



Promoting Objectivity in Research

1. Purpose/Objectives

Scientific integrity and lack of research bias are important to maintain Microbiotix' reputation, generate quality research and to facilitate the development of safe and effective medical products. It is the responsibility of all employees to ensure that research is performed objectively and without bias. Financial conflicts of interest have the potential to create bias and undermine scientific integrity. Microbiotix also intends to comply with regulations regarding financial disclosure and conflict of interest, as appropriate. Microbiotix also believes that public disclosure is important to maintain transparency.

2. Scope

This policy applies to all employees at Microbiotix, to all studies performed by Microbiotix and to certain consultants, subcontractors, collaborators and other individuals engaged in research.

3. Definitions

Conflict of interest: a situation, within which, personal considerations have the potential to compromise or bias professional judgment or objectivity

Covered family member: those who are financially dependent or interdependent

Dependent: an individual who is financially dependent upon the reporting employee

Employee: an individual employed by Microbiotix (as evidenced by deduction of withholding from paycheck)

Executive management: the Chief Executive Officer and Chief Scientific Officer

Financial interest: anything of monetary value, whether or not the value is readily ascertainable

Form: a document that has static content and is used to collect data or information

Impact: an effect

Interdependents: related or unrelated individuals living in the same household and sharing expenses and/or assets

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, which may include, but is not limited to Microbiotix employees, consultants, subcontractors, collaborators or others.

Key personnel: employees explicitly listed in an application or report; key personnel should include any persons responsible for the design, conduct or reporting of research

Policy: a document that describes general corporate philosophy and/or rules that direct and control operations and conduct

Quality assurance (QA): the functional group responsible for evaluating the overall effectiveness of the company's systems and releasing products manufactured in accordance with good manufacturing practice (GMP)

Significant financial interest: an interest of the Investigator, Investigator's spouse, Investigator's dependent children and/or interdependent(s) related to the Investigator's responsibilities at Microbiotix. Significant financial interest is defined in the applicable regulation(s).

Sponsor: for the purpose of this SOP, the Sponsor is Microbiotix

Standard operating procedure (SOP): written instructions that define a process; the objective of which is to obtain consistent results in accordance with corporate objectives and policies

Template: a document that has dynamic content that is used as a starting point for developing an official document

4. Policy

4.1. Disclosure, Review and Risk Mitigation

- It is the responsibility of every employee to disclose the nature and extent of conflict as described in the applicable regulation.
- Employees shall complete an annual financial disclosure and update the disclosure when the information changes in accordance with regulatory requirements.
- Principal Investigators shall ensure that all employees, consultants, subcontractors, collaborators and others have completed appropriate financial disclosure statements.
- Financial disclosure statements shall be reviewed and evaluated if a potential conflict of interest exists. Reviews will take place in accordance with applicable regulations.
- If a potential conflict of interest exists, a risk assessment shall be performed.
- Executive Management shall develop, implement and evaluate risk mitigation plans for managing conflicts of interest.
- Microbiotix may request additional information as deemed necessary.

4.2. Reporting

- Financial disclosure reports and/or notifications shall be performed in accordance with applicable regulations.

4.3. Training

- Employees must complete training on financial conflict of interest and must read the applicable regulations.

4.4. Records

- Records shall be maintained and may only be destroyed when regulatory requirements have been met.

4.5. Enforcement and Noncompliance

- Employees who fail to comply with regulatory requirements may be subject to disciplinary action.
- Employees have the right to appeal

4.6. Subrecipients

- Microbiotix shall obtain financial disclosure statements or assurances for each individual listed on an application.

4.7. Public Accessibility

- This policy shall be posted on the Microbiotix website.
- Financial conflicts of interest shall be made available to the public within 5 days of receipt of a written request.

4.8. Audits

- Periodic audits shall be conducted to ensure compliance.

5. References

- 21 CFR Part 54
- 21 CFR Part 312
- 21 CFR Part 812
- 42 CFR Part 50 Subpart F
- 45 CFR Part 94
- Conflict of Interest in Medical Research, Education and Practice. Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice; Lo B, Field MJ, editors. Washington (DC): National Academies Press (US); 2009.
- Steinbrook R. Controlling Conflict of Interest—Proposals from the Institute of Medicine. N Engl J Med 2009; 360:2160-2163.
- Guidance for Clinical Investigators, Industry and FDA Staff: Financial Disclosure by Clinical Investigators
- National Science Foundation Grant Policy Manual Section 510