

Financial Conflict of Interest Policy for Berkeley Madonna
Established August 5, 2023

This document outlines Berkeley Madonna's: 1. purpose for implementing a financial conflict of interest (FCOI) policy, 2. the FCOI Policy and key definitions/abbreviations, 3. a detailed protocol for identifying and handling FCOI, and 4. identification of individuals responsible for maintaining and enforcing the FCOI Policy. The most up-to-date version of this FCOI Policy is publicly available through our website at <https://www.berkeleymadonna.com>.

Section 1. Purpose

Berkeley Madonna strives to create an open, transparent, and honest working environment that promotes objectivity in research by establishing standards for how we design, conduct, and report on our research in an effort to ensure that it is free from bias that may arise from financial conflict of interest (FCOI). We apply these objectivity standards uniformly to all work that we produce including work funded and reported to the Public Health Service (PHS including the National Institutes of Health (NIH)), National Science Foundation (NSF), or any other government agency.

This FCOI Policy implements U.S. Federal requirements pertaining to "Objectivity in Research" as issued by the PHS of the U.S. Department of Health and Human Services (HHS) in U.S. Regulations 42 CFR Part 50, Subpart F and 45 CFR Part 94.

Section 2. FCOI Policy

Berkeley Madonna promotes objectivity in research by setting standards such that the design, conduct and reporting of all research, including publicly funded research through the PHS (including the NIH), NSF, or other federal agencies, is free from bias resulting from financial conflict of interest (FCOI). This policy applies to every employee who is planning to participate or is actively participating in research that is supported by public funds. Employees that meet this criteria must:

1. Disclose their significant financial interests (SFI) in non-Berkeley Madonna entities that would appear to be related to the employee's professional responsibilities on behalf of Berkeley Madonna;
2. Comply with a FCOI management plan, if a FCOI is identified; and,
3. Undergo FCOI training, at least once every four years.

Disclosure of SFI by employees is essential for Berkeley Madonna to determine if a FCOI exists, and in cases where a FCOI is determined to be present, the nature of the SFI will dictate how it will be managed and reported so as to remain in full compliance with government regulations. Employees that fail to disclose a SFI or are found to be in non-compliance with the FCOI management plan may be subject to disciplinary action including, without limitation, suspension or termination of employment.

Definitions & Abbreviations

Financial Conflict of Interest (FCOI): A SFI that could directly and significantly affect the design, conduct, or reporting of publicly funded research.

Financial Interest: Any interest of monetary value, even when the value is not readily ascertainable.

Covered Individual (CI): Any Berkeley Madonna employee who may be involved in or is actively involved in the design, conduct, and/or reporting of a publicly funded research project.

Employee Responsibilities: A CIs professional responsibilities on behalf of Berkeley Madonna means performing duties required of the position, such as normal business activities, conducting research, submitting patent applications, publication, technical committee membership, and teaching at institutes of higher education.

Equity Interest: Any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Immediate Family: A CIs spouse or domestic partner and dependent children.

Non-Significant Financial Interests (Non-SFI): These include the following types of financial interests:

- i. Remuneration paid by an entity to which a CI owes Covered Individual Responsibilities, if the CI is currently employed or otherwise appointed by such entity, including intellectual property rights assigned to such entity and any agreement to share in royalties related to such rights; or,
- ii. Any ownership interest in an entity held by the CI or income from investment vehicles, such as mutual funds and retirement accounts, as long as the CI does not directly control the investment decisions made in these vehicles; or,
- iii. Income from seminars, lectures, or teaching engagements sponsored by a US 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; or,
- iv. Income from service on advisory committees or review panels for a US 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.

Remuneration: This is defined as:

- i. Salary and any payment for services including consulting fees and honoraria;
- ii. Any equity interest; and,
- iii. Travel reimbursement related to the Covered Individual Responsibilities.

PHS Regulations: This phrase specifically refers to PHS issued US Regulations 42 CFR Part 50, Subpart F and 45 CFR Part 94.

Significant Financial Interest (SFI): As defined by PHS Regulations, a SFI is one or more of the following financial interests belonging to a Berkeley Madonna CI, or their Immediate Family, that reasonably appear to be related to Covered Individual Responsibilities, but specifically excludes any Non-SFI:

- i. Any Remuneration received from a publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds \$5,000; or,
- ii. Any Remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds \$5,000; or,

- iii. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

Section 3. Protocol for Identifying and Handling FCOI

This protocol provides a step-by-step implementation of the Berkeley Madonna FCOI Policy in Section 2. Capitalized terms throughout have the same meanings defined in Section 2. This protocol outlines the procedure that will be followed as per PHS Regulations.

A. Who is required to disclose financial interests

Berkeley Madonna employees (Covered Individuals) planning to or participating in research activity that is supported by public funds are required to disclose financial interests.

B. SFI disclosure

Covered Individuals are required to disclose SFIs to the Berkeley Madonna FCOI Official, as follows:

1. CIs planning to participate in publicly funded research are required to disclose all SFI's prior to submission of an application.
2. If the research project is funded all CIs must submit SFI Disclosures within thirty (30) days of acquiring any new or increased SFI.
3. When a new investigator joins an ongoing publicly funded project, the investigator must submit SFI disclosures within thirty (30) days of joining the project.
4. All CIs must submit an updated SFI disclosure annually.
5. SFI disclosures (except travel) must include the following information:
 - a. Name of sponsor/organizer; and,
 - b. Nature of SFI (e.g., salary, license income, stock).
5. Externally funded travel must be disclosed prior to submission of an application for publicly funded research, within thirty (30) days of the externally funded travel for ongoing publicly funded projects, and in an annual update. The following travel related information must be disclosed:
 - a. Purpose;
 - b. Identity of the sponsor/organizer;
 - c. Destination; and,
 - d. Duration.

C. Review of disclosures

All SFI disclosures, will be reviewed by the FCOI Official. The review will determine whether an SFI is related to the publicly funded research and therefore constitutes a FCOI. The designated FCOI Official may involve the relevant CI in the review and request additional information from the CI. When an SFI is identified that was not disclosed by a CI in a timely manner, the FCOI Official will determine if a FCOI exists, and if needed develop and implement a management plan within sixty (60) days of discovery. The FCOI Official will subsequently conduct a retrospective review of SFIs for the CI within one hundred twenty (120) days and document it.

D. Management of FCOI

For each disclosure that results in a FCOI, the FCOI Official will develop a management plan with which the CI must comply. The management plan will include the following elements at a minimum:

1. Clarification of the role and principal duties of the conflicted CI in the research project;
2. Conditions of the management plan (examples to follow);

3. Explanation of how the management plan will safeguard objectivity in the research project;
4. Confirmation of the CI's agreement to the management plan;
5. Details of how the management plan will be monitored to ensure compliance by the CI.

Examples of conditions that might be imposed to manage a CI's FCOI include, but are not limited to:

1. Public disclosure of FCOIs (e.g., in published research; in public presentations; in internal presentations to staff members working on the project; in documents or presentations presented to Berkeley Madonna Consultants or External Advisors);
2. For research projects involving human subjects, FCOI disclosures will be presented directly to participants;
3. Appointment of an independent monitor empowered to take measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
4. Changes to the research plan to remove or mitigate the FCOI;
5. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a part of the research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or,
7. Severance of relationships that create financial conflicts.

E. Reporting FCOI

Based on the FCOI management plan, the FCOI Official will submit an initial FCOI report to the PHS funding component, for example to the NIH using eRA Commons, and this document will consist of all elements required by PHS Regulations. The FCOI report will be submitted prior to the expenditure of funds under the Notice of Award. FCOIs identified during the period of award will be submitted to NIH within sixty (60) days of identification, including for new investigators joining an ongoing publicly funded project.

Annual FCOI reports, or revisions to reports resulting from retrospective reviews, will also be submitted to the NIH and will include the status of any financial conflicts, such as how they are being managed or why they no longer exist. FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

F. Training

Covered Individuals must undergo training with respect to this Policy as per PHS Regulations, as follows:

1. When a new employee joins Berkeley Madonna;
2. Prior to participating in publicly funded research, and at least once every four years;
3. When this Policy changes in a manner that effects CIs disclosure or compliance requirements; and,
4. If the Berkeley Madonna FCOI Official determines that a CI is not compliant with the FCOI Policy or an FCOI Management Plan.

NIH web-based training (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) will be used. Employees must save and print the FCOI Certificate as proof of completion, and provide this document to the FCOI Official.

G. Sanctions for policy violations

It is essential that CIs disclose SFIs so that Berkeley Madonna is able to successfully implement its FCOI Policy. If a CI fails to comply with this Policy by failing to disclose a SFI or showing non-compliance with a FCOI management plan, and these failures appear to have biased publicly funded research, the Berkeley Madonna FCOI Official will implement a

mitigation plan. The CI will be required to disclose the FCOI in each public presentation of the results of the research and to remedy previously published presentations or publications with an FCOI disclosure addendum. In addition, the employee may be subject to employment discipline including, without limitation, suspension or termination of employment. In any case, the PHS-funding agency will be promptly notified.

H. Retention of records

Records of financial disclosures and any resulting action will be maintained for three (3) years from the date of submission of the final expenditures report.

I. Subrecipient compliance

When working with a subrecipient, a written agreement will be put in place to clarify:

1. Which organization's (prime awardee or subrecipient) FCOI policy will be followed; and,
2. Clarify the timeline for disclosure and reporting.

Note that the prime awardee is responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest.

J. Public accessibility

As required by PHS regulation, the FCOI Policy is being made accessible on the Berkeley Madonna web site (<https://www.berkeleymadonna.com>).

If a CI holds financial interests that are determined to be a FCOI, as required by PHS Regulation, these will also be posted on the web site, as follows:

1. Include the minimum elements required by the regulation;
2. Update within sixty (60) days of a newly identified FCOI;
3. Update annually; and,
4. Remain available for three (3) years from the final expenditures report filing date.

Section 4. Administration of the FCOI Policy

The CEO is responsible for the administration of this policy, and is referred to as the FCOI Official throughout.