

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.
- 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 IRB will judge financial interests based on the following criteria:
 - 2.1.1. If individuals are considered to have an institutional responsibility
 - 2.1.2. If individuals subject to this policy are required to complete financial conflicts of interest training
 - 2.1.3. If “Significant Financial Interest” exists
- 2.2. The IRB will also be aware of:
 - 2.2.1. Actions that can be taken in response to violations of this policy or proscribed management plans
 - 2.2.2. Retention requirements for records related to disclosures and management of financial conflicts of interest
- 2.3. The financial disclosure threshold for <Human Research> does not vary by funding or regulatory oversight.
- 2.4. 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 <Conflict of Interest Officer>.
- 4.3. Refer institutional financial interests to <Conflict of Interest Officer>.
- 4.4. Once final review is completed, provide the IRB with the written report, and resume review of the submission.

5. REFERENCES

- 5.1. 42 CFR §50
- 5.2. 45 CFR §94