

## **SOP: Management of Financial Interests**

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### **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