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1. PURPOSE

- 1.1. This policy establishes the process to evaluate any **significant financial interest** of a **Principal Investigator** or research staff **engaged in human subjects research** conducted under the auspices of the University of Georgia (UGA).

2. POLICY

- 2.1. The institution applies the [UGA Policy on Conflicts of Interest in Sponsored Projects](#) to all **sponsored human subjects research**.
 - 2.1.1. For studies regulated by the FDA as identified on the IRB submission form, the University applies the [UGA Policy on Conflicts of Interest in Sponsored Projects](#) in accordance with 21 CFR Part 54.
- 2.2. The Principal Investigator and members of the research team engaged in human subjects research must disclose all **conflicts of interest** for themselves and their **immediate family members**:
 - 2.2.1. on submission of a new human research application;
 - 2.2.2. on submission of **continuing review** or **modification** to an approved study; and,
 - 2.2.3. within 30 days of discovery or acquisition of a new financial interest.
- 2.3. The IRB has the final authority to determine whether conflicts of interest have been eliminated or managed appropriately. The IRB will not approve a research protocol where conflicts of interest are neither eliminated nor managed.
- 2.4. The evaluation and management of conflicts of interests must not vary by funding source or regulatory oversight.
- 2.5. The Director, Conflicts of interest Review and Management (COI Director) carries out or ensures that the University's Conflict of Interest Committee (COIC) carries out the **procedures** and responsibilities described in this policy.

3. PROCEDURES: Director, Conflicts of Interest Review and Management

- 3.1. The process begins when the IRB or the COI Director identifies a potential individual conflict of interest related to the research, and ends when the IRB makes the final decision if the financial interest and its management, if any, allows the research to be approved.
 - 3.2. The COI Director applies the [UGA Policy on Conflicts of Interest in Sponsored Projects](#) to evaluate and manage any disclosure of an individual financial interest to the IRB.
 - 3.3. If the individual financial interest is determined to be a conflict of interest, the COI Director provides the IRB staff of the reviewing IRB with the written management plan so the IRB can
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make the final decision as to whether the financial interest and its management, if any, allows the research to be approved.

- 3.4. If there is no conflict of interests related to the research, the COI Director notifies the IRB staff of this determination in writing.
- 3.5. The IRB staff maintains a copy of determination(s) and any management plans in the IRB electronic portal.

4. MATERIALS

- 4.1. None

5. REFERENCES

- 5.1. [UGA Policy on Conflicts of Interest in Sponsored Projects](#)
- 5.2. 45 CFR §94
- 5.3. 21 CFR §54
- 5.4. 42 CFR §50

Revision History:

01/15/2016: REV0 New Document

05/24/2021: REV1 minor changes to reflect new role/person title
