

 <b>THE HOUSE INSTITUTE</b> FOUNDATION <small>FORMERLY HOUSE EAR INSTITUTE</small>	Effective Date: 9.1.2021	Policy #: 100-3
<b>Title:</b> Conflict of Interest	Revision Date: 1.1.2023	HIF Program: Research

**BACKGROUND:**

The HIF Conflict of Interest Policy protects the objectivity and integrity of the work of HIF leadership, faculty and research program staff. The policy is designed to ensure that Personnel identify, disclose, and works with HIF to appropriately manage or eliminate situations in which their interests might otherwise compromise or appear to compromise their objectivity as researchers or administrators. This conflict of interest policy helps both to safeguard the work and reputations of Personnel and to ensure HIF compliance with federal and other regulatory requirements relating to conflict of interest.

Conflict of interest (real, potential or perceived) arises when an individual in a position of trust has competing professional, financial or personal interests. Such competing interests may influence his or her professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A conflict of interest may exist even if no unethical or improper acts result from the conflict. Personnel should identify and work with HIF to manage conflicts of interest to maintain the public confidence and trust to maintain the independence and integrity of HIF.

**POLICY:**

All Personnel will attend training and will disclose *significant* financial conflicts of interest if participating in HIF funded research, or in accordance with sponsored (e.g., NIH, FDA) research policies or agreements. Disclosures are required annually, upon receipt of HIF or sponsored research funds, anytime a new *significant* conflict of interest arises, and annually for duration of funding and for two (2) years thereafter.

**DEFINITIONS:**

“Family Member” which includes at a minimum spouse, partner, domestic partner and dependent children.

“Personnel” HIF faculty, investigators, research staff and leadership

“Financial conflict of interest” means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

A financial interest is anything of monetary value, related to a Personnel’s responsibilities, whether or not the value is readily ascertainable, in any of these categories:

- “Remuneration” or compensation (e.g., salary, consulting fees, honoraria) from a public or private company
- “Equity” (e.g., stock, stock options or other ownership interest) in a public or private company
- intellectual property rights (e.g., patents, copyrights), and any royalties and licensing income from such rights
- a position in an outside entity that gives rise to a fiduciary duty, such as director, officer, partner, trustee, employee or any position of management
- and, for investigators with Public Health Service (e.g., NIH, FDA) funding, also any reimbursed or sponsored travel.
- Sunshine acts reportable information may also be a financial interest

A financial interest is deemed to be “*significant*” if:

1. the aggregate value of Remuneration and Equity Interests in lieu of payment received from a **US or foreign publicly traded** entity during the 12-month period preceding the disclosure exceeds \$5,000; or
2. the aggregate value of Equity Interests in a **US or foreign publicly traded** entity exceeds \$5,000 and the entity is sponsoring any of the Investigator’s research; or
3. the aggregate value of Equity Interests in a **US or foreign publicly traded** entity exceeds \$10,000 and the entity’s business, or any portion thereof, reasonably appears to be related to any of the Investigator’s institutional responsibilities; or
4. the aggregate value of Remuneration received from a **US or foreign non-publicly traded entity or non-profit institution** received during the 12-month period preceding the disclosure exceeds \$5,000; or
5. any Equity Interest is held in a **US or foreign non-publicly traded** entity; or
6. the aggregate value of Remuneration received from a **foreign governmental organization** during the 12-month period preceding the disclosure exceeds \$5,000; or
7. the aggregate value of income related to intellectual property rights and interests paid by an entity other than HIF exceeds \$5,000.

**PROCEDURE:**

**Training:** All Personnel will attend conflict of interest training every year.

**Reporting:**

1. Annually

2. Within 30 days of discovering or acquiring a new *significant* financial conflict of interest related to their research responsibilities, Personnel will submit a revised Form to the HIF Director of Research Administration.
3. Personnel should inform the HIF Director of Research Administration of any other potential or actual conflict of interest that is not financial as they may arise.

**Elements included in Significant Financial Interest Disclosure Form:**

- Project Title, HIF faculty or research program staff name, role on research, sponsor (e.g., HIF funds, NIH, FDA)
- Annual Disclosure or Adhoc
- Questions:
  - Have you or a family member received income or payment for services in the last 12 months or own equity interests in any publicly traded entity that might reasonably be related to your institutional responsibilities and which exceeds \$5,000 when aggregated? Note: This does not include interests in mutual funds and retirement funds in which you do not directly control investment decisions.
  - Have you or a family member received income or payment for services in the past 12 months from any non-publicly traded entity that might reasonably be related to your institutional responsibilities and which exceeds \$5,000 when aggregated? Note: This does not include payment or income from seminars, lectures, or teaching engagements sponsored by a government agency, a US institution of higher education or affiliated research institute, an academic teaching hospital, or a medical center.
  - Do you or a family member currently own any equity interest in any non-publicly traded entity that might reasonably be related to your institutional responsibilities?
  - Have you or a family member received any payments in the past 12 months for any intellectual property rights and interests (e.g., patents or copyrights assigned or licensed to a party other than HIF) that might reasonably be related to your institutional responsibilities and which exceeds \$5,000?
- Signature and date

**Consequences:** Consequences of non-compliance with this Policy including reporting and mitigating conflicts could include loss of funding, administrative sanctions or up to and including termination.

**REFERENCES:**

- [NIH Financial Conflict of Interest Policy](#)
- [42 CFR 50 Subpart F – Promoting Objectivity in Research](#)

**APPENDIX:**

Appendix A: Financial Conflict of Interest Disclosure Form

Appendix B: COI Management Plan

## Appendix A: Financial Conflicts of Interest Form



### Financial Conflict of Interest Form

**Project Title:**

**HIF Faculty or Research Staff Name:**

**Role:**

**Sponsor:**

1. Annual Disclosure  or Adhoc ?
  
2. Have you or a family member received income or payment for services in the last 12 months or own equity interests in any publicly traded entity that might reasonably be related to your institutional responsibilities and which exceeds \$5,000 when aggregated?  
Note: This does not include interests in mutual funds in which you do not directly control investment decisions.  
YES  NO
  
3. Have you or a family member received income or payment for services in the past 12 months from any non-publicly traded entity that might reasonably be related to your institutional responsibilities and which exceeds \$5,000 when aggregated?  
Note: This does not include payment or income from seminars, lectures, or teaching engagements sponsored by a government agency, a US institution of higher education or affiliated research institute, an academic teaching hospital, or a medical center.  
YES  NO
  
4. Do you or a family member currently own any equity interest in any non-publicly traded entity that might reasonably be related to your institutional responsibilities?  
YES  NO
  
5. Have you or a family member received any payments in the past 12 months for any intellectual property rights and interests (e.g., patents or copyrights assigned or licensed to a party other than HIF) that might reasonably be related to your institutional responsibilities and which exceeds \$5,000?  
YES  NO

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Signature

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Date

## Appendix B: COI Management Plan

The Program Committee of the Board of Directors will review each application for disclosure of conflicts of interest;

1. If the Personnel indicates on the COI disclosure that a conflict may exist, the Committee will determine whether the disclosed conflict of interest is likely to affect or appear to affect the design, conduct, or reporting of the research;
2. The Committee review should focus on those aspects of the conflicts of interest that may reasonably affect human participant protection and research objectivity, and the steps taken should be context-based and commensurate with the risks;
3. In determining the appropriate action, the Committee may take into consideration information presented by the Personnel such as:
  - a. The nature of the research,
  - b. The magnitude of the interest or the degree to which the conflict is related to the research,
  - c. The extent to which the interest could affect the research,
  - d. The fact that a specific individual is unique in his/her clinical or scientific qualifications to conduct the research,
  - e. The degree of risk to the human participants and research objectivity involved in the research that is inherent in the research, and/or
  - f. The management plan for the conflict of Interest already developed by the Personnel.
4. The Committee may approve the research and may require a management plan, which may include changes at the Personnel's expense, to eliminate or to mitigate the conflict. Required actions may include, but are not limited to the following:
  - a. Divestiture or termination of relevant economic interests,
  - b. Mandating Personnel recusal from a study,
  - c. Modifying or limiting the participation of the Personnel in all or in a portion of the research,
  - d. In cases involving equity, by imposing a ban on insider trading or requesting that the transfer of securities to an independent financial manager or blind trust, or limiting the timing of sales or distributions,
  - e. Monitoring research, i.e. independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data),
  - f. Independent clinical review of appropriateness of clinical care given to research participants, if applicable,
  - g. Monitoring the consent process and/or
  - h. Disclosure of the conflict to institutional committees, research participants, journals, and the data safety monitoring boards;
5. The Committee has the final authority to determine whether a conflict of interest has been eliminated or managed appropriately;

6. Any conflict of interest management plan will be documented in the research project file. Any discussion at the Committee meeting regarding the conflict of interest and the management plan will be documented in the Committee meeting minutes;
7. After a review by the Committee and input by the appropriate institutional official, if applicable, the Committee may reject research that involves a conflict of interest that cannot be appropriately managed.
8. The following activities/situations are presumptively prohibited as they create, in almost all circumstances, conflicts of interest that cannot be effectively managed.
  - Research at HIF is sponsored by a privately held outside entity, including a start-up, in which the Personnel or their family members has/have a Significant Financial Interest or otherwise holds a fiduciary role or executive-level position.
  - Research at HIF is sponsored by a privately held Outside Entity, including a start-up, in which the Personnel's current research assistants, trainees or others over which the Personnel have supervisory authority have a Significant Financial Interest or otherwise hold a Fiduciary Role or executive-level position.

The Committee may make exceptions in compelling circumstances, which will depend in each case upon the nature of the research, the status of the outside entity, the nature of the conflict of interest, how closely the conflict of interest is related to the proposed research, and the degree to which the interest may be affected by the proposed research. The Committee may, within its discretion, consult other offices as necessary and appropriate in its evaluation of the compelling circumstances or it may refer a case to HIF leadership/Board of Directors for adjudication.

Personnel wishing to engage in a presumptively prohibited activity must present a written request for exception to the Board. This request must include a list of compelling circumstances, and a proposal on how the conflict of interest could be effectively managed.

### **Appeals**

Should a Personnel wish to appeal a decision made by the Committee, the Personnel may present the appeal within 60 days of the Committee's decision in writing to the Board. The Board at their discretion will consider the case with input from others as necessary. The Personnel may be asked to present the appeal in person to the Board. The Board will convey their decision in writing to the Personnel. The decision of the Board shall be final.