Monell's Records Retention Schedule.

### **Enforcement**

Monell anticipates that all Investigators will fully comply with this Policy. Failure to comply with this Policy will be grounds for disciplinary action in accordance with the Center's policy on appropriate Employee Conduct (Handbook Policy II.19).

### **Compliance Reporting**

Any suspected violation of this policy must be reported to the Research Compliance Officer at Monell.

### **Sub-recipient requirements**

All proposed sub-recipients under a federally-funded research project of Monell shall have a financial conflicts of interest policy that conforms to the requirements of the FCOI Regulations. With respect to these sub-grantees, subcontractors, and collaborators, Monell will require these entities to enter into a written agreement and make a certification at the time of award that its financial conflicts of interest policy complies with the PHS FCOI Regulations. The written agreement shall include all of the terms required under the FCOI Regulations.

Sub-recipient Institutions who have a written and enforced FCOI policy must report identified FCOIs to Monell in sufficient time to allow Monell to report the FCOI to the PHS Awarding Component (e.g., NIH through the eRA Commons FCOI Module) to meet reporting obligations. For all other federal agencies, Monell will follow the established procedures according to the terms of the award/contract agreement.

### **References and Resources:**

"Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought," 42 C.F.R. Part 50, Subpart F

"Responsible Prospective Contractors," 45 C.F.R. Part 94