

A-02 Operations

A-02-22 Financial Conflict of Interest in Research

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OMRF is committed to performing medical research with integrity and openness. At the core of OMRF's mission is translating laboratory discoveries into therapies that improve human lives. Increasingly, for-profit entities play an important role in this process, but the financial incentives that accompany such involvement may also lead to conflicts of interest.

This policy is designed to identify any financial interests that could bias research at OMRF and to monitor and manage those situations to ensure that investigators' financial interests have no bearing on the research conducted at OMRF.

A. Investigator Annual Disclosure

1. Upon initial employment or affiliation with OMRF and on an annual basis thereafter, each Investigator (defined as any individual, regardless of title, who is responsible for the design, conduct or reporting of research at OMRF) must complete and submit a Financial Disclosure Statement using the OMRF Financial Conflict of Interest System.
2. Investigators also have an ongoing obligation to update their disclosures within 30 days whenever there is a change in status from their previously submitted disclosures.

B. Conflicts of Interest

1. Conflict of Interest Determination

If OMRF determines that an Investigator possesses a Conflict of Interest (defined as a financial interest that is related to the Investigator's research at OMRF and that could directly and significantly affect the design, conduct or reporting of that research), OMRF shall refer that Conflict to its Conflict of Interest Committee.

2. Conflict of Interest Committee Membership

The President and the Senior Vice President and General Counsel will serve on the Committee in an ex officio capacity and will determine the membership of the Committee, which will be drawn from members of the community, the OMRF Board of Directors, and OMRF staff.

3. **Conflict of Interest Committee Responsibility**

The Committee will review the Conflicts referred to it and will recommend steps to manage, reduce, or eliminate those Conflicts. The Committee will make recommendations to the President, who will report those recommendations to the Executive Committee of the OMRF Board of Directors for final action.

C. Managing Conflicts of Interest

Examples of strategies for managing Conflicts of Interest include:

1. Disclosure of financial interests to lab personnel and collaborators
2. Disclosure of financial interests in publications and posters
3. Disclosure of financial interests to audiences at conferences and seminars
4. Disclosure of financial interests to any human subjects participating in research studies
5. Appointment of an independent peer reviewer to monitor research
6. Modification of research plans
7. Disqualification of the Investigator from participating in research
8. Limitation of the Investigator's role in research
9. Divestiture of financial interests

D. Ongoing Training Requirements for Investigators

All Investigators must complete initial conflict of interest training and update their training at least every four years after their initial training. This training will be a requirement and will be satisfied by the completion of OMRF's online tutorial.

E. Reporting to Federal Agencies

1. Prior to expending any funds under a federal award, OMRF will report to the federal agency the existence of any Financial Conflict of Interest. A Financial Conflict of Interest exists when OMRF, through its designated official, the Senior Vice President and General Counsel, reasonably determines that an Investigator's Significant Financial Interest (as defined and explained below) is related to a federally funded research project and could directly and significantly affect the design, conduct or reporting of the federally funded research project.

2. In determining whether an Investigator possesses a Significant Financial Interest, remuneration includes payments for services, receipt of consulting fees, honoraria, paid authorship, royalties and intellectual property, as well as the value of any reimbursed or sponsored travel.
3. For a publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the 12 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.
4. For a non-publicly traded entity, a Significant Financial Interest exists: (a) if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000; or (b) when the Investigator or the Investigator's spouse or dependent children holds any equity interest in the entity.
5. Types of interests specifically excluded from the definition of Significant Financial Interest are:
 - a. 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 vehicle.
 - b. Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels for federal, state, or local government agencies, U.S. institutions of higher education, nonprofit academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education; or
 - c. Intellectual property rights or royalty shares assigned by OMRF to the Investigator.

F. Contents and Provision of Federal Reports

1. The information OMRF shall submit to the federal funding agency (via eRA Commons) about a Financial Conflict of Interest shall include:
 - a. Grant/contract number
 - b. Name of the principal investigator or project director
 - c. Name of the Investigator with the Financial Conflict of Interest
 - d. The name of the entity with which the Investigator has the Financial Conflict of Interest
 - e. Statement regarding whether the Financial Conflict of Interest was managed, reduced or eliminated

- f. The nature of the Significant Financial Interest involved (e.g., equity, consulting fees, travel reimbursement, honoraria)
 - g. The value of the financial interest, either by:
 - 1) Listing it within one of the following ranges:
 - \$0-\$4,999
 - \$5,000-\$9,999
 - \$10,000-\$19,999
 - amounts between \$20,000 and \$100,000 by increments of \$20,000
 - amounts above \$100,000 by increments of \$50,000 or
 - 2) Including a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value
 - h. A description about how the Financial Conflict of Interest relates to the federally funded research and the basis for OMRF's determination that the Significant Financial Interest conflicts with that research
 - i. A description of the key elements of OMRF's management plan, with that description including the following information:
 - 1) Role and principal duties of the conflicted Investigator in the federally funded research project
 - 2) Conditions of the management plan
 - 3) How the management plan is designed to safeguard objectivity in the research project
 - 4) Confirmation of the Investigator's agreement to the management plan
 - 5) How the management plan will be monitored to facilitate Investigator compliance
2. OMRF will provide annual reports to the federal funding agency for any previously reported Financial Conflict of Interest.
- a. The annual report will specify whether the conflict is still being managed, describe any changes to the management plan or explain why the conflict no longer exists.

- b. OMRF will provide annual reports to the funding agency for the duration of the project period, including extensions with or without funds, at the same time as OMRF's Grants Office submits the annual progress report or at the time of project extension.

G. Public Disclosure

1. OMRF shall make its Conflict of Interest in Research Policy publicly accessible via its website [link].
2. OMRF will also post on its website the following information regarding any identified Financial Conflict of Interest:
 - a. The name of the Investigator
 - b. The title and role of the Investigator in the federally funded research project
 - c. The name of the entity in which the Significant Financial Interest is held
 - d. The nature of the Significant Financial Interest
 - e. The value of the financial interest, either by:
 - 1) Listing it within one of the following ranges:
 - \$0-\$4,999
 - \$5,000-\$9,999
 - \$10,000-\$19,999
 - amounts between \$20,000 and \$100,000 by increments of \$20,000
 - amounts above \$100,000 by increments of \$50,000 or
 - 2) Including a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.

H. Non-Compliance and Enforcement

1. If an Investigator fails to comply with this policy and such failure implicates federally funded research, within 120 days of determining such non-compliance, OMRF must complete a retrospective review of the Investigator's activities and research. This review will document OMRF's determination as

to whether there existed any bias in the design, conduct or reporting of the federally funded research.

2. If bias is found, OMRF must submit a mitigation report addressing: the impact of the bias on the research project, including the extent of the harm done; any qualitative and quantitative data to support any actual or future harm; whether the project is salvageable; and the actions OMRF has taken or will take to eliminate or mitigate the effect of the bias. Depending on the nature of the Financial Conflict of Interest, OMRF may determine that additional interim measures are necessary regarding the Investigator's participation in the research until the completion of the retrospective review.
3. If an Investigator violates this policy or fails to comply with a written management plan, he or she will be subject to disciplinary action that includes, but is not limited to, suspension of the ability to submit new grant applications, limitations on or suspension of current funding, and termination of employment.

I. Records

1. Financial Disclosure Statements and Descriptions of Financial Interest shall be maintained by the Office of Technology Transfer for a period of at least three years.
2. Where a management plan has been created that relates to federally funded research, the Grants Office will retain a copy of any financial conflict of interest report filed with a federal agency for a period of at least three years after submission of the final expenditures report or, for federal research contracts, three years after final payment.