



Orlando Health Institutional Review Board
PHS FUNDED (OR OTHER GRANT FUNDED)
RESEARCH FINANCIAL DISCLOSURE FORM

Form with fields: IRB #, Protocol #, Name of PHS Agency, Project Title, Name of Investigator, Department, Contact Person, Phone #.

General Statement:

Use this form for research studies receiving funding from a United States Public Health Service (PHS) grant agency (for example, NIH, CDC, HRSA, etc.) or from a private grant from any non-PHS organization. Orlando Health, Inc. is committed, within the laws of the state and the federal government, to assist physicians and other medical personnel in their pursuit of research. Orlando Health, Inc. also recognizes that physicians and medical personnel may also engage in outside activities which may provide service to the community and could increase the professional reputation of the organization. To ensure that research is conducted with the highest integrity Orlando Health, Inc. requires that whenever a question, or appearance of conflict, could arise between the research investigator's outside activities and their duties as a researcher as outlined in FDA guidelines and/or CFR 42 Part 50 Subpart F, the investigator is obligated to report that situation to the Institutional Review Board (IRB). The outside activities that are required to be disclosed are outlined below in this document. The IRB is responsible for reviewing each disclosure to determine if the activity is permitted or not permitted, or if there are conditions necessary to manage, reduce or eliminate the conflicts or potential conflicts before the research activity can be permitted. Please review policy 5706-0174 for further clarification and information. For questions on this form, please contact the Office of Grants Administration (OGA) at PG-GrantsAdministration@orlandohealth.com.

Disclosure of Financial Interests (stock, options, etc.) and Relationships (consulting or other compensated or uncompensated involvement) for yourself or your immediate family (spouse and dependent children)

1. Do you or members of your immediate family have a significant financial interest in the sponsor of the trial/research project? Significant financial interest exists if any value of any remuneration has been received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, is greater than \$0. 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 value of any remuneration has been received from the entity in the 12 months preceding the disclosure, when aggregated, is greater than \$0, 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). [] YES [] NO

If YES, please provide the dollar amount and nature of the equity interest below.

2a. Do you or any members of your immediate family have any proprietary or financial interest in the product such as a patent, trademark, copyright, or licensing agreement? [] YES [] NO

- 2b. To your knowledge, does any person affiliated with the Project have any proprietary or financial interest in the product such as a patent, trademark, copyright, or licensing agreement? YES NO

If YES, please list the name of the person(s), the specific type(s) of financial interest or relationship, and the name(s) of the entity.

3. Are you receiving significant payments of other sorts, excluding payments for conducting the trial? These would include payments made to the investigator that have any monetary value > \$0. These payments could include, for example, grants to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation or honoraria for speaking. YES NO

If YES, please describe below.

4. To your knowledge, do you or does any other person affiliated with the Project have any financial arrangement with any entity which could, or which potentially could, benefit directly or indirectly from the outcome of the trial? These arrangements could include, for example, compensation that is explicitly greater for a favorable outcome, or compensation in the form of an equity interest in the sponsor or in the form of compensation tied to sales of the product such as a royalty interest. YES NO

If YES, please describe below.

5. Have you received travel reimbursement or have had 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? YES NO

If YES, please describe below.

Disclosure of Governance or Administrative Affiliations

1. Do you or any member of your family or does any other person involved with the project have any governance or administrative affiliation with the sponsor of this protocol? YES NO

If YES, please list the name of the person(s), and their relationship to the sponsor:

Other

1. Have you disclosed any potential financial conflict of interest to the sponsor? YES NO

If YES, please give details.

2. Have you previously disclosed any potential conflict of interest for this study to Orlando Health, Inc.? YES NO

If YES, please give details.

3. Is there anything not disclosed which you believe might constitute a conflict of interest in connection with the protocol? YES NO
- If YES, please give details.

Investigator’s Statement and Signature:

My electronic signature certifies that I have answered the above questions to the best of my ability and I agree to the following:

- I attest that I have used reasonable diligence in preparing this Financial Disclosure Form and that it is true and complete, to the best of my knowledge. I understand that this information is being used to ensure that research is conducted with the highest integrity and that the rights and interests of human subjects (if any) are protected.
- I agree to cooperate in the development of an appropriate management plan and to provide any further information that may be requested during any aspect of the conflict of interest review.
- I agree to comply with the terms and conditions of any management plan approved by the IRB and (if applicable) by a Conflict Of Interest Committee (COIC) and to take any and all other reasonable measures to ensure that my financial interests and external commitments do not adversely affect this research project or any human subject enrolled herein.
- I acknowledge my obligation to submit an updated Financial Disclosure Form to the IRB at any time during the study or up to one year after completion when there is change in any previously reported financial relationships or a new financial relationship.

(CORO Use Only) If you marked a yes above, this form will be forwarded to the Corporate Office of Research Operations for review of any potential conflicts of interest.

Approved on _____ by COI Officer. **No required changes**

Approved on _____ by COI Officer.
Additional changes required:

Signature of COI Officer _____

Approved on _____ by the Conflict of Interest Committee. **No required changes**

Approved on _____ by the Conflict of Interest Committee.
Additional changes required:

Signature of COIC Designee _____

Reported to IRB on _____