I. PURPOSE & INTENT

An institutional conflict of interest ("Institutional COI") describes a situation in which the financial interests of an institution or institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research conducted under the auspices of the institution. Institutional COIs are of significant concern when financial interests create the potential for inappropriate influence over the institution's research. This Policy is intended to protect against exposure from risks related to Institutional COIs as they may affect research performed at or under the auspices of the University of South Florida System (USF System).

The USF System, including its officials, must balance many competing pressures. It engages in relationships with a variety of sponsors that may lead to financial benefit for the institution in many forms, including major gifts, royalty payments and equity from licensing intellectual property as well as sponsored educational and research agreements. In addition, USF System-industry relationships are essential to advance scientific frontiers and enable the commercial development of academic discoveries to the benefit of the public. Nonetheless, while generally part of legitimate educational, research, and business activities, relationships with commercial entities cannot be allowed to compromise, or appear to compromise, the integrity of the USF System’s primary missions, including the safety and integrity of its research.

II. DEFINITIONS OF TERMS

A. Covered Official: The President, members of the Board of Trustees, the Provost and Vice Provosts, Deans, Senior Vice Presidents, Associate Vice Presidents, individuals in the forenamed positions serving in a temporary or interim capacity, and any other individual who has oversight or supervision of research in the USF System as determined by the USF COI Committee.

B. Institutional Conflict of Interest: An Institutional COI may occur whenever the financial interests of the institution, or of a Covered Official who has authority to act on behalf of the institution, might affect or reasonably appear to affect institutional processes for the design, conduct, reporting, review or oversight of research.

C. Investigator: The project director or principal investigator and any other person (faculty, staff, students or collaborators/consultants) regardless of title or position,
who is responsible for the design, conduct or reporting of a USF System research project.

D. Major Gift: Any donation of $1 million or greater made to the USF System.

E. Significant Financial Interest: An opportunity for a Covered Official for economic gain or an external commitment that relates to, or could be reasonably affected by, the outcome of the proposed or current USF System research project including:

- Salary or other payments (e.g. consulting fees, royalties or honoraria) exceeding $5,000 paid or given to the Covered Official, directly or indirectly, for services rendered in the previous USF fiscal year.
- Equity interests (e.g. stocks, stock options or other ownership interests) when the Covered Official’s interest represents more than a 5% ownership interest in a single entity and the Covered Official received more than $5,000 from that entity in the previous USF fiscal year.
- A proprietary interest in the USF System research project, including a patent, trademark, copyright or licensing agreement in the test article or method. A proprietary interest is considered to be present as soon as protection is sought (e.g. upon submission of an Invention Disclosure Form to the USF Technology Transfer Office, upon filing of a patent application, etc.).
- Any other financial interest or external commitment that a Covered Official believes may interfere with his or her ability to oversee or supervise research without bias.

Significant Financial Interest does not include:

- Salary or other remuneration from the USF System.
- Any “arm’s length” financial interest (e.g. mutual fund or employer retirement plan) where the Covered Official has no control over the investment decision, except where the value of the equity in one publicly-traded company related to the research exceeds $50,000.

III. IDENTIFICATION OF POTENTIAL INSTITUTIONAL CONFLICTS OF INTEREST

A. Significant Financial and Fiduciary Interests of the Institution: The following significant financial and fiduciary interests of the USF System warrant formal review for potential Institutional COI with respect to research:

1. Royalties: An Institutional COI may be present when the USF System has received significant milestone payments of $100,000 or more and/or royalties from business entities in the prior fiscal year from the sales of an investigational product that is the subject of the research;
2. **Non-publicly traded equity:**
   a. When, through its technology licensing activities or investments related to such activities, the USF System has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company that is:
      1. The sponsor of human subjects research under the purview of an IRB, which is conducted at or under the auspices of the USF System; or
      2. The manufacturer of a product to be studied or tested in human subjects at or under the auspices of the USF System.
   b. When, through its technology licensing activities or investments related to such activities, the USF System has obtained an equity interest or an entitlement to equity estimated at ≥ $100,000 (including options or warrants) in a non-publicly traded company that is sponsoring non-human subjects research conducted at or under the auspices of the USF System or is the manufacturer of a product to be studied or tested at or under the auspices of the USF System.

3. **Publicly traded equity:** When, through technology licensing activities or investments related to such activities, the USF System has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding $100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly-traded company that is:
   a. The sponsor of research conducted at or under the auspices of the USF System; or
   b. The manufacturer of a product to be studied or tested at or under the auspices of the USF System.

4. **Gifts from sponsors:** When the USF System has received a Major Gift (including gifts in kind) such that even when held in the general endowment for the benefit of the entire institution, that Major Gift might affect, or reasonably appear to affect, oversight of research conducted at or under the auspices of the USF System, the following circumstances should be evaluated:
   a. Whether the gift is from a potential commercial sponsor of research or a company that owns or controls products being studied or tested in USF System research;
   b. Whether a gift is held for the express benefit of the college, school, department, institute or other unit where the research is to be conducted; or
   c. Whether any institutional official who has the authority, by virtue of his or her position, to affect or appear to affect the conduct, review or oversight of the proposed research has been involved in solicitation of the gift.
B. Significant Financial Interests of Covered Officials: When, with regard to a specific research project to be conducted at or under the auspices of the USF System, a Covered Official holds a Significant Financial Interest related to the research, the commercial research sponsor or an entity that owns or controls the investigational product, a formal review is warranted for potential Institutional COI with respect to research.

C. Individuals responsible for purchasing: When a Covered Official with research oversight authority participates materially in a procurement or purchasing decision involving major institutional purchases from, or non-routine supply contracts with, a company that sponsors research at the institution, or whose product is being studied or tested in research at the institution, a formal review is warranted for potential Institutional COI with respect to research.

In addition to those circumstances indicated above, other financial interests or relationships with research sponsors may warrant formal scrutiny, depending on the circumstances. In general, the institution should assess the potential for conflicts of interest and weigh the magnitude of any risk to the integrity of the research.

IV. ADMINISTRATION OF INSTITUTIONAL CONFLICTS OF INTEREST IN RESEARCH POLICY

A. Administration of Institutional COIs: Administration of Institutional COIs will be handled by USF’s Conflict of Interest in Research Program (COI Program), located in USF Research & Innovation, Research Integrity & Compliance.

B. Reporting of Institutional COIs: In order to make the COI Program aware of potential Institutional COI situations and transactions, the following offices shall report at least annually, 90 days after the close of the fiscal year, to the COI Program on institutional interests, including those described in Section III.A. above:

1. The Technology Transfer Office; and
2. Any Foundations at USF, including the USF Foundation and the USF Research Foundation.

C. Reporting of Covered Officials’ COIs: In order to make the COI Program aware of Covered Officials’ Significant Financial Interests, which may create Institutional COIs, University Audit & Compliance and USF Health Faculty Affairs shall, at least quarterly, provide the COI Program a list of disclosures, including outside activity reports and Florida Code of Ethics disclosures, submitted by Covered Officials.

V. INSTITUTIONAL CONFLICT OF INTEREST COMMITTEE

A. Committee Establishment: USF shall utilize the existing Conflict of Interest Committee to review Institutional COIs. The Committee composition shall be as set forth in the USF Conflict of Interest in Research Committee Operating Procedures. The Committee will be advisory to the Senior Vice President for Research, Innovation & Economic Development, who holds final authority to determine whether an Institutional COI has been adequately managed and the related research may proceed. If the Senior Vice President for Research, Innovation & Economic
Development has an apparent or perceived personal or professional conflict of interest and thus cannot review an Institutional COI, the USF System President will review the COI Committee’s recommendation and hold final authority.

B. **Review of Institutional COIs:** When reviewing Institutional COIs, non-voting ex-officio members may be invited to attend the COI Committee meeting when, as determined by the COI Program Manager and the COI Committee Chairperson, their expertise is required. Such non-voting ex-officio members may include, for example:

1. A senior USF official who has sufficient seniority, expertise and independence to evaluate competing interests at stake and make credible and effective recommendations.
2. The Associate Vice President for the Technology Transfer Office.
3. A representative from the Office of General Counsel.
4. A representative from USF Research & Innovation, Research Integrity & Compliance.

VI. **REVIEW AND MANAGEMENT OF POTENTIAL INSTITUTIONAL CONFLICTS OF INTEREST**

A. **Review of Institutional COIs:** Investigators and Covered Officials are responsible for reporting Institutional COIs of which they are aware to the USF COI Program Manager prior to conducting research. When a potential Institutional COI is identified by the USF COI Program Manager, s/he will review the related research, gather necessary information and prepare a summary to be presented to the COI Committee at its next regularly scheduled meeting. The COI Committee will review the research according to the guidelines set forth below in Sections VI. B. and C.

B. **When the USF System has a Significant Financial or Fiduciary Interest Related to the Research:**

1. **Human Subjects Research:** There is a rebuttable presumption that human subjects research should not be carried out at USF when the institution has a significant financial interest or fiduciary interest (see Section III. A. for examples of significant financial and fiduciary interests) related to the research. The presumption may be rebutted if the circumstances are deemed compelling by the COI Committee, provided that the COI Committee approves, and the Senior Vice President for Research, Innovation & Economic Development or the USF System President, as appropriate, affirms, a formal COI management plan. Whether the presumption is successfully rebutted will depend in each case upon an analysis of:
   a. The nature of the science;
   b. The nature of the overlapping interests;
   c. How closely the interest is related to the research;
   d. The degree to which the interest may be affected by the research;
   e. The degree of risk that the research poses to human subjects;
   f. The degree to which the Institutional COI can be effectively managed; and
Whether the institution is uniquely qualified, by virtue of its attributes (e.g. special facilities or equipment, unique patient population) and the experience and expertise of its Investigators, to conduct the research and safeguard the welfare of the human subjects involved.

2. **Non-Human Subjects Research:** The primary reason to manage Institutional COIs related to non-human subjects research is to protect the integrity of USF System research. With regard to non-human subjects research, the COI Committee must weigh the potential value of the research against the potential risks related to the Institutional COI. Management of non-human subjects research may include external oversight.

3. **When a Covered Official has a Significant Financial Interest Related to the Research:**

   1. **Human Subjects Research and Non-Human Subjects Research:** In the case in which a Covered Official has a Significant Financial Interest related to human subjects or non-human subjects research, the rebuttable presumption does not apply because in most cases alternative supervision can be arranged. The COI Committee should review the Covered Official’s role in relation to the research and the researchers and the nature of the Covered Official’s conflict of interest and then develop a management plan.

**VII. SANCTIONS**

Failure to report as required by this policy and related policies or procedures may be grounds for disciplinary action under the provisions of any applicable USF System regulation, policy, or collective bargaining agreement.

**VIII. RELATED USF SYSTEM REGULATIONS & POLICIES**

- [USF System Policy 0-309, Individual Conflicts of Interest in USF System Research Projects and USF System Financial Conflict of Interest (FCOI)]
- [USF System Regulation 10.107, Ethical Obligations: Conflicts of Interest, Outside Employment, Employment of Relatives, and Public Office]
- [USF Human Research Protection Program (HRPP) Policy and Procedure Manual]

Authorized and Signed by:

Paul R. Sanberg, Ph.D., D.Sc., Senior Vice President for Research, Innovation & Economic Development

Judy Genshaft, President