1. **PURPOSE**

1.1. This SOP establishes the process to evaluate and manage Investigator financial conflicts of interests related to Human Research or an institutional financial interest Related to the Research.

1.2. This procedure begins when an individual discloses a financial conflict of interest related to Human Research or the IRB staff have detected a financial interest related to Human Research.

1.3. This procedure ends when the Conflicts of Interests Official communicates the results of the evaluation to the IRB to make the final decision as to whether any financial interest and any management plan allows the research to be approved.

2. **REVISIONS FROM PREVIOUS VERSION**

2.1 Revised from the 5/1/2022 version

2.2 Revised from the 5/30/2017 version

3. **SOP Statement**

3.1. Financial Conflicts of Interest of investigators are managed in accordance with Texas A&M University System Regulation 15.01.03 and University Rule 15.01.03.M1 ‘Financial Conflicts of Interest in Sponsored Research’. These documents provide the following information:

3.1.1. Describes when individuals are considered to have an institutional responsibility

3.1.2. Describes when individuals subject to this policy are required to complete financial conflicts of interest training

3.1.3. Defines “Significant Financial Interest”

3.1.4. Describes actions that can be taken to manage, reduce or eliminate a financial conflict of interest

3.1.5. Describes actions that can be taken in response to violations of this policy or procribed management plan

3.1.6. Describes retention requirements for records related to disclosures and management of financial conflicts of interest

3.2. Investigators are required to disclose financial interests related to their institutional responsibilities online through the Huron COI management module.

3.3. The IRB has the authority to decide whether a financial interest and its management, if any, allow the research to meet criteria for approval.

4. **RESPONSIBILITY**

4.1. HRPP/IRB staff members carry out these procedures.

5. **PROCEDURE**

5.1. Stop review of the submission when a potential financial conflict of interest is identified.

5.2. Refer individual financial interests to the TAMU Conflicts of Interest Official.

5.3. Once final review is completed, provide the IRB with the written report, and resume review of the submission.

6. **MATERIALS**

6.1. Texas A&M University System Regulation 15.01.03 Financial Conflicts of Interest in Sponsored Research

6.2. University Rule 15.01.03.M1 Financial Conflicts of Interest in Sponsored Research

7. **REFERENCES**

7.1. 42 CFR §50

7.2. 45 CFR §94

7.3. AAHRPP 1.6.A, 1.6.B., I.7.A