

SOP: Management of Financial Interests

Document No.:	Edition No.:	Effective Date:	Page:
HRP-120	002	19 Oct 2017	Page 1 of 1

1. PURPOSE

- 1.1. This procedure establishes the process to evaluate and manage individual and institutional financial interests <Related to the Research>.
- 1.2. This procedure begins when an IRB submission includes a disclosure of a financial interest that has not been evaluated under “UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL POLICY FOR PROMOTING OBJECTIVITY IN BIOMEDICAL RESEARCH”:
- 1.3. This procedure ends when the [Organization] decides that the financial interest is not a conflict of interest, or informs the IRB of the management plan.

2. POLICY

- 2.1. The document “UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL POLICY FOR PROMOTING OBJECTIVITY IN BIOMEDICAL RESEARCH”:
 - 2.1.1. Describes when individuals are considered to have an institutional responsibility
 - 2.1.2. Describes when individuals subject to this policy are required to complete financial conflicts of interest training
 - 2.1.3. Defines “Significant Financial Interest”
 - 2.1.4. Describes actions that can be taken in response to violations of this policy or proscribed management plans
 - 2.1.5. Describes retention requirements for records related to disclosures and management of financial conflicts of interest
- 2.2. The financial disclosure threshold for “Human Research” does not vary by funding or regulatory oversight.
- 2.3. The IRB has the authority to decide whether a financial interest and its management, if any, allow the research to meet criteria for approval.

3. RESPONSIBILITY

- 3.1. IRB staff members carry out these procedures.

4. PROCEDURE

- 4.1. Stop review of the submission.
- 4.2. Refer individual financial interests to the UMMS Committee on Oversight of Individual Financial Conflicts of Interest in Research with Human Subjects.
- 4.3. Refer institutional financial interests to the UMMS Committee on Oversight of Institutional Financial Conflicts of Interest in Research with Human Subjects.
- 4.4. Once the campus committee review is completed, the IRB is provided with the written report and review of the submission resumes. When the UMass system-wide COI committee review is additionally required, IRB approval will occur after review and receipt of the final letter of determination from the Chair of the UMass COI Systems Committee.

5. REFERENCES

- 5.1. 42 CFR §50
- 5.2. 45 CFR §94