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**1. POLICY STATEMENT AND PURPOSE**

- 1.1. The University of Georgia is committed to maintaining objectivity in its research enterprise and seeks to avoid even the appearance of impropriety. Situations where financial interests may appear to compromise the integrity of research outcomes should be managed appropriately and monitored to ensure objectivity.
- 1.2. This policy seeks to protect research subjects and the integrity of the Institution’s research programs by establishing processes to manage risks related to institutional financial conflicts of interest in research activities involving human subjects while working to eliminate possible bias.

**2. DEFINITIONS**

- 2.1. The **Institution** means the University of Georgia.
  - 2.2. An **Institutional Leader** is an individual among the Institution’s key administrators who because of his or her position with the Institution has the capacity to affect, or could reasonably appear to affect, the design, conduct, reporting, review, or oversight of Human Subjects Research Activities and who, with respect to a particular Human Subjects Research Activity, is not an “Investigator” under the UGA Policy on Conflicts of Interest in Sponsored Programs. Such individuals include but are not limited to the Vice President for Research, the Provost, and the President of the Institution. The Office of Research Integrity and Safety in the Office of Research may issue further guidance from time to time regarding those individuals included within the definition of “Institutional Leader.”
  - 2.3. **Human Subjects Research Activity** means any research for which approval is required from the Institution’s Institutional Review Board.
  - 2.4. **Significant Institutional Financial Interest** means any one or more of the following:
    - 2.4.1.If received by an **Institutional Leader** – consulting fees, advisory board fees, remuneration, honoraria, or gifts from a company or other business entity (other than the Institution and cooperative organizations) that, when combined, exceeds \$10,000 annually from a particular company or other external entity, including consortium, trade group, or affiliated entities;
    - 2.4.2.If held by an **Institutional Leader** – a fiduciary role in a company or other external entity (other than the Institution or cooperative organizations);
    - 2.4.3.If held by an **Institutional Leader** or by the **Institution**, the **UGA Foundation**, or the **UGA Research Foundation** – a directly held equity interest in a non-publicly traded company or other external entity (other than cooperative organizations);
    - 2.4.4.If received by the **Institution**, the **UGA Foundation**, or the **UGA Research Foundation** – one or more cash or in-kind gifts, all of which are directed to be used by a specific
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Department, Center, or Institute at the Institution, that in total exceed a value of \$500,000 in any calendar year from a particular company or other external entity and its affiliates (other than cooperative organizations); and

2.4.5.If received by the **Institution** or the **UGA Research Foundation** – royalties (patent or other) or other technology licensing payments from a company or other external entity (other than cooperative organizations) that sponsors Human Subjects Research Activity, all of which exceed \$100,000 from the same company or its affiliates in total in any calendar year.

2.5. An **Institutional Conflict of Interest** may exist, as will be determined by this policy, when a Significant Institutional Financial Interest could significantly and directly affect, or reasonably appears that it could affect, the design, conduct, reporting, review, or oversight of Human Subjects Research Activity performed by the Institution.

### 3. POLICY AND PROCEDURES

3.1. **Disclosures by Institutional Leaders.** Each Institutional Leader shall provide to the Office of Research Integrity and Safety annual disclosures of the Institutional Leader’s Significant Institutional Financial Interests under Section 2.4.1 (compensation), Section 2.4.2 (fiduciary role), and Section 2.4.3 (investments) received or held over the past year (as well as any others not previously reported).

3.2. **Disclosures by Institution.**

3.2.1.The Office of Research Integrity and Safety shall request and the UGA Division of Development and Alumni Relations and/or the Business and Accounting Office shall provide to the Office of Research Integrity and Safety a quarterly report of Significant Institutional Financial Interests under Section 2.4.3 (investments) and Section 2.4.4 (gifts) received by the Institution or the UGA Foundation over the past quarter (as well as any others not previously reported).

3.2.2.The Office of Research Integrity and Safety shall request and Innovation Gateway will provide to the Office of Research Integrity and Safety a quarterly report of Significant Institutional Financial Interests under Section 2.4.3 (investments) and Section 2.4.4 (gifts) received by the UGA Research Foundation over the past quarter (as well as any others not previously reported).

3.2.3.The Office of Research Integrity and Safety shall request and Innovation Gateway will provide to the Office of Research Integrity and Safety a quarterly report of Significant Institutional Financial Interests under Section 2.4.5 (royalties and licensing payments) that



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have been received by the UGA Research Foundation or the Institution over the past quarter (as well as any others not previously reported).

**3.3. Review and Management of Institutional Conflicts of Interests.**

3.3.1. When a company or other business entity and its affiliates where appropriate (but excluding cooperative organizations) provides funding, materials, or other compensation for a Human Subjects Research Activity and that company is the subject of a Significant Institutional Financial Interest, the Director, Conflicts of Interest Review and Management (COI Director) will make an initial determination as to whether an Institutional Conflict of Interest exists based on the following factors:

- 3.3.1.1. the nature of the Human Subjects Research Activity;
- 3.3.1.2. the nature of the Significant Institutional Financial Interest; and
- 3.3.1.3. the risk, whether apparent or actual, that the Significant Institutional Financial Interest could affect the design, conduct, reporting, review, or oversight of Human Subjects Research Activity performed by the Institution.

3.3.2. If the COI Director determines that no Institutional Conflict of Interest exists with respect to a particular Human Subjects Research Activity, then the COI Director will notify Sponsored Projects Administration and the Institutional Review Board and such determination will be recorded.

3.3.3. If the COI Director determines that an Institutional Conflict of Interest may exist, then the Institutional Conflict of Interest shall be referred to the University Conflicts of Interest Committee (UCIC). The UCIC promptly shall review the matter and work cooperatively with the COI Director to determine whether an Institutional Conflict of Interest exist and the steps necessary to mitigate, eliminate, and/or otherwise manage any identified conflicts. The UCIC promptly shall provide its determination, including any management plan, in writing to the COI Director. The COI Director shall notify the Principal Investigator of the Human Subjects Research Activity in question of the UCIC’s determinations, including any management plan.

3.3.4. The UCIC shall operate in harmony with the Institution’s Policy on Conflicts of Interest in Sponsored Programs.

3.3.5. When the UCIC determines that an Institutional Conflict of Interest exists with respect to a particular Human Subjects Research Activity, that activity may only proceed in compliance with the determination of the UCIC, including any management plan. Management plans may include the following:



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- a description of the nature of the conflict;
  - justification for research to be carried out at the University of Georgia; and
  - conflict management mechanisms, which may include, but are not limited, to:
    - Recusal from decision-making regarding the proposed arrangement by the financially-interested Institutional Leader and disclosure of the recusal to the appropriate individuals implementing the recusal;
    - Reduction in the magnitude of the financial and/or fiduciary interest (generally to below the thresholds set forth in this policy);
    - Severance of relationships that create actual or potential conflicts;
    - Disclosure of the conflict to the research sponsor;
    - Disclosure of the conflict in publications or presentations for which the results of the research will be submitted.
    - Disclosure of the conflict to the IRB;
    - Disclosure of the conflict to potential research participants during the informed consent process; and
    - Disclosure to an independent advisory board that will monitor the data.
- 3.4. The IRB has final authority to approve human subjects research and may require additional safeguards to be implemented to guard against research bias.
- 3.5. Any Institutional Leader with an Institutional Conflict reasonably related to a sponsored project or human subjects research will not be allowed to conduct the review or oversight of the research. A qualified substitute will be appointed by the University administrator that serves at the next higher level of review.
- 3.6. **Violations.** Violations of the requirements of this Policy by any employee of the Institution may, if not resolved, subject the employee to review and, where appropriate, corrective action as permitted by University policy.