

Appendix 1

CONFLICT OF INTEREST IN RESEARCH FINANCIAL DISCLOSURE FORM

**University of Connecticut Health Center
Conflict of Interest Financial Disclosure Form**

Please complete this form for each business with which you have a relationship, and return to your departmental conflict of interest (COI) officer. To help you understand how to answer these questions, review definitions that accompany this form. The Individual COI Policy is available at the UCHC web site.

Last name:

First name:

Department:

Home Address:

Telephone:

1. Do you, or any members of your immediate family, have a significant financial interest in a business whose activities relate in any way to your research as an employee of the University of Connecticut Health Center?

Yes _____ (If you check Yes, please continue to question 2)

No _____ (If you check No, please sign form and return to your department head)

2. Please provide the following information about the significant financial interest identified above.

Name of business: _____

Activities or products of the business: _____

Is this business a for-profit entity? _____

Is this business publicly traded? _____

Is the business non-publicly traded? _____

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3. Please describe the nature of your or your immediate family's relationship to the business identified above, e.g., consulting, employee, executive position, board of directors, honoraria, stock ownership. Provide details about the nature of activities with the business.

I have answered fully and to the best of my ability and will update this form promptly if my circumstances change.

Signature

Date

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DEFINITIONS¹

Business means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes.

Clinical Investigation (DHHS) means any experiment in which a drug is administered or dispensed to, or used, involving one or more human subjects. An experiment here is any use of a drug except for the use of a marketed drug in the course of medical practice.

Clinical investigation (FDA) means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.

Conflict of Interest means a situation in which significant financial interests in a business, or other personal considerations provided by a business, may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research, the results of which could affect the aforementioned business, either directly or indirectly.

Human Subject (DHHS regulations "Protection of Human Subjects" 45 CFR Part 46, as administered by OHRP) means a living individual about whom an investigator conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information

Human Subject (FDA regulations 21 CFR 50) means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Immediate Family means the investigator's spouse, minor children, and any other persons living in the same household.

Investigator means the principal investigator and any other person at UCHC who is responsible for the design, conduct or reporting of research, and the investigator's immediate family. This

¹ Definitions in this Section have been adapted from the following documents:

Harvard University Faculty of Medicine, Policy on Conflict of Interest and Commitment.
Association of American Medical Colleges, Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research, 1990. Department of Health and Human Services, Federal Register, 7/11/95. Notice of Final Rule, Objectivity in Research.
National Science Foundation, Federal Register, 7/11/95. Notice of Final Rule, Investigator Financial Disclosure Policy.

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shall include faculty and research staff (research associates and assistants, postdoctoral fellows, graduate students, visiting scientists, and medical or dental students engaged in research conducted in the department).

Participate means to be part of the described activity in any capacity, including but not limited to serving as the principal investigator, co-investigator, research collaborator or provider of direct patient care. The term is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis) or, in the case of clinical research, to the trial participants, unless they are in a position to influence the study's results or have privileged information as to the outcome.

Research (HHS regulation 45 CFR 46.102(d)) means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Significant Financial Interest (DHHS/PHS/NIH) means anything of monetary value, including, but not limited to:

1. Salary or other payments for services (e.g., consulting fees or honoraria); or
2. Equity interests (e.g., publicly and non-publicly traded stocks, stock options or other ownership interests); or
3. Intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

1. Salary, royalties, or other remuneration from UCHC; or
2. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities²; or
3. Income from service on advisory committees or review panels for public or non-profit entities; or
4. An equity interest that when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than 5% ownership interest in any single entity; or
5. Salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and dependent children over the next 12 months, are not expected to exceed \$10,000.

² These definitions are different from the State of Connecticut definitions such that it may be a prohibition under state codes of ethics to receive outside interests. See section 8.

Significant Financial Interest (FDA) means:

1. Compensation made to the investigator in which the value of compensation could be affected by study outcome. This requirement applies to all covered studies, whether ongoing or completed as of February 2, 1999.
2. A proprietary interest in the tested product, including, but not limited to, a patent, trademark, copyright or licensing agreement. This requirement applies to all covered studies, whether ongoing or completed as of February 2, 1999.
3. Any equity interest in the sponsor of a covered study, i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices. This requirement applies to all covered studies, whether ongoing or completed;
4. Any equity interest in a publicly held company that exceeds \$50,000 in value. These must be disclosed only for covered clinical studies that are ongoing on or after February 2, 1999. The requirement applies to interests held during the time the clinical investigator is carrying out the study and for 1 year following completion of the study; and
5. Significant payments of other sorts, which are payments that have a cumulative monetary value of \$25,000 or more made by the sponsor of a covered study to the investigator or the investigators' institution to support activities of the investigator exclusive of the costs of conducting the clinical study or other clinical studies, (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for 1 year following completion of the study. This requirement applies to payments made on or after February 2, 1999.

Significant Financial Interest (NSF) means:

The term 'significant financial interest' means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

1. salary, royalties or other remuneration from the institution; or any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program; or
2. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; or
3. income from service on advisory committees or review panels for public or nonprofit entities; or
4. financial interests in business enterprises or entities if the value of such interests do not exceed \$5,000 or represent more than a 5% ownership interest for any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children.

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Sponsor means an individual company which takes responsibility for the initiation, management, and/or financing of a clinical trial, but who does not actually conduct the investigation.

Technology means any compound, drug, device, diagnostic, medical, dental or surgical procedure intended for use in health care or health care delivery.