

Instructions for Completing Page 2

In order to ensure compliance with federal law and Center Policy, the Principal Investigator must confirm for the IRB that:

- All Key Personnel described in this protocol and any person who will Participate in Human Subjects Research have disclosed any Conflict of Interest; AND
- Any Conflict of Interest has been managed reduced or eliminated...

Please note that the Project Specific Disclosure Forms you may have already submitted to Grant and Contract Administration address conflict of interest on a project or program basis while this Protocol Disposition Form will address conflict of interest review on a protocol-specific basis. If you have any questions, please contact the Office of the General Counsel at x1224.

The following capitalized terms appear throughout the Conflict of Interest questions:

Affiliate: An individual with a recognized and approved relationship with the Center who may not be receiving pay, benefits, or a stipend through the Center's payroll system.

Business Entity: A sole proprietorship, partnership, joint venture, or any other form of enterprise, whether conducted for profit or not.

Conflict of Interest: Any situation in which an individual has the opportunity or appears to have the opportunity to (a) influence the Center's decisions; (b) use Center resources or Center confidential or proprietary information in ways that could lead to professional, personal or financial gain; or (c) otherwise obtain improper advantage for himself/herself, for his/her spouse, domestic partner or dependent child (i.e. immediate family), or for organizations in which s/he or his/her immediate family holds any official position or has any Prohibited or Significant Financial Interests.

Human Subjects Research: A systematic investigation which is designed to develop or contribute to generalizable knowledge in which an individual (or those under his/her control) a) obtains data about living individuals ("subjects") through intervention or interaction; or b) has access to individually identifiable information about such subjects. Intervention includes both physical procedures by which data are gathered and manipulations of the subjects' environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the individual and subject. For purposes of this definition, Human Subjects Research includes only research that is financed in whole or in part by funds administered by the Center.

Key Personnel: Individuals responsible for the design, conduct, or reporting of research

Participate in Human Subjects Research: With respect to a specific IRB approved research protocol, 1) acting as principal investigator for such protocol; 2) consenting

human subjects to such protocol; 3) recruiting human subjects to such protocol; or 4) evaluating the response of human subjects enrolled on such protocol. Please note that the term “consenting” excludes individuals who may be consenting human subjects solely as part of their clinical attending duties.

Prohibited Financial Interest: 1) an ownership of any amount or any nature in a for-profit entity (including stock, stock options and partnership interests) but excluding an ownership interest in a publicly traded, diversified mutual fund; 2) royalties, fees or any other one time or periodic payment or the right to receive any such payment in the future under a patent or a copyright license, assignment or other agreement where the Conflict of Interest Committee determines that the technology or copyrighted work which is the subject of the license or other agreement is directly and significantly related to Human Subjects Research; and 3) payments of any kind (for example, consulting fees, expense reimbursement, honoraria, gifts or in-kind compensation) from a for-profit entity that in the aggregate have, in the prior calendar year, exceeded \$10,000 or are expected to exceed \$10,000 in the next twelve months. Payments under a multi-year agreement with a for-profit entity which are expected to exceed \$10,000 over the term of the agreement will constitute a Prohibited Financial Interest unless the agreement can be terminated at the election of the Center employee or affiliate not less frequently than every twelve (12) months, and the payments under the agreement do not otherwise constitute a Prohibited Financial Interest.

Protocol Involving a Commercial Sponsor or the Testing of a Commercial Product and/or Service: A protocol in which either a for-profit entity is providing funding for the protocol or the objective of the protocol is to specifically test a product or service of a for-profit entity regardless of funding source. Examples include 1) any protocol receiving monetary or in-kind support from a for-profit entity; 2) any protocol designed to test the efficacy or safety of a new investigational drug whether or not funded by a for-profit entity; 3) any protocol designed to test the efficacy or safety of a new indication for an existing FDA-approved drug whether or not funded by a for-profit entity. A protocol that is not funded by a for-profit entity and in which a commercial product or service is merely being used as the accepted standard of care does not fall within this definition.

Significant Financial Interest: Anything of monetary value, including but not limited to salary or other payments (for example, consulting fees and honoraria), ownership interests in Business Entities (for example, stock, stock options and partnership interests), intellectual property rights (for example, patents, copyrights, royalties) and any other form of direct or indirect pecuniary gain. The term does not include: 1) Salary, royalties or other remuneration from the Center; 2) Income from seminars, lectures or teaching engagements sponsored by public entities or nonprofit entities; 3) Income from services on advisory committees or review panels for public or nonprofit entities; 4) An equity interest that when aggregated for the individual (or his/her immediate family) 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 a five percent ownership interest in any single entity; or 5) Salary, royalties or

other payments that when aggregated for the individual (and his/her immediate family) over the next twelve months, are not expected to exceed \$10,000.