

Standard Operating Procedures for Clinical Research at USF Morsani CRC			
	INSTITUTIONAL CONFLICTS OF INTEREST		
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PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to outline relationships that may produce a real or perceived institutional conflict of interest (ICOI) for research conducted at the CRC.

SCOPE: This SOP applies to Principal Investigators (PIs), research personnel who conduct human subjects research in the CRC.

RESPONSIBILITY: The PI is responsible for reporting a potential or actual COI to a USF IRB approved independent IRB for review and approval of the research. Individual research personnel who are aware of a financial or business relationship that may compromise or appear to compromise the safety or welfare of human subjects or the outcome of human subjects research are responsible for reporting the relationship to USF Conflict of Interest Review program (COIRP) for evaluation and management.

DEFINITIONS:

Applications for Research Compliance (ARC): Name of website for all electronic applications managed by the Division of Research Integrity and Compliance (DRIC)

Disclosure: Disclosure is the formal written process of documenting all aspects relating to the development of potential intellectual property for the purpose of determining and assigning ownership.

Gifts: A voluntary and irrevocable transfer of money or property made in support of the University's teaching, research and service mission without expectation of direct economic benefit or other tangible compensation commensurate with the worth of the gift. Transactions received by USF that meet this definition will be directed to the USF Foundation, Inc.

Human subjects research: The process of conducting research AND obtaining information from human subjects in the research.

Immediate Family: Spouse or domestic partner, and each dependent child

Institutional Conflict of Interest: A situation in which the financial investments, licenses, technology transfer or patents of, or gifts to, the USF System or the personal financial interests or holdings of USF System Senior Administrative Officials might affect, or reasonably appear to affect, institutional processes for the design, conduct, reporting, review or oversight of human subjects research. Potential ICOIs may arise in the following areas:

- when a company that has a financial or business relationship with USF System also donates a gift to USF System;
- when USF System owns equity in a company and the company has a financial or business relationship with USF System;
- when USF System licenses an invention to an entity that also has a financial or business relationship with USF System;

DEFINITIONS (cont.):

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- when a USF System Senior Administrative Official has a business or financial relationship with an external entity, which sponsors USF System Human Subject Research Projects.

Investments: Stocks, warrants, membership or other forms of equity in companies or establishments held by the USF System and/or USF System Senior Administrative Official, when these companies or establishments sponsor research or conduct other activities within the USF System.

Licensing: Equity positions, warrants or obligations for payment held by the USF System, and/or a Direct Support Organization, and/or a USF System Senior Administrative Official, when such equity, warrants or obligations for payment are derived from the licensing, sale or assignment institutional intellectual property or research materials

USF System Senior Administrative Official: A USF System employee or member of the USF System Board of Trustees who has direct authority over faculty appointments, salaries, promotions, and/or allocation of institutional resources, such as assignment of graduate students or other trainees, funding for space or for faculty who are conducting human subjects research.

PROCEDURE:

1. Individuals who are aware of a business or financial relationship that may potentially compromise the rights and welfare of human subject participants or the integrity of the research are required to report it to the IRB.
2. Each individual with a COI must report the details of the financial or business relationship via the eCOI module on ARC **prior to final IRB review/approval of the research.**
3. The individual with the COI will login to ARC to create a new COI, complete the required information, and submit the COI with the research protocol attached.
4. The COI Administrator will review the conflict to determine whether if the disclosure represents an ICOI. If an ICOI exists, he/she will prepare a summary of the relevant facts and circumstances to present to the USF COI Committee.
5. If necessary, the USF COI Committee will develop a COI management plan to minimize or manage the conflict, or will make a recommendation regarding how the conflict may be eliminated.
6. The COI Committee will identify an individual, who will be directly responsible for ensuring that the requirements of the management plan are implemented and monitored for continued compliance.

PROCEDURE (cont.):

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7. Following its review, the COI Committee will communicate in writing to the IRB reviewing the research, with all of the relevant documentation that either the ICOI has been eliminated in connection with the proposed human research activity or a management plan has been recommended for the IRB's review.
8. The reviewing IRB will take action on the human subjects research, with consideration given to the management or elimination of the ICOI as recommended by the COI Committee.
9. The reviewing IRB will have final authority to decide whether the ICOI and its management, if any, allows the research to be approved.
10. If a COI management plan is determined, the designated research designee will include and attach a copy of the plan to the initial IRB submission.
11. More information can be obtained from USF COI policies and procedures web page.

REFERENCES:	21 CFR 54 Financial Disclosure by Clinical Investigators PHS Regulations, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought" (42 CFR 50) NIH Guide—Objectivity in Research (July 14, 1995) NSF Policy on Conflict of Interest (NSF Grants Policy Manual, Section 510) Florida Statutes, Section 112.313, "Standards of Conduct for Public Officers and Employees of Agencies" (2004)
RELATED POLICIES:	USF HRPP Policy and Procedures, and USF DRIC, Conflict of Interest Program in Research
APPENDICES:	None
REVISION HISTORY: Keep a running history of all revision dates.	

Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	