

Georgetown University
Study Specific Disclosure Form

Name of Investigator Submitting Disclosure: _____
Dept/Div: _____ Tel: _____ Email: _____
Project/Grant Title: _____
Project PI: _____ Dept/Div: _____
IRB/GUACUC #: _____ RX# (if known): _____
Sponsor: _____ Agency/Sponsor Grant# (if known): _____

Is there more than one sponsor? Yes No If Yes, please attach a separate form for each sponsor.

1. Do you or any member of your family have a financial interest in or a professional relationship with a business or outside entity whose activities relate to the project listed above, or an intellectual property interest that relates to the project listed above?
 Yes No

(In this context, "member of your family" means a spouse, dependent children, or other household member or relative whose interest you believe could be seen as affecting your objectivity. See Question 2 below for types of financial interests or other professional relationships to be considered in answering this question.)

If you checked YES to #1 above, complete #2 (A - E) below. If you checked NO to #1, sign and date this form at the bottom. Return this completed form, with the corresponding protocol application to the IRB Office, Georgetown University Medical Center, 3900 Reservoir Rd NW, Medical-Dental Building room SW 104, Washington DC 20057.

2. Name and address of business or outside entity (indicate: for profit; or non-profit), or description of intellectual property:
Name: _____ Address: _____

Intellectual property: _____

A. Type of financial interest or other professional relationship you or your family member has in the business or outside entity (check all applicable items):

- Consulting income
- Stock, stock option, partnership share or other ownership interest
- Service (compensated or uncompensated) in an executive position for, or on a board of, a Business or outside entity.
- Salary for other employee position
- Payments supported by commercial entities for commissioned papers, editing, lectures, or expert testimony
- Intellectual property such as royalties for inventions or publications, or inventor on patent or pending patent
- Gifts, gratuities, favors or anything of monetary value, including loans
- Other conduct requiring disclosure under the Conflicts Policy – (Please explain on separate page, as in E below)

B. Your GU activities that might relate to the activities of the business or outside entity, or intellectual property interest (check all applicable items):

- I conduct research supported by or involving technology owned by or licensed to the business
- I assign or supervise the work of students, fellows or other faculty engaged in such research
- I make clinical referrals to the business
- I make or influence administrative or supervisory decisions regarding purchasing by, or contracting on behalf of, GU; I render professional advice to GU; or I engage in managerial, supervisory, or advisory functions related to the conduct of sponsored programs
- I serve on an internal or external body with jurisdiction to award or distribute government funds (e.g., committees of NIH, FDA, or other governmental agencies, private professional or regulatory body) where participation would reasonably appear to be influenced by the business interest or consulting relationship
- Other (Please explain on an attachment)

C. Indicate the aggregate fair market value of ownership interest by checking the appropriate box(es):

- \$10,000 or less More than \$10,000 but less than \$25,000 \$25,000 or more
- More than 5% of the capital stock of the company Not applicable

D. Indicate the aggregate annual amount of income/compensation by checking the appropriate box(es):

- \$10,000 or less More than \$10,000 but less than \$25,000 \$25,000 or more Not applicable
- If a loan, amount \$ _____; security _____; interest _____ % per annum.

E. Please provide explanations of A and B above on a separate page.

I have read the Georgetown University Financial Conflicts of Interest Policy, and the answers on this disclosure form are accurate to the best of my knowledge. If I am submitting a grant application for NIH, NSF or other federal agency funding, I acknowledge that I have received a summary of the applicable federal regulations relating to financial conflict of interest in extramural research and I agree to abide by the disclosure responsibilities of "an investigator" as defined in these regulations. If Georgetown University determines that a conflict of interest exists, I agree to comply with any condition imposed by the institution pursuant to the Georgetown University Financial Conflicts of Interest Policy to manage, reduce, or eliminate the conflict, or I will withdraw as an investigator on this research. I will update this disclosure promptly if my circumstances change, either because of a change in my or my family's financial interests, a change in my University activities, or any other changes that could affect the fact or appearance of a conflict.

Name (printed): _____

Campus Address: _____

Signature: _____ Date: _____

Guidance for Conflicts Disclosure in Informed Consent

Conflicts of interest exist when an investigator or the institution has financial or personal relationships that may compromise or present the appearance of compromising an individual's, group's, or institution's judgment in conducting, reviewing, or reporting research. These relationships vary from those with negligible potential to those with great potential to influence judgment, and not all relationships represent true conflicts of interest. **A fully informed consent is one in which all related financial interests are disclosed.**

To facilitate appropriate disclosure of potential conflicts of interest in the informed consent document, the following suggested language is provided. It is not mandatory to use these specific provisions. Language should be modified to fit the specific facts and circumstances.

This study is paid for by [name of sponsor] which [has no financial interest in its outcome] (or) [owns the {drug} (or) {device} being tested and thus has a financial interest in the outcome of the study]. Payments are made to Georgetown University (GU) and the funds are used to cover the expenses of the study and related academic and research activities of the institution. [The investigators and Georgetown University do not have any financial interest in the outcome of the study] (or) [insert disclosure of potential conflict(s) of interest by investigator(s) and/or institution(s); using such statements as the following:

1. The investigator, Dr. _____ (full name), owns equity (stock) of the company which is paying for this research.
2. The investigator, Dr. _____ (full name), personally receives consulting or other payments from the company which is paying for the study (or occasionally serves as a paid consultant or paid scientific advisor).
3. GU/MedStar owns equity (stock) of the company which is paying for this study.
4. The investigator, Dr. _____ (full name), is an inventor of [the drug, compound, device, etc.], for which a patent may be filed by the institution. If the patent is pursued, based on data from this and other research, royalties and other compensation may be received by the institution and the investigator. Thus, GU/MedStar and the investigator have a financial interest in the outcome of this study.

If you require further information regarding the financial arrangements described in this paragraph, you should discuss the matter with the investigator,

Dr. _____,
Phone: _____.

Guidance for Conflicts Disclosure in Publications and Presentations

Financial and/or Intellectual property interests (e.g. patents or patent applications) must also be disclosed in all related publications and presentations.

Questions about the Georgetown University **Study Specific Financial Disclosure Form** can be directed to the Office of Regulatory Affairs, Conflicts Regulation Office at 202-784-5313 or coigumc@georgetown.edu