



For the protection of human subjects, the Dillard University Institutional Review Board (IRB) has adopted the following Conflict of Interest (COI) Policy and Statement. Each protocol submitted to Dillard University Institutional Review Board (IRB) for review must be accompanied by a COI Disclosure Statement for each person who is directly involved in research activities and/or interacting with research subjects in the covered study.

NOTE: Each protocol must be accompanied by all appropriate COI Statements. This policy is effective November 3, 2022 (date will change once voted on) and is part of the IRB protocol review process. Protocols submitted without the appropriate COI Statements will not be accepted or reviewed until all appropriate COI documents are received.

COI Statements MUST be completed, signed and submitted with each Initial and Continuing Application for IRB Review.

Additionally, if the research is externally funded. Federal regulations require a separate Financial Conflict of Interest (FCOI) declaration submitted through the Division of Institutional Advancement for all researchers responsible for the design, conduct, or reporting of externally funded research.

- The FCOI declaration should be submitted prior to filling out this form.
- Any change to FCOI declaration information requires a re-submission within 30 days of the change.

Purpose: It is Dillard University's IRB obligation to ensure research participant protections, the integrity of IRB review, and the conduct of research is not jeopardized by an unidentified or unmanaged conflict of interest. Use this form to disclose financial conflicts of interest or other interests that are/or may be perceived to be related to the research.

CONFLICT OF INTEREST POLICY

This policy is intended to serve subjects of human research. This policy is not intended to eliminate all situations of conflict of interest, but rather to enable individuals to recognize situations that may be subject to question and resolve them so as to avoid conflicts of interest. Thus an integral part of the policy is disclosure whereby individuals regularly review their professional activities.

THE POLICY - Individuals directly involved in the conduct, design or reporting of research involving human subjects should not have more than a minimal personal financial interest in a company that sponsors the research or owns the technology being studied. A conflict of interest arises when a researcher is or may be in a position to put his or her own interest before the best interests of research subjects. Conflicts involving the IRB itself or conflicts involving the institution must be managed. In order to manage such conflicts, the IRB must be informed of potential conflicts of interest. Researchers submitting protocols using human subjects must disclose all interests that may be perceived as a conflict with the best interest of the subject in order for the research to be considered for approval.

EXAMPLES OF REPORTABLE AND NON-REPORTABLE ACTIVITIES

1. Non-Reportable Activities

The following activities and relationships do not need to be reported and do not represent a conflict of interest because they have been generally accepted practices and do not violate fundamental ethical principles.

- a. Receiving royalties for published scholarly works and other writings.
- b. Accepting honoraria for commissioned papers and occasional lectures.
- c. Receiving payment for reasonable travel and lodging expenses related to presentations of scholarly work or to a person's academic endeavor.
- d. Investing in mutual funds.
- e. Participating in a University approved practice corporation.

f. Payments for clinical research to an approved practice corporation or to a department fund for salary or other expenses of conducting clinical trials.

2. Reportable Activities

- a. Conducting research in applied and/or clinical research on a technology developed by the investigator or a member of his/her immediate family (spouse, children, parent, in-laws, siblings).
- b. The financial relationship of an investigator or his/her immediate family member with the sponsor of his/her research (acting as scientific advisor or consultant, or receiving honoraria exceeding \$5,000 annually, or acting as director or other executive).
- c. Conducting applied and/or clinical research on a technology owned by a business in which the investigator or a member of his/her immediate family holds 5% or more of the outstanding stock or stock options.
- d. Receiving royalties under institutional royalty-sharing policies from marketing the drug, device or procedures that is the subject of the research.
- e. Receiving payments directly from the sponsor, rather than through John Peter Smith, the University or an approved DU entity, for recruiting subjects.

CONFLICT OF INTEREST STATEMENT

For the protection of human subjects, the Dillard Institutional Review Board (IRB) requires that each protocol submitted to the IRB for review must be accompanied by a Conflict of Interest (COI) Disclosure Statement for each investigator/key personnel who is involved in the research activities and/or interacting with research subjects in the covered study. COI Disclosure Statements must be completed, signed and submitted with each Initial and Continuing Application for IRB Review.

Name of Principal Investigator: (add your text here)
Title of Protocol: (add your text here)
IRB Protocol #: (add your text here)
Name of Person (Investigator/Key Personnel) completing this statement: (add your text here)

In order to protect subjects from financial conflicts of interest or perceived conflicts of interest, the Dillard University IRB requires that such potential conflicts be disclosed. If the Dillard University IRB determines that a conflict exists that could influence the research or jeopardize the well being of subjects, the Dillard University IRB may require additional information about the conflict or may require that the conflict be resolved before the research is approved. In addition, it may require that the conflict be disclosed to the subject in the Informed Consent document.

If you or any member of your immediate family (spouse, children, parent, in-laws, and siblings) has a financial interest in either a public or private company whose drug, procedure, technique, device, or software is used or tested in this study, please indicate the following:

1. ___ Yes ___ No. Do you and or does any member of your Family or any Associated Entity such as a Family-owned Business have an equity or other ownership interest in a Business or other outside entity that relates to your activities at Dillard University that, when aggregated for yourself, your spouse and your dependent children, either (a) has fair market value of more than \$10,000 or (b) represents more than five percent (5%) of the ownership interest in that Business or entity?

2. ___ Yes ___ No. Do you and or does any member of your Family receive salary, royalties, or other payments from a Business or other outside entity that relates to your activities at Dillard University that when aggregated for yourself, your spouse and your dependent children over the next twelve months are expected to exceed \$10,000?

3. ___ Yes ___ No. Do you or does any member of your Family occupy an Executive position in a Business or other outside entity that relates to your activities at Dillard University?

4. ___ Yes ___ No. Have you and or has any member of your Family or any Associated Entity, prior to completing this form, received a financial benefit in money or in kind from an outside entity the activities of which relate in way to your activities at Dillard University?

If you checked YES to questions 1, 2, 3, or 4, complete question 5 (A-D), then sign and date form below. If you checked NO to 1, 2, 3, and 4, sign and date the form below.

5. Name and Address of Business or outside entity: _____ For profit _____ Non-profit

General description of Business or outside entity:

A. You and your Family's aggregate financial interest in the Business or outside entity: Please check all that are applicable.

1. Consulting income (check annual amount)

less than \$10,000

more than \$10,000 but less than \$20,000

more than \$50,000

2. Stock, stock option, partnership share or other ownership interest exceeding \$10,000 fair market value or 5% of the outstanding ownership of a Business.

3. Service in an Executive position for a Business: List position and describe duties: _____

4. Compensation for service on Board of Directors.

5. Payments for commissioned papers, editing, lectures, or expert testimony

6. Royalties for inventions or publications or rights arising from patents or copyrights

7. Gifts, gratuities, favors or anything of monetary value

8. Loan(s) from or indebtedness to the Business or outside entity

9. Any other income or ownership interest (describe on separate sheet of paper)

B. Your activities at Dillard University that might relate to the Business or outside entity. Please check all that apply.

1. Design, conduct, or report research supported by, potentially supported by, or involving Technology owned by the Business or material affecting the Business or outside entity.

2. Assign or supervise the work of students, fellows or other faculty engaged in such research.

3. Make clinical or other referrals to the Business or outside entity.

4. Make or influence University decisions that relate, directly or indirectly, to the Business or outside entity, including decisions regarding purchasing by, contracting on behalf of, or collaborating with, Dillard University, rendering professional advice to the University, or decisions related to the conduct of Sponsored Programs at Dillard University.

C. Indicate the fair market value of the aggregate ownership interest that you and your Family hold in the Business or outside entity by checking the appropriate box:

- less than \$10,000 more than \$10,000 but less than \$50,000 more than \$50,000 but less than \$100,000
 more than \$100,000 not applicable

D. Indicate the amount of aggregate annual income/compensation that you and your Family receive from the Business or outside entity by checking the appropriate box:

- less than \$10,000 more than \$10,000 but less than \$50,000 more than \$50,000 but less than \$100,000
 more than \$100,000 not applicable

Please include a separate letter of explanation if there is further information that the Dillard University IRB should consider.

If I have not checked any of the boxes above, or attached a letter of explanation for consideration by the Dillard University IRB, my signature below is my representation that I have no financial or other conflict of interest that could adversely affect a subject in this study.

The PI must keep completed copies of all protocol investigator's IRB COI forms for their records.

Following the IRB review and approval of the research protocol, the PI must review, at least annually, this form with all applicable personnel and promptly report any changes to the IRB.

I acknowledge that I am required to notify the Dillard University IRB within 10 business days if a change in my disclosure status occurs.

Signature: _____

Date: _____