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**Responsible Officer: Co-Founders**

**Adoption Date: 11/25/2020**

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## **WORK LIFE HELP FINANCIAL CONFLICT OF INTEREST POLICY**

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### **I. Policy Statement**

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Work Life Help (WLH) is committed to the principle of free, open and objective inquiry in the conduct of its research and service missions. In the fulfillment of these missions, it is natural that opportunities arise for WLH personnel to develop relationships with external entities and to explore commercial activities. WLH encourages such endeavors as they enhance personal competency, enrich our trainings, and benefit the company overall.

These interactions, however, create the potential for Financial Conflicts of Interest where an individual's financial or personal considerations may affect or appear to affect their WLH activities related to externally sponsored programs. The existence of a real or apparent financial conflict does not necessarily mean that the activity at issue must be avoided or discontinued.

It is through disclosure of Significant Financial Interests (as defined below) to WLH that such activities may be reviewed and, if warranted, managed. This policy establishes the process of disclosure, review and management.

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### **II. Reason for Policy/Purpose**

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This document sets forth WLH's policy on the disclosure, review, management and resolution of Financial Conflicts of Interest and pertains to Principal Investigators and their designated Senior/Key Personnel.

This policy is required by, and is intended to establish compliance with, the US Public Health Service (PHS), National Institutes of Health Regulation (42 CFR Part 50, Subpart F) "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." It is also intended to establish compliance with the National Science Foundation (NSF) and other granting agencies' policies on Conflict of Interest.

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### **III. Applicability**

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This policy applies to all persons, including WLH co-founders, WLH associates, WLH employees, and collaborators and consultants, who are involved with externally sponsored programs at WLH **and** meet the definition of "Investigator" or "Senior/Key Personnel" as defined below.

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## IV. Definitions

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1. **Conflict of Interest.** The situation in which personal considerations have the potential to compromise or bias professional judgment and objectivity.
2. **Financial Interest.** Anything of monetary value, whether or not the value is readily ascertainable.
3. **Financial Conflict of Interest (FCOI):** A Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research.
4. **Investigator.** The Project Director or Principal Investigator, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by PHS, or proposed for such funding, which may include collaborators or consultants.
5. **Company Official.** The Company Official in charge of WLH's FCOI Policy and process are the Co-Founders.
6. **Investigator's Company Responsibilities.** An Investigator's professional responsibilities on behalf of and as defined by WLH, including but not limited to, activities such as research, research consultation, and professional practice.
7. **Management Plans.** Actions taken by the company to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.
8. **Senior/Key Personnel.** The Project Director/Principal Investigator, Co-Principal Investigator, Co-Investigator, and any other persons listed on WHL's grant applications, progress reports, or any other report of a proposed or funded research project.
9. **Significant Financial Interest (SFI).** A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Company Responsibilities:

With regard to any publicly traded entity, a SFI 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 a fair market value;

With regard to any non-publicly traded entity, a SFI 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

Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their company responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Disclosure information must include the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The Company Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the research.

**SFI does not include** the following types of financial interest: salary, royalties, or other remuneration paid by the company to the Investigator if the Investigator is currently employed or otherwise appointed by the company, including intellectual property rights assigned to the company and agreements to share in royalties related to such rights; any ownership interest in the company held by the Investigator, if the company 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, 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

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## **V. Policy Procedure**

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### **1. Required and Annual Disclosure to WLH**

- 1.1 Investigators must submit disclosures annually or at the time of a funding proposal submission. When Investigators submit funding proposals, they

must list all other Investigators and Senior/Key Personnel on their project and ensure that required disclosures have been submitted to WLH from all listed persons.

- 1.2 When a new Investigator is added to a funded project, the new Investigator must complete a FCOI Disclosure Form and submit it to WLH. If a FCOI is indicated on the FCOI Disclosure Form, the FCOI Details Disclosure Form must also be completed and submitted.
- 1.3 Additionally, in September of each year, Investigators and Senior/Key Personnel are required to complete a FCOI Disclosure Form and submit it to WLH. If a FCOI is indicated on the FCOI Disclosure Form, the FCOI Details Disclosure Form must also be completed and submitted.

## **2. Required Submission of Revised Forms to WLH**

If there is a material change (an acquisition of a SFI) to the information provided on the FCOI Disclosure Form and/or the FCOI Details Disclosure Form, a new form must be submitted to WLH within 30 days of that change.

## **3. Management Plans**

- 3.1 Upon reviewing an Investigator's FCOI Details Disclosure Form, the Co-Founders will decide whether a Management Plan is needed. Should management of a potential or actual FCOI be required, the Co-Founders will work with the Investigator to draft a Management Plan and approve the Management Plan. The CO-Founders will also monitor Investigator compliance with management plans until completion of the project.
- 3.2 These written plans will manage, reduce, or eliminate the FCOI(s). Such plans may also address the use of WLH facilities, involvement of personnel and overlap between private and WLH activities. Such plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, and protect the sensitivity of disclosed information.
- 3.3 Management Plans may include a single element or several elements such as:
  - Monitoring of the sponsored program by independent researchers or reviewers, or their designee
  - Modifications to the research or program plan
  - Appointment of an oversight panel or person to review research/scholarship
  - Limitations on the employees' involvement in personnel decisions on behalf of WLH

- Divestiture of SFIs and/or
- Other arrangements that manage, reduce, or eliminate a potential FCOI

#### **4. Retrospective Review**

WLH is required by federal regulation to conduct a retrospective review in those cases of non-compliance with the federal regulations. This must be done within 120 days of WLH's determination of non-compliance. WLH will notify the awarding agency promptly and submit a report to the awarding agency in cases where bias is found. The report will address the impact of the bias on a research project and the management plans taken by or to be taken by WLH to eliminate or mitigate the bias.

#### **5. Monitoring**

Co-Founders may conduct random and for-cause monitoring of FCOI Management Plans.

#### **6. Non-Compliance**

6.1 Failure to comply with this policy or to follow an agreed upon Management Plan will be reported to the funding agency.

6.2 Failure to comply with this policy or to follow an agreed upon Management Plan will result in a Retrospective Review (described above) and may result in the following actions:

- Termination of Investigator's external funding project(s) at WLH.
- Termination of Investigator's ability to submit proposals for external funding through WLH.

6.3 Failure to comply with this policy may subject a WLH employee to other disciplinary processes within WLH.

6.4 Violations of this policy include, but are not limited to:

- Failure to comply with the disclosure process (by refusal to respond; by deliberately responding with incomplete, inaccurate, or misleading information, or otherwise);
- Failure to remedy FCOI; and
- Failure to comply with a prescribed Management Plan.

6.5 In any case in which the Department of Health and Human Services determines that a PHS-funded research 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 an FCOI that was not managed or reported by the Institution as required by the regulation,

the Institution shall require the Investigator involved to:

- Disclose the FCOI in each public presentation of the results of the research; and
- To request an addendum to previously published presentations.

## **7. Training Requirement**

Each Investigator and Senior/Key Personnel must complete Conflict of Interest training prior to engaging in research related to any PHS-funded grant or contract and at least every four years. In addition, training must be completed immediately under the following circumstances:

- WLH FCOI policies change in a manner that affects Investigator requirements.
- An Investigator is new to WLH.
- WLH finds an Investigator noncompliant with the institutional policy or his/her Management Plan.

At the time of training, Investigator and Senior/Key Personnel shall provide acknowledgement that they have read and understand this policy.

WLH will make available tools and training opportunities.

## **8. Public Disclosure**

8.1 WLH will make this policy available to the general public by posting it on the WLH website.

8.2 WLH is required by federal regulation to make certain information about FCOIs related to PHS-funded research by Senior/Key Personnel available to the public. WLH will do so by responding to any request for information about these specifically covered FCOIs within five business days. Information that must be made available is:

- Investigator's name
- Investigator's title and role with respect to a research project
- Name of the entity in which the SFI is held
- Nature of the SFI
- Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,000; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through references of public prices or other reasonable measures of fair market value).

## 9. Additional Responsibilities

- 9.1 WLH maintains this written FCOI Policy and will implement a process to identify and manage, reduce or eliminate these conflicts.
- 9.2 WLH shall, for any federal research funding from the PHS or any other federal funding agency that imposes FCOI requirements:
- Include in the subaward agreement terms that establish whether this policy or that of the subrecipient will apply to the subrecipient's Investigators and provide FCOI reports regarding subrecipient Investigators to the awarding federal funding agency;
  - Maintain the records of, and related to, FCOI disclosures;
  - Report conflicting SFI to the awarding component of the funding agency;
  - Inform the National Science Foundation Office of the General Counsel if it is unable to satisfactorily manage a FCOI related to a project funded by NSF;
  - Report to the NIH the existence of any conflicting Financial Interests and assure that the interest has been managed, reduced, or eliminated in accordance with NIH regulations:
    - Prior to the expenditure of funds;
    - Within 60 days of identification for an Investigator who is newly participating in the project;
    - Within 60 days for new, or newly identified, FCOIs for existing Investigators;
    - At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and
    - Following a retrospective review to update a previously submitted report if appropriate.
  - Maintain records related to Investigator disclosures of Financial Interests and the institution's review of, or response to, such disclosures and all actions under this policy or retrospective review for at least three years from the date of the final expenditure report.

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## VI. Links To Related Information

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1. [NIH](#)
2. [NSF](#)

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## VII. Contacts

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If you have any questions on the policy or procedure for FCOI you may:

Send an email to [worklifehelpconsulting@gmail.com](mailto:worklifehelpconsulting@gmail.com)

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## VIII. History/Revision Dates

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**Origination Date:** November, 25, 2020

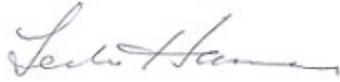
**Last Amended Date:**

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## IX. Policy Adoption

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Approved



Co-Founder

Date 11/25/2020

Approved



Co-Founder

Date 11/25/2020