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Type of Policy:	**ADMINISTRATIVE**	Category:	**EXTERNAL ORGANIZATION RELATIONSHIPS**

Title:	***FINANCIAL CONFLICTS OF INTEREST FOR GRANTS AND RESEARCH***	Policy #:	**5706-0174**
		Replaces #:	
Page:	1 of 13	Developed By:	Corporate Office of Research Operations and Office of Grants Management
Issue Date:	**10/12**	Approved By:	Philip Giordano, MD Chief, Corporate Research Operations Orlando Health
Revision Dates:	4/16, 3/20		John W. Bozard, President Orlando Health Foundation

I. PURPOSE:

This policy describes the process for evaluating and responding to a financial interest reported by an investigator or research staff involved in clinical and/or basic research. This policy seeks to ensure that there can be a reasonable expectation that the design, conduct, or reporting of the study will not be biased by any conflicting financial interest.

II. DEFINITIONS:

When used in this policy these terms have the following meanings:

A. Research: A systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

B. Related to the research: A financial interest in the sponsor, in the product or service being tested, or in a product or service that competes with the product or service being tested in a research study.

C. Financial Interest: anything of monetary value, whether or not the value is readily ascertainable

D. Public Health Service (PHS): The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

E. Significant Financial Interest Non-PHS (SFI-Non-PHS): A Financial Interest held by the Investigator (or his/her Immediate Family or Household Member) that meets the level of significance that requires disclosure as required by Orlando Health's current Orlando Health Research Financial Disclosure Form.

F. Significant Financial Interest PHS (SFI-PHS): Any Financial Interest held by the Investigator (or his/her Immediate Family or Household Member) is considered significant and must be disclosed.

G. Financial Conflict of Interest (FCOI): A Significant Financial Interest as defined above that could directly and significantly affect the design, conduct or reporting of research.

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H. Investigator: Any person, regardless of title or position, who is responsible for research design, conduct or reporting.

I. Senior/key personnel: These are the program director/principal investigator and any other person identified as senior/key personnel by the Institution in a grant application, progress report, or any other report submitted to the PHS by the Institution.

J. Sub-recipient: A sub-recipient relationship is established when federal funds flow down from or through an awardee Institution to another individual or entity and the sub-recipient will be conducting a substantive portion of the PHS-funded research project and is accountable to the awardee institution for programmatic outcomes and compliance matters.

K. Immediate family: An individual's spouse, domestic partner, and dependent children

L. Equity Interest: Means any stock, debt obligation, or derivative thereof, including options, exclusive of diversified mutual funds. (e.g., stocks, stock options or other ownership interests)

M. Intellectual property rights: Patents, copyrights, trademarks, or the right to royalties from such rights.

N. Institutional responsibilities: This is an investigator's professional responsibilities on behalf of Orlando Health, which include but are not limited to activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards (IRB).

O. Compensation: Any payment including salary, bonus, fees, honorarium, royalties, or in kind products or services including royalties from Orlando Health, but excluding:

1. Salary and other non-royalty compensation from Orlando Health.
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
3. Income from service on advisory committees or review panels for public or nonprofit entities.

P. Conflict of Interest Officer (COIO): Institutional official responsible for implementing procedures related to the disclosure, review and management of conflicts of interest. The Chief of Corporate Research Operations or his designee will serve as the COIO for Orlando Health.

Q. Conflict of Interest Committee (COIC): A committee convened by the COIO to analyze a more complex financial interest to assure that it does not represent a conflict.

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R. Institutional Responsibilities: The Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Institutional Official: The individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's family related to the Investigator's institutional responsibilities.

III. POLICY:

It is the policy of Orlando Health to provide a reasonable expectation that the design, conduct, and reporting of basic and clinical research funded with PHS and Non-PHS monies will be free from bias resulting from Investigator financial conflicts of interest. The OH Chief, Corporate Research Operations or his designee will serve as the COIO for Orlando Health. Further, it is the policy of Orlando Health that Investigators are required to report financial interests for PHS and Non-PHS sponsored research in accordance with current standards and regulations.

IV. PROCEDURE:

A. All investigators are required to complete an Orlando Health Research Disclosure form. The process begins when the IRB staff notifies the COIO that an investigator or research staff involved with clinical or basic research has reported a financial interest. The process ends when the COIO has evaluated the reported interest and communicated the results of this evaluation to the IRB. The COIO may convene a Conflict of Interest Committee (COIC) to analyze and/or remedy conflicts that are more complex. A COIC will include the IRB Chairman, the VP, Corp Integrity, the Institutional Official and any other member as deemed necessary,

B. All Investigators are required to certify that they will notify Orlando Health of any financial status change during the course of the research project.

C. For Non-PHS Funded Projects:

The following financial interests require disclosure using the form entitled The Orlando Health Research Financial Disclosure form:

1. Compensation related to the research that when aggregated for the investigator and the investigator's immediate family are expected to exceed $25,000 in any calendar year.

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2. Compensation related to the research of any amount to the investigator or any member of the individual's immediate family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
3. Equity interest related to the research whose value when aggregated for the individual and the individual's immediate family exceeds $25,000.
4. Equity interest related to the research whose value when aggregated for the individual and the individual's immediate family represents more than a five percent (5%) ownership interest in any single entity.
5. Equity interest related to the research in a non-publicly traded corporation of any value by the individual or a member of the individual's immediate family.
6. Equity interest related to the research of any amount to the investigator or any member of the individual's immediate family where an arrangement has been entered into such that the amount of compensation will be affected by the outcome of the research.
7. Intellectual property rights related to the research held by the individual or the individual's immediate family likely to result in royalties that will exceed $25,000 per year.
8. Board, executive, or fiduciary interest related to the research.

D. For PHS Funded Projects

1. Regulatory Authority: This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.
2. Training: Each Investigator must complete conflict of interest training, review this policy, complete the form for the investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by Orlando Health in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to the institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

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3. Any of the following are considered reportable significant financial interests by the institution, and per federal policy as defined **by 42 CFR Part 50 Subpart F**:
   a. With regard to any publicly traded entity, a significant financial interest exists if any remuneration is received from the entity in the 12 months preceding the disclosure and any equity interest in the entity as of the date of disclosure, when aggregated. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value. With regard to any non-publicly traded entity, a significant financial interest exists if any remuneration is received from the entity in the 12 months preceding the disclosure, when aggregated, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

E. Disclosures:
1. Disclosure of Financial Interests: All Investigators are required to disclose their outside financial interests as defined above to the Institution on an annual and on an ad hoc basis, as described below. The IRB is responsible for the distribution, receipt, processing, review and retention of disclosure forms.
2. Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the disclosure or submit to the IRB an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.
3. In addition, all Investigators must submit to the IRB an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.
4. Prior to expenditure of funds, Investigators are required to disclose any SFIs related to the project to the COIO.

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5. Investigators on PHS-funded projects must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

F. Financial interests which do not require review include (Section 50.603 (3)):
1. Salary royalties, or other remuneration paid by Orlando Health to the investigator if the investigator is currently employed or otherwise appointed by Orlando Health.
2. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
3. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles
4. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
5. Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

G. Determine whether the financial interest and research protocol has already been processed under this standard operating procedure. If yes, notify the IRB staff of this determination in writing.

H. Investigator non-compliance:
1. Clinical Trials: Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial. However, in the event of non-compliance with reporting and/or management of a financial conflict of interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the investigator must disclose the financial conflicts of interest in each

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public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

2. Reporting to PHS: The institutional official will report financial conflicts of interest, non-compliance, and mitigation reports to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.
3. Disciplinary Action: In the event of an Investigator's failure to comply with this Policy, the Institutional official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.
4. A Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The institution will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

I. Review:

1. Determine whether the financial interest is prohibited under Florida law or requires an exemption.
   a. If the financial interest is prohibited under Florida State law, notify the investigator of this determination.
   b. If the financial interest requires a Florida State exemption, take steps to obtain an exemption.
2. Prior to the expenditure of funds, the COIO:
   a. Reviews all Investigator SFI disclosures
   b. Determines if any SFIs relate to PHS-funded research
   c. Determines if an FCOI exists

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d. Develops and implements management plans related to any existing FCOIs

3. If the COIO determines that the financial intent results in a conflict that cannot be simply remedied then a COIC will be convened, If the financial interest does not require review by a committee, notify the IRB staff of this determination in writing.
4. The COIC will have at least five individuals to review the financial interest and will:
    a. Exclude individuals who:
        i. Have a fiduciary or promotional relationship related to the research.
        ii. Are involved in the design, conduct, or reporting of the research and individuals.
        iii. Are involved in competing research.
    b. Include individuals who:
        i. At least one, but no more than two, individuals from the investigator's department.
        ii. At least one individual from the IRB and one individual from the Compliance Department.
5. The Investigator and/or the IRB will provide the committee members with a description of the financial interest, a copy of the protocol, and supporting documents to review.
6. The COIC will follow these steps:
    1. Review the financial interest in the context of the research protocol.
    2. Determine the likelihood that the financial interest could directly and significantly affect the design, conduct, or reporting of the clinical or basic research by considering the following questions:
        i. What is the value of the financial interest?
        ii. What is the scope of the relationship?
        iii. What is the extent of discretion?
7. Retrospective Review: If the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial

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Conflict of Interest, the Institutional Official will appoint a committee to complete a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

a. Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

b. The Institutional official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the institution will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

c. The COIC will complete and document retrospective reviews within 120 days of the Institution's determination of noncompliance.

L. Decision and Reporting

1. If the COIC determines that the reported financial interest cannot directly and significantly affect the design, conduct, or reporting of the clinical or basic research, no further action is required by the COIC. If the COIC determines that the reported financial interest can affect the research then the following questions (part 2 below) must be considered by the COIC.

2. Determine the seriousness of harm that could result by considering the following questions:

   a. Risks to human subjects: to what extent could the conflict of interest increase the risk (considering the role specified for the researcher with the conflict of interest in recruiting or treating research participants)?

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b. Risks of bias in data collection, analysis, and reporting: to what extent could the researcher with the conflict of interest compromise the integrity of the data?
c. Risks to reputation: to what extent could the reputation of the researcher with the conflict of interest or the researcher's institution be damaged, even if the institution establishes a plan to manage the conflict?
d. Expected benefits to medicine, science, and public health: how do the expected benefits of allowing the research to proceed compare with the risks?

3. If a conflict of interest exists, determine under what circumstances, if any, should a conflicted individual be allowed to participate in:
   a. Subject recruitment.
   b. Prescreening for inclusion/exclusion criteria.
   c. The consent process.
   d. The treatment of subjects, separate from the research interventions or procedures.
   e. Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting.
   f. Basic research.
4. The COIC will devise and implement a plan within 60 days to eliminate, reduce, or manage the conflicts of interest, considering at a minimum the following options:
   a. Asking an individual with a conflict of interest to reduce or eliminate the value of a financial relationship so that it falls below a threshold amount or to sever or modify relationships that create the conflicts of interest.
   b. Modifying the design of a research project or having a researcher with no conflict of interest serve as the principal investigator.
   c. Disqualifying the researcher from participation in all or a portion of the clinical or basic research, such as involvement in the consent process, recruitment, safety monitoring, or data analysis.

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d. Providing an independent observer to monitor the consent process or the conduct of the research for effects of the financial interest on the research.

e. Public disclosure of the financial interests.

5. The COIC will devise and implement a plan to monitor the conflict elimination, reduction, or management plan.

6. The COIC will provide the management plan to the investigator for comment and review.

7. The COIC will finalize the written management plan.

8. The COIC will provide the IRB staff with the written management plan.

M. Records

1. The IRB will maintain a copy of determinations and management plans in the records.

2. For PHS-funded projects:
Orlando Health shall make the parts of this policy related to PHS Funded Projects available via a publicly accessible web site that shall be updated at least annually and within sixty days of Orlando Health identifying a new significant financial conflict of interest.

a. Record Retention: The IRB will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

b. Confidentiality: To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

c. Public Accessibility: Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the

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request, information concerning any Significant Financial Interest that meets the following criteria:

i. The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
ii. A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
iii. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.
iv. The information to be made available shall be consistent with the requirements of the PHS regulation.

d. Subrecipient requirements:
i. If the PHS-Funded Research or portions of it is carried out through a subrecipient, the Orlando Health will take reasonable steps to ensure that any subrecipient Investigator complies with 42 CFR Part 50, Subpart F by incorporating the following as part of the written agreement with the subrecipient:
ii. Terms that establish whether this policy or the subrecipient's FCOI policy will apply to the subrecipient Investigators;
iii. Time period(s) for the subrecipient to report all identified FCOI or for submission of all subrecipient FCOI disclosures to Orlando Health.
iv. Terms that allow Orlando Health to solicit and review subrecipient Investigator disclosures in order to identify, manage and report identify FCOIs.
v. Providing FCOI reports to the PHS awarding component regarding all Financial Conflicts of Interest of all sub-recipient investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

V. DOCUMENTATION:

The Orlando Health PHS Funded Research Financial Disclosure Form or the Orlando Health Research Financial Disclosure form must be on file with the ORMC IRB or APMC IRB prior to research project approval.

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VI. REFERENCES:

A. Administrative Policy and Procedure #5706-0329, Conflict of Interest.
B. Administrative Policy and Procedure #5706-0310, Conflict of Interest Disclosure.
C. 42 Code of Federal Regulations Part 50, Subpart F.

VII. ATTACHMENTS:

Orlando Health PHS Funded Research Financial Disclosure Form
Orlando Health Research Financial Disclosure form