



**CONFLICTS OF INTEREST IN RESEARCH
ANNUAL DISCLOSURE FORM AND CERTIFICATION**

Investigator: _____	Date: _____
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I) Do you, your family or any Associated Entity have a Financial Interest in a Business that could appear to affect or be affected by this Research? **No** (please go to Section III) **Yes**

If **YES**, please check all of the following that apply:

- Consulting Income
- Compensation for an executive or other employee position
- Compensation for service on Board of Directors
- Stock, stock option, partnership share, other ownership interest
- Was the ownership interest acquisition related to your research activity?
 - No
 - Yes, please explain below

- Honoraria for commissioned papers, lectures, or teaching engagements
- Royalties
- Intellectual Property Rights (patent, copyright, trademark)
- Compensation for service on advisory committees or review panels
- Gifts or gratuities
- Loans, leases or special favors
- Other _____

II) If you have checked any of the boxes above, please describe the financial interests of you, your Family, and any Associated Entity. (Please use a separate form for each business).

a. Identity of the Business: _____

b. List all of the holder(s) of the Financial Interest (you, your Family, or any Associated Entity): _____

c. Total Financial Interest:	>\$0-5,000	\$5,000 –10,000	\$10,000 – 20,000	> \$20,000
\$ Amount of Income/Year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
\$ Amount of Equity or Ownership Interest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Percentage of your partnership Share, stock, or other ownership Interest	> 0 – 5% <input type="checkbox"/>	5 – 10% <input type="checkbox"/>	10 – 20% <input type="checkbox"/>	>20% <input type="checkbox"/>

III) I have read and understand the Conflict of Interest Policy. I have completed this form truthfully and to the best of my ability, and I agree to update this form promptly if there is any change.

Investigator Signature



A part of its commitment to promoting objectivity in research and in compliance with federal regulations on conflict of interest, Hebrew SeniorLife/Institute for Aging Research has adopted an Annual Disclosure Policy for all Investigators. This policy requires that the investigators submit an annual disclosure form to ensure that the design, conduct and reporting of sponsored program activity will not be biased by the significant financial interests or obligations of any investigator. To comply with this policy, each investigator must submit an annual disclosure form on or before October 1, but no later than:

- ❑ Submission of an application to an external sponsor, or
- ❑ Acceptance of an award where there was no prior disclosure submitted for that work

The submission of this annual disclosure satisfies the requirements of the Department of Health and Human Services (PHS) which requires that, by the time an application is submitted, each investigator planning to participate in PHS funded research has disclosed his/her known significant financial interest (and those of his/her family).

DEFINITIONS

For the purposes of this disclosure, the following definitions shall apply to the capitalized words and phrases contained herein.

Associated Entity of an Investigator means any trust or enterprise, other than HSL or any Affiliate over which the Investigator, alone or together with his or her Family, exercises a Controlling Interest.

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, but excluding any Affiliate, any Private Medical Practice, or any other entity controlled by, controlling, or under common control with HSL.

Clinical Research means any research or procedure involving human subjects in vivo or the use of human samples for the development and evaluation of patient therapies such as diagnostic tests, drug therapies, or medical devices. It includes early clinical studies, evaluation research, epidemiological studies and clinical trials. It does not include a Family Member's participation in the design of clinical study for which he/she is neither a participant nor an author.

Executive Position refers to any position that includes responsibilities for a material segment of the operation or management of a Business.

Investigator is (1) a principal investigator, and/or (2) co-principal investigator, and/or (3) any other person who is independently responsible for the design, conduct, or reporting of research, and/or (4) responsible for the treatment or evaluation of research subjects and/or (5) responsible for obtaining the informed consents of research subjects. This definition does not include students, post doctorate fellows, technicians, and other HSL employees whose work is directly supervised or monitored by an Investigator.

Family of an Investigator includes his or her spouse, minor children, and other persons living in the same household.

Financial Interest is an interest in a Business consisting of (1) any stock, stock option or similar ownership interest in such Business, but excluding any interest arising solely by reason of investment in such Business by a mutual, pension, or other institutional investment fund over which the Investigator does not exercise control, or (2) receipt of, or the right or expectation to receive, any income from such Business, whether in the form of fee (e.g. consulting), salary, allowance, forbearance, forgiveness, interest in real personal property, dividend, royalty derived from the licensing of Technology, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

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

XIII Disclosures of Interests Related to Research

Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*, was established to ensure that the design, conduct, and reporting of research will not be biased by a conflicting financial interest of an Investigator. While Subpart F only applies to federally funded research, Section XIII shall apply to all research at Hebrew SeniorLife (HSL), regardless of the funding source.

A. Disclosures by Investigators

1. Each Investigator, no less frequently than annually, shall complete the Conflicts of Interest in Research Disclosure Form and Certification and submit it to the Vice President, Research Administration. The Vice President, Research Administration shall be the Institutional Official pursuant to 42 CFR 50.604.
2. Investigators who are not employed by HSL but who in the course of their research, makes significant use of research facilities at HSL must also disclose their interests. It shall be the responsibility of the principal investigators to ensure these individuals make the required disclosures. It shall be acceptable for non-HSL based investigators who serve as key personnel for a Sponsored Research project to submit copies of any disclosure forms they completed as part of their home institutions' conflict of interest review process.
3. The interests of all Investigators on a Sponsored Research project must be disclosed to HSL and Conflicts of Interests managed, reduced, or eliminated before any Sponsored Research funds may be expended.
4. New Investigators who intend to begin work on a project after the project has been approved and funded shall disclose any interests prior to the commencement of their work on any Sponsored Research.
5. If a change in the Investigator's interest related to the research occurs, such change must be reported to the Vice President, Research Administration within thirty (30) days.

B. Process for Reviewing Disclosures and Managing Conflicts

1. The Vice President, Research Administration shall review the information disclosed by each Investigator to determine whether an Investigator has a Material Interest pursuant to the guidelines set forth below. If the Investigator does not have a Material Interest, the Vice President, Research Administration shall process the funding application in accordance with the standard procedures.

Material Interest.

- a) Consulting fees, honoraria (including honoraria from a third party, if the

original source is a materially interested company), gifts, or “in kind” compensation from a Materially Interested Company (or entitlement to the same), whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research, that in the aggregate exceeds \$10,000 in any twelve (12) month period. A Materially Interested Company is a commercial entity with financial or other interests that would reasonably appear to be affected by the conduct or outcome of research.

- b) Equity interests, including stock options, of any amount in a non-publicly traded Materially Interested Company (or entitlement to same).
- c) Equity interests (or entitlement to same) in a publicly-traded Materially Interested Company that in the prior calendar year exceeded \$10,000 in value or five percent (5%) ownership, or is expected to exceed those amounts in the next twelve months.
- d) Royalty income or the right to receive future royalties under a patent license, trademark or copyright, where the research is directly related to the licensed technology or work.
- e) Any non-royalty payments or entitlements to payment in connection with the research that are not directly related to the reasonable costs of the research. This includes any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a Materially Interested Company or from HSL.
- f) Service as an officer, director, or in any other fiduciary role for a Materially Interested Company, whether or not remuneration is received for such service.
- g) Holding an elected or appointed office or position in a branch of government or in a regulatory agency having authority or jurisdiction over providers of health care.
- h) Competing with HSL or an affiliate in the purchase or sale of property or any property right, interest or service.

Exceptions. Material Interests shall not include the following:

- a) Interests of any amount in publicly traded, diversified mutual funds.
- b) Stock in a publicly-traded company that (when valued in reference to current public prices) is less than \$10,000 in value or five percent (5%) ownership interest.

c) Payments to HSL or via HSL to an Investigator that are directly related to reasonable costs incurred in the conduct of Research as specified in the research agreement between the Sponsor and HSL.

d) Salary and other payments for services from HSL

2. In the event that the Vice President, Research Administration determines that an Investigator has a Material Interest, he/she shall refer the matter to the Conflicts Committee who will follow the procedures as outlined in Article III of this Conflict of Interest Policy.

3. If the Sponsored Research shall be funded by the Public Health Service (PHS), the Vice President, Research Administration shall report the existence of any Investigator's Conflict of Interest and assure that the Conflict of Interest is being managed, reduced, or eliminated to the agency before grant funding is received. In the event that an Investigator's interest changes and a Conflict of Interest arises after funding is received, the Vice President, Research Administration shall report its management within thirty (30) days of the Investigator's notification.

4. The Vice President, Research Administration shall consult with the Conflicts Committee for guidance in the identification, management, reduction, or elimination of Conflicts of Interest from time to time as he or she deems necessary. The Vice President, Research Administration shall report regularly, but no less than once per year, to the conflicts Committee about the Conflicts of Interest identified and managed.

5. The Vice President, Research Administration shall keep records of all correspondence.

C. **Guidelines for the Management, Reduction or Elimination of a Conflict of Interest in Research**

Resolution of any Conflicts of Interest in Research shall be based upon the following theories:

1. No research shall be conducted at HSL where payments from a Sponsor are conditioned upon a particular research result or are tied to successful research outcomes. Payment for enrollment in a Clinical Trial shall only be permitted to the extent that such payments:

- a. Are reasonably related to costs incurred, as specified in the research agreement with the Sponsor;
- b. Reflect the fair market value of services performed; and
- c. Are commensurate with the efforts of the individual(s) performing the research.

2. There is a Rebuttable Presumption that, in absence of compelling circumstances, a Materially Interested Individual may not conduct human subjects research. A Materially Interested Individual is a covered individual who holds a significant financial or other interest that would reasonably appear to be affected by the individual's research or other professional activities. When considering a request by a Materially Interested Individual to conduct human subjects research, the Executive Committee should evaluate the nature of the research, the magnitude of

the interest and the degree to which it is related to the research, the extent to which the interest could be directly and substantially affected by the research, and the degree of risk to human subjects involved that is inherent in the research protocol.

3. Potential Management Solutions:

- a. Disclosure of the Material Interest to all research personnel.
- b. Public disclosure of the Material Interest in publications, presentations, and, in the case of human subjects research, in the informed consent document.
- c. Objective review by non-interested colleagues of any manuscripts or other information made available to the public based on the results of the proposed Sponsored Research project.
- d. Revision of the Sponsored Research proposal.
- e. Designation of a co-investigator (peer or superior) who has no Material Interest in the Sponsored Research project.
- f. Disqualification of the Investigator from participating in part or all of the proposed Sponsored Research activities.
- g. Placing interests in escrow for the term of the project and perhaps a period beyond the end of the project to provide for publication and critique of the project.
- h. Reduction or divestiture of the Material Interest held by the Investigator or his or her Family and restrictions on re-investment after the project is completed for an appropriate period to provide for publication and critique of the project.
- i. Severance of other relationships with the Sponsor or competitor that create actual or potential Conflicts of Interest.
- j. Prohibition from conducting the proposed Sponsored Research.