



## Hebrew SeniorLife Administrative Policy and Procedure

<b>Policy Title:</b>	Policy on Financial Conflicts of Interest in Sponsored Awards
<b>Responsible Department:</b>	All
<b>Original Effective Date:</b>	August 24, 2012
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<b>Approved By:</b>	 Kathryn W. I. Tasker Vice President - Research Administration The Hinda and Arthur Marcus Institute of Aging Research   Rachel Lerner General Counsel and Chief Compliance Officer Hebrew SeniorLife, Inc.

- I. **PURPOSE:** This Policy establishes institutional guidelines that are in compliance with federal regulations to promote objectivity in research and implement standards to ensure that the design, conduct, and reporting of research funded by extramural sponsors will not be biased by any conflicting financial interest of an Investigator.<sup>1</sup> Hebrew SeniorLife, Inc. and its programs, subsidiaries and affiliates, including the Marcus Institute for Aging Research (collectively “HSL”) encourages its Investigators to engage in appropriate outside relationships, but Significant Financial Interests (SFI) related to these relationships need to be disclosed, reviewed, and, to the extent they constitute Financial Conflicts of Interest (FCOI), managed in accordance with this Policy. [Note: Capitalized terms not defined within the document are defined in the Definitions section at the end of this Policy.]
- II. **SCOPE:** This Policy applies to all Investigators engaging in Sponsored Research and using HSL resources. As noted throughout the Policy, certain requirements also apply to HSL employees that hold faculty appointments at Harvard Medical School but are not necessarily actively engaged in Sponsored Research. The HSL Policy requirements are in addition to the rules set forth in the Harvard Faculty of Medicine Policy on Conflicts of Interest and Commitments (HMS COI Policy), which apply to HSL personnel who also have appointments to Harvard Medical School (HMS).

In the event an HSL Investigator (herein referred to as ‘Investigator’) is appointed to the HMS faculty and the proposed Research would not be permitted to proceed pursuant to the Research Rules and other prohibitions outlined in the HMS COI Policy, nothing in this Policy alters that conclusion.

In addition to complying with the requirements of this policy, Investigators remain subject to any and all requirements imposed by the HSL Institutional Review Board (IRB) and/or other IRB or oversight committee with jurisdiction over their Research, as well as the HSL Research Compliance Committee (RCC).

<sup>1</sup> The regulations at 42 CFR Part 50 and 45 CFR 94 apply to research and include any activity for which research funding is available from the NIH through a grant or cooperative agreement (e.g. a research grant, career development grant, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award).

### III. POLICY:

#### A. Training

All Investigators and Marcus Institute research personnel are required to complete Conflicts of Interest training prior to engaging in Research (Sponsored or not) at or under the auspices of HSL, and at least every four years. Current training requirements include the completion of the Collaborative Institutional Training Initiative (CITI) online training modules. This policy is distributed annually. Additionally, Investigators will be required to receive training in the event of the following circumstances:

- HSL revises this Policy or related procedures governing FCOI in any manner that affects the requirements applicable to Investigators and research personnel;
- HSL finds that an Investigator or research personnel is not in compliance with this Policy or an imposed management plan.

#### B. Investigator and HMS Appointee Disclosure and Assurances to HSL

##### 1. Project-Specific Disclosure and Assurances Statements

- a) At the time of any specific application for PHS and non-PHS Sponsored Research funding, HSL Grant Managers will obtain completed Disclosure and Assurances Statements from Investigators and HSL Sponsored Award Applicants (herein referred to as 'Applicants'). (*Note: Non-HSL Investigators receiving funding via sub-awards are managed by their home institutions; See Section F*). The HSL Disclosure and Assurances Statements allow Investigators/Applicants to provide financial information and potential conflicts related to the specific project and/or Sponsor prior to the application for funding being submitted to the Sponsor.

All completed Disclosure and Assurances Statements that reveal a potential financial conflict will be forwarded by the Grant Managers to the RCC (and if human subjects research, to the IRB) for review. Recipients of Sponsored Awards who disclose conflicts will be required to complete the HSL Annual Conflict of Interest Disclosure Form, or to provide additional information and documentation required by the RCC (or IRB).

At the time of IRB review, IRB staff will obtain completed Disclosure and Assurances Statements (or the HSL Annual Conflicts of Interest Disclosure Form, as applicable) from Investigators who are not otherwise required to complete this form, and non-HSL Investigators who are engaged in the research and whose conflicts are managed by the HSL IRB rather than their home institutions (i.e. either because there is no funding or because funding is received directly by their home institutions, and those institutions are relying on the HSL IRB for review and approval of the Research). Any Disclosure and Assurances Statements that reveal a potential financial conflict will be forwarded by the IRB staff to the RCC for review (as described in Section C), as well as to the IRB.

##### 2. Annual Disclosure Forms

- a) HSL Annual Conflict of Interest Disclosure Forms are distributed to Marcus Institute Investigators, HSL staff who hold HMS appointments, and any other individuals that

previously disclosed a conflict on a Disclosures and Assurances Statement by email by a representative of the Research Compliance Committee (RCC) ordinarily by December 1<sup>st</sup>; completed forms are due back to the RCC by December 31<sup>st</sup> of each year.

b) All individuals listed in Section 2(a) above must disclose the information and interests required by the HSL Annual Conflict of Interest Disclosure Form, which includes the disclosure of any Reviewable Interests (i.e. Significant Financial Interests (SFIs) belonging to the Investigator or HMS appointee or the Investigator's/HMS appointee's Family, and any Travel, to the extent the Investigator/HMS appointee determines that either relates to his or her Institutional Responsibilities).

c) Travel Disclosures

Marcus Institute Investigators and HMS appointees must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator/HMS appointee and not reimbursed to the Investigator/HMS appointee so that the exact monetary value may not be readily available) equal to or over \$5,000 USD that is related to the Investigator's/HMS appointee's Institutional Responsibilities (defined as "Travel" herein). This disclosure requirement also applies to Travel expenses for the Investigator's/HMS appointee's spouse and dependent children. The following information must be provided in connection with any Travel equal to or over \$5,000 USD:

- The purpose of the trip;
- The identity of the sponsor/organizer of the trip;
- The destination of the trip; and
- The duration of the trip.

Notes:

- All foreign support for sponsored travel must be reported, regardless of amount, must be reported:
- The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:
  - a US federal, state, or local government agency,
  - a US Institution of higher education as defined at 20 U.S.C. 1001(a),
  - a US academic teaching hospital,
  - a US medical center, or
  - a US research institute that is affiliated with an Institution of higher education.

d) Additional Information Requested by HSL

Investigators/Applicants must provide in a timely manner any information related to their disclosed Reviewable Interests that HSL, in its discretion, deems relevant to its review and FCOI assessment.

e) In the event an Investigator/Applicant discovers or acquires a new Reviewable Interest (SFI or Travel) at any time during the year, it must be disclosed on the Annual Form and submitted to the RCC within 30 days from the discovery or acquisition.

### C. Review by HSL<sup>2</sup>

The HSL designated official(s) (i.e. the RCC) will review all financial disclosures by Investigators/Applicants to determine:

1. **Whether there is a Significant Financial Interest (SFI)** as that term is defined in the Definitions section of this Policy.
2. **Whether the SFI is related to Sponsored Research or is otherwise a Reviewable Interest**, meaning (a) the SFI is related to the Investigator's/Applicant's Sponsored Research, or is in an entity whose financial interest could be affected by the research results and outcomes, and/or (b) the SFI otherwise satisfies the definition of Reviewable Interest listed in the Definitions section of this Policy. HSL may involve the relevant Investigator/Applicant in the determination of whether a SFI is related to Sponsored Research or otherwise constitutes a Reviewable Interest.
3. **Whether the Reviewable Interest is a Financial Conflict of Interest (FCOI)**, as that term is defined in the Definitions section of this Policy.
4. **If the RCC determines that a Reviewable Interest constitutes a FCOI**, the RCC will have sixty (60) days from the date the interest was disclosed to:
  - (i) Implement, on at least an interim basis, a management plan that specifies the actions that have been, or will be taken to manage the Financial Conflict of Interest.
  - (ii) Submit a FCOI report to the study sponsor.
5. **New Interests that Arise During an Ongoing Sponsored Research Project.** To the extent a new Reviewable Interest is disclosed to the Designated Official(s) in the course of an ongoing Sponsored Research project (i.e., an Investigator new to participating in the Sponsored Research discloses a Reviewable Interest, or an existing Investigator discloses a new Reviewable Interest), or HSL identifies a Reviewable Interest that was not previously reviewed in a timely manner in accordance with this Policy, the RCC will, within 60 days from the date of the disclosure or identification:
  - (i) determine whether the Reviewable Interest constitutes a Financial Conflict of Interest, and if so,
  - (ii) Implement, on at least an interim basis, a management plan that specifies the actions that have been, or will be taken to manage the Financial Conflict of Interest.
  - (iii) The RCC may, depending on the circumstances of the FCOI, conclude that additional interim measures are necessary with regard to the Investigator's/Applicant's participation in the Research between the date of disclosure or identification and the completion of the RCC's review (including, where warranted, a retrospective review as discussed below).

### D. Retrospective Review, Identification of Bias and Mitigation Reporting

#### 1. Retrospective Review

In the event of failure to meet applicable regulations or policy requirements in the context of a Sponsored Research project, including: failure by the Investigator/Applicant to disclose timely a Reviewable Interest that is determined to constitute a FCOI; HSL's failure to review or manage such a FCOI; or Investigator/Applicant failure to comply with

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<sup>2</sup> HSL applies the same standards for PHS and non-PHS Sponsored Research.

a FCOI management plan; HSL will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's/Applicant's activities and the Sponsored Research project to determine any bias in the design, conduct or reporting of Research during the time period of the noncompliance. HSL will document the retrospective review in accordance with its policies and procedures and applicable regulations.

## **2. Mitigation**

If bias is found during the retrospective review, HSL will notify the relevant sponsor promptly, develop and implement a mitigation plan if applicable, and submit any required mitigation report to the sponsor, which will include at least the elements documented in the retrospective review and a description of the impact of the bias on the Research project and HSL's plan of action or actions taken to eliminate or mitigate the effect of the bias. Any FCOI report submitted to the sponsor with respect to such Research will be updated as necessary in light of the results of the retrospective review.

## **3. Disclosure for PHS-Funded Drug/Device Research**

In any case in which the U.S. Department of Health and Human Services (HHS) determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by HSL, the Investigator will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

## **E. Management of Identified FCOIs**

The RCC will take appropriate action to manage the FCOI in order to reduce the potential for it to compromise the safety of the research participants or the validity of the Sponsored Research. Sponsored Research in which an Investigator/Applicant is found to have a FCOI will not be permitted to proceed until the Investigator/Applicant has agreed to implement an acceptable management plan.

**1. HSL FCOI Management Plans** will specify the actions that have been, and shall be, taken to manage such Financial Conflicts of Interest. Examples of conditions or restrictions that might be imposed to manage a Financial Conflict of Interest include, but are not limited to:

- i. Public disclosure of Financial Conflicts of Interest (e.g., when presenting or publishing the research);
- ii. Disclosure of Financial Conflicts of Interest to research collaborators and research personnel (including to any mentees or students) working on the specific research project, regardless of their location or institutional affiliation;
- iii. For research projects involving human subjects research, disclosure of Financial Conflicts of Interest directly to participants;
- iv. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
- v. Modification of the research plan;
- vi. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

- vii. Reduction or elimination of the financial interest (e.g., sale of an equity interest);  
or
- viii. Severance of relationships that create financial conflicts.

## **2. Management of Disclosed Interests That are Not FCOIs**

HSL reserves the right to impose any requirements it sees fit, for example transparency in publications and presentations, on any disclosed interest, even those that are not prohibited by the HMS COI Policy, do not constitute SFIs and/or do not constitute an FCOI requiring management in accordance with this Policy and/or applicable regulations. Additionally, Investigators/Applicants must comply with any additional requirements and/or conditions imposed by the RCC, the HSL IRB or other oversight body with jurisdiction over their Research.

## **3. Compliance with Management Plans**

Investigators/Applicants have an ongoing obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this Policy. HSL will monitor Investigator/Applicant compliance with an imposed management plan on an ongoing basis until the completion of the Sponsored Research project.

## **4. Communication of Management Plans to Investigator and Others**

Management Plans will be developed by the RCC and forwarded to the appropriate Grant Manager (when there is a Sponsor, PHS or otherwise). The Grant Manager will be responsible for forwarding the Management Plan to the Investigator/Applicant, and any Institution providing a subcontract to HSL for the sponsored research. When there is no Sponsor, the RCC will forward Management Plans directly to the Investigator. For HSL faculty who hold HMS appointments, HSL management plans will be forwarded by the RCC to the HMS Office of Research Integrity, per HMS policy.

## **F. Sub-recipient or Subcontractor**

A sub-recipient or subcontractor relationship is established when funds to support Sponsored Research flow down from or through an awardee Institution to another individual or entity and the sub-recipient or subcontractor will be conducting a substantive portion of the Sponsored Research and is accountable to the awardee institution for programmatic outcomes and compliance matters.

When proposed Sponsored Research at HSL is to be carried out in whole or in part through a sub-recipient or subcontractor, HSL will incorporate as part of a written agreement with the sub-recipient or subcontractor terms that establish: (1) whether this Policy, or that of the sub-recipient/subcontractor's institution will apply to the sub-recipient's/subcontractor's Investigators; (2) the time frames within which the sub-recipient/subcontractor must provide any information necessary to ensure that HSL is able to meet its reporting obligations to the awarding agency, as well as to any other institutional reviewing bodies (e.g. the HSL IRB) prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

Sub-recipient/subcontractor institutions are expected to assess and manage the FCOIs of their Investigators (whether in accordance with this Policy or theirs). As part of the agreement with sub-recipient/subcontractor institutions, HSL requires reporting to HSL Grant Managers all identified FCOIs and management plans of non-HSL Investigators receiving funds via subcontract for Sponsored Research performed at HSL or under the auspices of HSL. Consulting Agreements would not be appropriate for any individuals who would be responsible for the design, conduct and reporting of the research, and would ordinarily be

required to obtain a subcontract – see Grant Managers and VP for Research Administration for more information.

The process of HSL review of the sub-recipient's/subcontractor's FCOI and management plan is as follows:

1. FCOI report and management plan is sent by the sub-awardee institution to the HSL Grant Manager.
2. The HSL Grant Manager forwards the FCOI report and management plan to the HSL Research Compliance Committee (RCC).
3. At the next convened meeting (after receipt of an FCOI report and management plan), the RCC will review the sub-awardee's FCOI report and management plan.
  - a. If the RCC agrees with the sub-awardee institution's review and management plan, it will notify the appropriate HSL Grant Manager.
  - b. If the RCC disagrees with the sub-awardee institution's review and management plan, it will contact the sub-awardee's COI office to discuss the issue.
4. Once the FCOI report and management plan are agreed upon by HSL and the sub-awardee institution, the HSL Grant Manager will notify the HSL Principal Investigator (PI) as well as the individual sub-awardee with the FCOI, that the FCOI report will be submitted to the appropriate awarding agency.
5. The HSL Grant Manager will submit the FCOI report to the appropriate awarding agency and will forward evidence of receipt to the RCC, the HSL PI, the individual sub-awardee with the FCOI, and the sub-awardee's institutional COI office.
6. Upon receipt of the awarding agency's review/determination regarding the FCOI, the HSL Grant Manager will forward this documentation to the RCC, the HSL PI, the individual sub-awardee with the FCOI, and the sub-awardee's institutional COI office.
7. Any follow-up with the awarding agency will follow a similar process and flow of communication as set forth at Items 1-6, above.

#### **G. Reporting FCOIs**

HSL is required to report FCOIs in Sponsored Research to the awarding agencies, as follows:

##### **1. PHS Awards**

- **Content of Report**

For all PHS awards, prior to expenditure of any funds under the award, HSL is required to submit FCOI reports to the PHS awarding agency.

- **Timing of Report**

HSL is responsible for submitting FCOI reports to PHS initially (prior to expenditure of funds), annually during the award period, and within 60 days of any subsequently identified FCOI.

##### **2. Non-PHS Award and Contracting Agencies or Institutions**

HSL will comply with reporting requirements outlined in non-PHS award and contracting agreements.

## H. Non-Compliance and Sanctions

In the event an Investigator/Applicant fails to comply with this policy or a FCOI management plan imposed hereunder, HSL may impose a wide variety of sanctions, including but not limited to:

- Restricting or conditioning the Investigator's/Applicant's ability to apply for awards through HSL;
- Ineligibility of the Investigator/Applicant to apply for IRB approval of Research at HSL, or supervise graduate students in research activities;
- The inclusion in the Investigator's/Applicant's file of a letter from HSL administration calling into question the individual's good standing as an HSL employee;
- Formal admonition;
- Dismissal; or
- Any other restriction, limitation or punishment recommended by the Research Compliance Committee to the HSL Research Board Committee, the Chief Executive Officer, and/or the Director of the Marcus Institute, as appropriate.
- Additionally, for PHS-funded Research, if the failure of an Investigator to comply with this policy or a FCOI management plan appears to have biased the design, conduct or reporting of the Sponsored Research, HSL shall promptly notify the PHS awarding agency of the corrective action taken or to be taken.

**Per PHS regulations**, when an Investigator fails to comply with this Policy or an FCOI management plan, HSL shall within 120 days:

- complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine any bias in the design, conduct or reporting of research;
- document the retrospective review consistent with the regulation; and
- document the Institution's determination as to whether any NIH-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the Institution's Financial Conflict of Interest policy (i.e. this Policy) or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research.

**If bias is found**, HSL shall notify the NIH promptly and submit a mitigation report to the NIH that shall address the following:

- impact of the bias on the research project, and
- HSL's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, HSL shall submit FCOI reports annually, in accordance with the regulation. Depending on the nature of the Financial Conflict of Interest, HSL may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date that the Financial Conflict of Interest is identified and the completion of HSL's independent retrospective review, in accordance with 42 CFR 50.605(a)(3) and 42 CFR 50.605(b)(3).

## I. Public Accessibility

For PHS-funded Research, HSL will ensure public accessibility of information concerning the FCOIs currently held by Senior/Key Personnel subject to this policy. HSL will provide a written response within five (5) business days of receipt by the Vice President for Research



Administration of a complete written request for information regarding any SFI disclosed and still held by a Senior/Key Personnel that has been determined to relate to the PHS-funded research and constitute an FCOI pursuant to this policy. Individuals seeking to make such requests should mail them to the attention of the Vice President for Research Administration, Hebrew SeniorLife, 1200 Centre Street, Roslindale, MA, 02131.

#### J. Record Retention

HSL will retain documentation related to its FCOI review and management process, and all actions required by this Policy, to the extent required by law, which for PHS-funded Research will be at least three years from the date the final expenditures report is submitted to the PHS, and any other applicable Sponsored Award and HSL record retention policies.

- Disclosure and Assurances Statements collected by Grant Managers will be kept with the Grant Management file in accordance with the HSL Record Retention Policy;
- Disclosure and Assurances Statements collected by the IRB will be kept with the IRB file and maintained for 7 years;
- Annual Disclosure Forms will be maintained for 7 years;
- RCC review materials will be maintained for 7 years.

#### IV. DEFINITION OF TERMS:

The following definitions apply specifically in the context of this Policy or the related Disclosure and Assurances Statements or Annual Disclosure Forms:

**Applicant.** The individual who submits applications on their own behalf, or who signs the award application and its associated certifications and assurances that are necessary to fulfill the requirements of the application process. Note: this person is not the Authorized Organizational Representative who is authorized by HSL to act for the Sponsored Award Applicant.

**Business.** Any legal entity organized for profit or non-profit purposes.

- This term includes, but is not limited to: corporations, partnerships, sole proprietorships, associations, organizations, holding companies, and business or real estate trusts.
- A Business is considered to be “non-profit” if it is legally organized for charitable purposes (e.g., 501(c)(3) and equivalents), unless it is principally organized, funded and/or managed by one or more for-profit entities engaged in commercial or research activities of a biomedical nature.
- This term does not include Hebrew SeniorLife or any of its affiliated entities, including the Institute for Aging Research.

**Clinical Research. Any** Research that involves interventions in human subjects or their identifiable specimens or identifiable data and that is not “Nominal Risk Clinical Research”, as determined by the HSL Institutional Review Board and/or Research Compliance Committee.

Nominal Risk Clinical Research includes Clinical Research that is:

- (i) minimal risk (as that term is defined in [45 CFR Part 46.102\(i\)](#)) and
- (ii) falls within one or more of the following categories:
  - a. Use of bodily fluids, secretions or other biospecimens, (excluding such materials obtained for clinical care purposes, which are covered in b. below) that are obtained through non-invasive, routine and established collection procedures from a healthy, non-pregnant individual who is not a member of a vulnerable population (as defined in 45 CFR part 46) and provided that the samples cannot be linked to any individually identifiable person by any Investigator who participates in the Nominal Risk Research;

- b. Use of excess bodily fluids, secretions or other biospecimens, which may be linked by an Investigator who participates in the Nominal Risk Research to an individually identifiable patient, where the samples are otherwise obtained during the course of clinical care by an individual who (1) does not participate in the Nominal Risk Clinical Research; (2) is not under the direction or control of any individual who participates in the Nominal Risk Clinical Research; and (3) is not supervising any individual who participates in the Nominal Clinical Risk Research;
- c. Medical records review, including collection of coded identifiable data, provided, however, that the protocol ensures that, after collection of the data, any Investigators who participate in the Nominal Risk Research cannot link it to an individually identifiable patient;
- d. Non-sensitive survey research on individuals or group characteristics or behavior, provided that if the subjects are considered members of a vulnerable population as defined by 45 CFR Part 46, HSL's Research Compliance Committee and/or IRB may, on a case by case basis, conclude that the research is not Nominal Risk Clinical Research; or
- e. Such other categories of research activities as may from time to time be designated by the Harvard Medical School Faculty of Medicine Standing Committee on Conflicts of Interest and approved by the HSL IRB.

**Clinical Investigation.** *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 the chapter, regarding non-clinical laboratory studies.

**Designated Institutional Official.** The Designated Institutional Officials for HSL are the members of the Research Compliance Committee.

**Entity** means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

**Family.** Spouse or domestic partner, and dependent children.

**Financial Conflict of Interest (FCOI).** A Reviewable Interest that could directly and significantly affect the design, conduct, or reporting of Research. A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to Sponsored Research and could directly and significantly affect the design, conduct or reporting of that Sponsored Research.

**Institutional Responsibilities.** An Investigator's professional responsibilities on behalf of HSL. These may include, for example, activities such as Research, Research consultation, teaching, and professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**Intellectual Property:** Any and all intellectual property rights arising at law or in equity, including trademarks and service marks, or other forms of company, program or product identification, including all of the following: (i) Inventions and all classes or types of patents (including, without limitation, originals, divisions, continuations, continuations-in-part, extensions or reissues), and applications for

these classes or types of patent rights in all countries of the world on a world-wide basis; (ii) works of authorship, Copyrights and other rights in works of authorship; (iii) protocols, tools and guidelines; (iv) Computer Software; (v) Research Data; (vi) Tangible Materials; (vii) domain names and other web based and/or electronic media identifiers; and (viii) know-how, show-how and trade secrets.

**Investigator.** The project director (PD) or principal investigator (PI) and any other person, regardless of title or position (including post-doctoral fellows, graduate students, collaborators, consultants, advisors, mentors, etc.), who is responsible for the design, conduct, or reporting of the Research (pending or awarded, sponsored or non-sponsored). This may include consultants and collaborators.

**PHS.** The Public Health Service, which includes various agencies that fund research (for example, the National Institutes of Health (NIH)). The PHS, through its funding agencies, enforces the Department of Health and Human Services' (DHHS) Rule entitled "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors" and codified at 42 C.F.R. Parts 50 and 94.

**Research.** Systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and Clinical Research, including applied research and product development. The term 'Research' includes any such activity for which research funding is available from a PHS awarding component through an award or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research award, career development award, center award, individual fellowship award, infrastructure award, institutional training award, program project, or research resources award.

**Reviewable Interest.** Any Significant Financial Interest (SFI) belonging to an Investigator or an Investigator's Family, and any Travel, to the extent either relates to the Investigators' Institutional Responsibilities. HSL may in the future determine additional interests to constitute Reviewable Interests.

**Senior/Key Personnel.** The PD or PI and any other person identified as senior/key personnel by HSL in the award application, progress report, or any other report submitted to the PHS by HSL.

**Significant Financial Interest (SFI).**

- (1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse, domestic partner and dependent children) that reasonably appears to be related to the Investigator's Institutional responsibilities:
  - (i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  - (ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

- (iii) Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests. Royalties from and agreements to share in royalties related to intellectual property rights paid to an Investigator (or his/her spouse or dependent children) are covered by the regulation and are subject to the \$5,000 threshold. If the royalties paid to the Investigator (or his/her spouse and dependent children) satisfy the definition of “Significant Financial Interest,” then they must be disclosed. However, if the royalties or agreement to share in royalties relate to intellectual property owned by the employing or appointing applicant or awardee Institution and are licensed or potentially licensed through the applicant or awardee Institution (i.e., they are not personally owned by the Investigator), they are considered remuneration from the Institution and would not be considered a Significant Financial Interest of the Investigator. Royalties received by the Investigator from the Institution would be excluded from the definition of Significant Financial Interest if the Investigator is currently employed or otherwise appointed by the Institution.

Unlicensed intellectual property that does not generate income is also excluded from the definition of Significant Financial Interest. Nonetheless, such interests have the potential to become significant and generate income, at which point they would become subject to the regulation. Disclosure requirements and the documentation needed to verify the value of royalties or agreements to share in royalties should be defined by the Institution’s Financial Conflict of Interest policy and procedures.

- (2) The following needs to be disclosed for **Clinical Investigations** covered by FDA regulations:
- (i) Compensation made to the Investigator in which the value of compensation could be affected by the outcome of the study/research project.
  - (ii) A proprietary interest in the tested product, including, but not limited to, a patent, trademark, copyright or licensing agreement.
  - (iii) 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., an award 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 one year following completion of the study.
- (3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; \*income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

**\*Note:** The regulation refers to exclusions of Institutions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency when disclosing financial

interests. However, these references refer to a U.S. Institution of higher education or a federal, state, or local government agency within the U.S. Therefore, Investigators, including subrecipient Investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).

**Sponsored Award.** This category includes all funding arrangements in which HSL is providing a return benefit to, or agrees to provide a defined deliverable or complete a set of activities for, the sponsor in exchange for the funds, regardless of whether the funding instrument is designated a contract, cooperative agreement, grant, consortium agreement, subcontract, subaward or otherwise. This category includes all sponsored contract or sponsored award funding from federal or nonfederal sources, including foreign entities or international organizations, whether pursuant to a contract or sponsored award. Sponsored awards most often support research activities, but in some cases, may be provided for non-research, demonstration, service or capital projects.

**Sponsored Research.** Research, training and instructional projects involving funds, personnel, certain proprietary materials, or other compensation from outside sources under an agreement that (i) the institution classifies as a sponsored award in accordance with institutional policy or (ii) gives the donor, or an identifiable third party designated by the donor, preferred access to or ownership rights over the Research or the products of the Research, e.g. raw data, scientific developments or intellectual property. Provision of periodic general reports and copies of publications shall not be considered preferred access. Notwithstanding the forgoing, Sponsored Research **shall not** incorporate the following agreements:

1. **Gifts:** Agreements that an institution classifies as a gift in accordance with institutional policy except as specifically set forth below:  
Investigators who hold equity in the donor company are prohibited from receiving gifts that are made solely for the support of the Investigator's Research or that of the Investigator's laboratory.
2. **Certain Material Transfer Agreements:** Agreements that provide for the provision of tangible materials, including equipment ("Material") from an outside source pursuant to a material transfer or other agreement provided each of the following factors are met:
  - a. The proposed protocol does not consist of Research on the Material in question, either directly or indirectly (e.g., the primary usefulness of the Material in the proposed protocol is as a research tool to achieve scientific aims distinct from the donor company's business aims and not as a potential product or integral component of such product);
  - b. The proposed agreement does not grant to the Business any rights to intellectual or tangible property created in or resulting from the use of the Material in the proposed Research, except:
    - i. Options to negotiate (even if such options are exclusive) a license to intellectual property made in, and derived directly from the use of the Material in, the Research; or
    - ii. A non-exclusive license for research purposes to intellectual property made in, and derived directly from the use of the Material in, the Research.

## V. APPLICABLE POLICIES AND/OR REGULATIONS

- [http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)
- [http://www.nsf.gov/pubs/policydocs/pappguide/nsf10\\_1/aag\\_4.jsp](http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_4.jsp)
- <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=54&showFR=1>
- <https://hms.harvard.edu/about-hms/integrity-academic-medicine/faculty-policies-integrity-science/faculty-medicine-policy>
- <http://policy.uconn.edu/2011/05/24/financial-conflicts-of-interest-in-research/>
- Marcus Institute Record Retention Policy
- HSL Record Retention Policy