Section I. Introduction.

A. Background and Purpose

Georgia State University ("University") is committed to ensuring that its research involving human subjects is conducted with integrity and free from any actual or apparent bias due to institutional financial interests. This policy provides the standards and procedures that the University follows when the University has Significant Institutional Financial Interests that are related to human subject research conducted by its Investigators.

This Policy on Institutional Financial Interests in Research Involving Human Subjects ("Policy") promotes objectivity in University research by establishing processes that provide a reasonable expectation that the design, conduct, and reporting of human subjects research are free from bias resulting from financial interests of the University.

References to the University in this Policy include the Georgia State University Foundation and the Georgia State University Research Foundation, as applicable. The Georgia State University Foundation accepts several types of gifts on behalf of the University in accordance with the Georgia State University Foundation’s Gift Acceptance Policy. The Georgia State University Research Foundation receives grants and research agreements from external funding sources and owns and controls intellectual property on behalf of the University. When the University, through the Georgia State University Research Foundation, licenses its intellectual property ("IP"), the University may receive equity in a company as a result of a licensing agreement for University IP; receive royalties or other fees as compensation for the use of that IP; and/or may receive equity or other financial interest as part of a co-investment in a licensee or related company.
B. Scope

This Policy applies to all human subject research at the University. This Policy shall not limit University employee obligations for disclosure and/or management of other financial interests that are required by other University policies or procedures.

Section II. Definitions.

A. An "Institutional Conflict of Interest" exists when the University Institutional Conflict of Interest Review Committee determines that a Significant Institutional Financial Interest held by the University or an Institutional Leader could significantly and directly affect or reasonably appear to affect the institutional processes for the design, conduct, reporting, review, or oversight of human subject research.

B. "Human Subjects Research" is any research that meets the definition of “research” with “human subjects,” as those terms are defined in the University Institutional Review Board Policies & Procedures, and that requires review and approval by the University Institutional Review Board.

C. "Significant Institutional Financial Interest" means

1. The University’s:
   
   a. receipt of equity through a licensing agreement when the licensee is the sponsor, provider of study material, or financial supporter of Human Subject Research;
   b. receipt of a cash gift that is more than $50,000 annually from an entity to be used by a specific Department or Center when such Department or Center’s faculty is performing Human Subject Research and the donor is the sponsor, provider of study material, or financial supporter of Human Subject Research; or
   c. receipt of royalties or licensing fees that exceed $50,000 annually for technologies being tested or evaluated in Human Subject Research under University IRB oversight or its designated IRB; or

2. An Institutional Leader’s:
   
   a. equity interest or entitlement of equity of any amount in a non-publicly traded company that is the sponsor, provider of study material, or financial supporter of Human Subjects Research;
   b. consulting fees, advisory board fees, remuneration, honoraria, or gifts that exceed $5,000 annually from a company that is the sponsor, provider of study material, or financial supporter of Human Subject Research;
   c. fiduciary role in a company that is the sponsor, provider of study material, or financial supporter of Human Subject Research; or
d. receipt of royalties or licensing fees that exceed $5,000 annually for licensed technology that is the subject of the Human Subject Research.

E. “Institutional Leader” means an individual who, because of his or her position with the University, has the capacity to affect, or can reasonably appear to affect, University processes for the design, conduct, reporting, review, or oversight of human subject research. Such officials can include but are not limited to the Vice Presidents, Associate Vice Presidents, Deans, Associate Deans of Research, Department Chairs, Center Directors and the Conflict of Interest Officer. Institutional Leaders provide a Disclosure of Significant Financial Interest annually.

F. “Conflict of Interest Officer” means the Associate Vice President for Research Integrity or other designee of the Vice President for Research and Economic Development.

Section III. Policy.

The University will seek to eliminate or manage any Institutional Financial Conflict of Interest involving Human Subject Research. This policy does not require that the University refrain from conducting University business with entities that have a financial relationship with the University; however, certain relationships must be identified promptly and resolved appropriately. The primary goal is to ensure that the welfare of human subjects and the integrity of the research are not compromised.

A. Separation of Administrative Oversight for Human Subjects Research Program

The functions and responsibilities related to administrative, ethical, and scientific oversight of University research programs involving human subjects shall be separate from the functions and responsibilities related to the administration and management of the University’s investments and endowment. The criteria that govern the making of University investment decisions shall specifically preclude consideration of information related to the University’s Human Subject Research activities.

B. Licensed Intellectual Property in Human Subject Research

The University shall maintain a list that includes all entities in which the University holds an equity interest as part of a licensing arrangement; and a list of technologies sorted by licensee where the University has received more than $50,000 in royalties annually. This list shall be updated as equity license agreements are executed and threshold levels are reached.

When a University investigator undertakes to perform Human Subject Research on University licensed technology or other IP and the license fees exceed $50,000 annually or the University receives equity in the sponsor through the license agreement, the University’s relationship with the sponsor must be reviewed pursuant to the procedures in Section IV below.
C. Gifts

When accepting gifts, the University must affirm that the gift or donation carries no obligations to the University that may conflict with state law or Board of Regents policy. The University may receive gifts from corporate donors that may also sponsor research involving human subjects. The University Development Office shall provide on an annual basis to the Conflict of Interest Officer and the IRB a list of corporate donors that give more than $50,000 in cash per annum to the University.

When a gift meets the Significant Institutional Financial Interest threshold and the donor is a sponsor of University Human Subject Research, the gift must be reviewed pursuant to the procedures in Section IV below.

D. Significant Financial Interests of Institutional Leaders

On an annual basis and in accordance with the University’s policies on individual conflicts of interest, each Institutional Leader shall provide a disclosure of his or her equity interest or entitlement of equity of any amount in a non-publicly traded company; consulting fees, advisory board fees, remuneration, honoraria, or gifts that exceed $5,000 from an outside entity; fiduciary role in an outside entity; and receipt of royalties or licensing fees that exceed $5,000 annually.

Section IV. Procedures for Identifying andReviewing Institutional Financial Interests

A. IRB protocols

All human subject research protocols submitted for IRB review must indicate the nature and source(s) of all materials, drugs, devices, or biologics that will be used in the proposed research, and the source(s) of all funding and/or provision of materials used in supporting the research.

B. Assessment and Review

When a protocol is submitted for IRB approval and an entity listed in any of the materials described in Section III above is the sponsor or provider of study material, the Conflict of Interest Officer will perform the following assessment and review.

Using the information described in Section III above, the COI Officer will make an initial assessment of whether a Significant Institutional Financial Interest exists and then take the following actions:

1. If the COI Officer determines that a Significant Institutional Financial Interest does not exist, he or she shall notify the IRB that no action is necessary.

2. If the COI Officer determines that a Significant Institutional Financial Interest exists but it cannot directly and significantly affect the proposed research, the COI Officer shall notify the investigator and instruct him/her how to disclose the University’s
relationship in all publications, proposals, consent documents, and presentations and also provide such information to the IRB.

3. If the COI Officer determines that a Significant Institutional Financial Interest could potentially directly and significantly affect the research, the COI Officer shall request the investigator to provide a detailed written explanation of compelling circumstances why the research should proceed at the University.

Compelling Circumstances. When an Investigator is proposing to perform Human Subject Research for which a Significant Institutional Financial Interest could directly and significantly affect the research, the Principal Investigator shall be responsible for drafting and submitting to the COI Officer a detailed explanation of the compelling circumstances surrounding the research. This explanation must include the steps taken to secure an alternate research site, not affiliated with the University, and the justification for why the alternate research site is inadequate. The Principal Investigator should also consider including comments that address the Criteria for Evaluating an Institutional Financial Conflict of Interest discussed below.

4. When an Investigator submits an explanation of Compelling Circumstances, the COI Officer will appoint a committee comprised of one representative from the Office of Legal Affairs, one member from the GSU faculty, and at least one member who is external to the University (the “Institutional Conflict of Interest Committee” or “Committee”). Members of the Committee shall complete a Disclosure of Significant Financial Interest prior to appointment. No member of the Committee shall have an interest or relation with GSU, other than employment or having attended as a student. The Institutional Conflict of Interest Committee will formulate a recommendation as to whether an Institutional Financial Conflict of Interest exists and how it could be managed. In reviewing the research, the Significant Institutional Financial Interest, and the explanation of Compelling Circumstances, the Committee will use the Criteria for Evaluating an Institutional Financial Conflict of Interest discussed below. The Committee may determine that the Significant Institutional Financial Interest is too great and the research should not occur at the University, unless divestiture is possible prior to the commencement of the study. The Committee shall make its recommendation to the Conflict of Interest Officer. The Conflict of Interest Officer shall follow the URSA Procedures for Conflicts of Interest in Sponsored Research for notifying the IRB and obtaining IRB approval of the Committee’s recommendation.

C. Criteria for Evaluating an Institutional Financial Conflict of Interest

The following criteria shall be used in evaluating an Institutional Financial Conflict of Interest:

- Nature of the research, current phase of development and intentions for subsequent phases
- Magnitude of potential risks to human subjects inherent in the research, and how those risks could be affected as a result of the conflict
• Degree to which the Institutional Financial Interest could be directly and substantially affected by the research
• Whether the studies involve University Intellectual Property that is used as a platform technology or a generic method used broadly
• Likelihood that a societally important development project will be substantially impeded if the research is not performed at the University
• Societal impact of successful development, relative to potential risk to the University
• Magnitude of potential risks posed to students or trainees engaged in the research project
• The effectiveness of managing, reducing or eliminating the Significant Institutional Financial Interest through recusal, divestiture, or independent oversight of the affected research
• Whether the University’s resources are fundamentally important to the progress of the science or the University investigator is truly uniquely qualified or integral to administer the study
• The proportion of the total subjects in the study that are under the supervision of the University
• The degree of risk to the human subjects involved that is inherent in the research protocol.

In cases where an Institutional Financial Interest involves an Institutional Leader, the following shall also be considered:

• The degree of direct and immediate authority the Institutional Leader has over the research and the people involved in the performance and reporting of the research
• Whether a plan for separation of oversight of the faculty/staff conducting the human subject research by the Institutional Leader with the conflict can be implemented that is both practical and effective while the Institutional Leader remains in the assigned leadership position.

D. Institutional Conflict of Interest Management Tools

If the University Institutional Conflict of Interest Committee determines that a Significant Institutional Financial Interest exists and may be managed, the Committee must include in its finding a justification as to why the University and/or its investigator must be involved in the research despite the conflict. The management plan must require disclosure to the public and to the human subjects enrolled in any studies determined to be related to the Significant Institutional Financial Interest. Additional management tools that may be used to minimize the risk to the University may include:

• An independent monitoring mechanism to be established, which could include a data safety monitoring board, independent monitor, or independent reviewer.
• Permitting the research to proceed subject to a plan of divestiture of financial interests.
• Permitting only certain procedures and analysis to occur at the University.
• Other tools as determined by the Committee.
The Conflict of Interest Officer must share the findings and any management plan of the Committee with the IRB. The IRB may require additional tools to protect the welfare of human subjects involved with the study. The IRB shall review the management plan as part of its initial review of a new protocol. If an Institutional Conflict of Interest arises after initial IRB approval has been granted, the IRB will review the management plan following notice by the Committee.

Section V. Violations and Sanctions

Failure to report a Significant Institutional Financial Interest, or refusal or failure to cooperate in the management plan of an Institutional Financial Conflict of Interest may be cause for disciplinary action up to and including dismissal. Possible violations of this policy include, but are not limited to, providing false, misleading, or incomplete information.