

Human Health Exposure Analysis Resource (HHEAR) Conflict of Interest Policy

1. Introduction and Purpose

In 2019, the National Institute of Environmental Health Sciences (NIEHS) established the Human Health Exposure Analysis Resource (HHEAR) to provide the research community access to laboratory and statistical analyses to add or expand the analysis of environmental exposures in their research.

Central to the success of this goal is assuring the public trust in the scientific process and in the credibility and rigor of the research undertaken by HHEAR. A conflict of interest (COI), which exists when professional judgement may be influenced by a secondary interest, has the potential to undermine that trust.

The purpose of this COI policy is to identify and manage conflicting relationships, with a goal to preserve transparency, independent decision making, and the integrity of HHEAR research. As members of a scientific and intellectual community, the HHEAR program recognizes that objectivity about one's own situation and credibility with external observers requires an evaluation external to oneself. *Moreover, the fact that a HHEAR member has a conflict does not imply that the conflict is unethical or impermissible; it means simply that he or she must disclose.* The relation of the conflict to the individual's institutional responsibilities must be disclosed and in some cases managed, because conflicts — real, potential or perceived — may impair performance of HHEAR's mission as well as jeopardize public trust and support.

This policy describes the HHEAR program's approach and process for identifying, reviewing, and managing conflicts of interest to help ensure the integrity of HHEAR endeavors. Through this policy, the HHEAR Program seeks to identify, disclose, and manage conflicts of interest to foster trust and transparency in the HHEAR review process and mission.

2. Scope and Definitions

2.1 Responsible Person

This policy applies to members of the HHEAR Program and other individuals external to the HHEAR Program, who are *participating in HHEAR application review activities in a decision making role, where that role involves influence on the expenditures of HHEAR resources.* Henceforth, these individuals will be referred to as **Responsible Person(s)** (RP).

Members of the HHEAR Program include individuals from each HHEAR component (Coordinating Center, Data Center and Lab Hubs), and funding institutions (NIEHS, NCI, NHLBI and ECHO). Individuals external to the HHEAR Program include those serving on the HHEAR Scientific Expert Panel (SEP). Not every member of the HHEAR program is a RP.

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2.2 Conflict of Interest

Broadly, this policy considers COI that arise from **relationships**, between an RP and an institution, Principal Investigator (PI), co-PI, or other key staff on an application requesting HHEAR services, such that the relationship has the potential to compromise or bias professional judgement of the RP. **Relationships** may be institutional, professional and personal affiliations, associations or intellectual collaborations. The policy covers actual, potential and perceived COI. See Appendix A for examples of COI.

There are two types of HHEAR applications subject to this policy: 1) applications requesting HHEAR laboratory or data services for analysis of biological and/or environmental samples and associated data; and 2) applications requesting Pilot and Feasibility (P&F) Program funding. In addition, ECHO-wide concept proposals, ECHO-wide analysis proposals and ECHO OIF applications are subject to this policy. Henceforth these HHEAR and ECHO applications/proposals will be referred to as **Application(s)**.

The requirements of this policy will not replace any institutionally required COI reporting requirements.

2.3 Term of Disclosure

A potential conflict of interest should be reported if it occurs in the period 3 years before to and/or 3 years after the RP is asked to participate in an Application review activity.

2.4 Obligations and Requirements

Every RP has an obligation to read and sign the COI Policy signature page annually, to indicate their agreement to declare any relationship that may be a COI and to ensure that any conflict arising from the relationship is documented and managed appropriately.

Failure to comply with this policy could result in a discussion with NIH Program Officials regarding the consequences of misconduct.

3. Procedures for Reporting a COI

When a RP is asked to participate in the review of an Application, it will be incumbent on the RP to consider any relationship that may be a conflict of interest and to make a verbal report to HHEAR Executive Committee (EC). The procedures for making a verbal report of a COI to the EC are as follows:

- 1) The HHEAR Coordinating Center (CC) will send an email notification inviting the RP to participate in an Application review activity.
- 2) Upon receipt of the notification, the RP will review the Application to identify any relationship that may be a COI.

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- 3) If the RP identifies a relationship that may be a COI, he/she will notify the CC by e-mail within 2 days.
- 4) The CC will invite the RP to the next scheduled EC meeting. The RP may not participate in an Application review activity until after he/she has reported on the relationship to the EC.
- 5) The RP will make a verbal report of the COI to the EC. The content of the report should include the project number and title of the Application. The remainder of the report will be dictated by the RP's definition of the relationship as a COI and proposed plan for management of the COI.

Circumstance # 1: If the RP has determined the relationship is a COI, proposes to manage the COI by recusing him or herself from all Application review activities and recuses his/her institution from all HHEAR services, he/she will declare this. In this circumstance, the RP is not required to report on the nature of the relationship.

All Other Circumstances: In **all** other circumstances, the RP must fully disclose the nature of the relationship. Other circumstances may include, but are not limited to the following:

- The RP is not sure if the relationship is a COI;
 - The RP or a member of the RP's institution is needed to evaluate the Application;
 - The RP's institution is the only institution that can provide the requested services; and,
 - The RP's institution is not the only institution that can provide the requested services, but the RP is interested in continuing a collaboration with the applicant and in providing the requested services.
- 6) The EC will evaluate all verbal disclosures and designate the COI and a management strategy (see Section 4 below).
 - 7) The CC will document the RP's verbal report, and the EC's decision in the EC meeting minutes.

4. Procedures for EC Evaluation of Disclosures/Reports

The EC will follow the guidance in this policy to discuss and evaluate all verbal reports of relationships that may be a COI and designate the COI and a management strategy.

4.1 Criteria for Evaluating Relationships

The criteria for evaluating verbal reports of relationships include the following:

- Strength of RP's relationship with the individual;

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- Strength of RP's relationship with the institution;
- Role of individual on Application proposal;
- Risk the relationship poses to the integrity of HHEAR research, either in appearance or in fact;
- Existence of compelling circumstances (see Section 4.3 below); and
- The extent to which research objectivity and integrity can be assured through COI management strategies.

4.2 Designation of a COI and Management Strategy

The EC will assign one of the following designations and management strategies to each verbal disclosure:

- 1) **No COI exists.** No management is needed.
- 2) **A COI exists** and can be managed as follows:
 - a. The RP will not participate in any Application review activities.
 - b. The RP's institution will not provide any of the requested HHEAR services.

Application review activities include:

- Discussions or deliberations;
 - Discussions to influence outcome of deliberations;
 - Making motions;
 - Voting; and
 - Prioritizing.
- 3) **A COI with compelling circumstances exists.** The EC will designate a COI with compelling circumstances if they conclude that compelling circumstances override the presumption of COI and they can implement an effective management and monitoring plan to protect the integrity of HHEAR research. A COI with compelling circumstances will be managed as follows:
 - a. The individual will be recused from all review activities for the Application and the individual's institution provides services; or,
 - b. The individual will participate in discussions or deliberations to evaluate the Application, but will not participate in discussions to influence the outcome of deliberations, making motions, voting, or prioritizing, and the individual's institution does not provide services; or,
 - c. The individual will participate in discussions or deliberations to evaluate the Application, but will not participate in discussions to influence the outcome of deliberations, making motions, voting, or prioritizing, and the individual's institution provides services; and,

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- d. The EC will monitor the application review process and post-approval services, and as well as future COI between the RP and the same individual or institution. The EC may choose to re-visit or revise the management strategy if it influences the perception of HHEAR's impartiality as a resource. If there is a dispute over the COI designation and/or management strategy, the EC will discuss with NIH Program Officials.

4.3 Compelling Circumstances

Compelling circumstances derive from widely accepted national standards and include unique circumstances such as special facilities or equipment, and/or special qualifications and/or specialized expertise to conduct the intended research related activities. There may be compelling circumstances where, despite a conflict, the interests of the HHEAR Program are best served by allowing the individual with a conflict to recuse him or herself from the Application review process, but remain involved in providing laboratory or data analysis services. Other compelling circumstances may exist in which the interests of the HHEAR Program are best served by allowing an individual to remain involved in the Application review process but to recuse him or herself from any decision making or voting processes.

Examples of compelling circumstance are provided in Appendix B.

5. Conflicting Policies

In a situation where the HHEAR COI Policy is in conflict with the ECHO COI Policy, the policy for the Program in which the Application originates will take precedence.

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Document Control

Revision History

Revision Number	Revision Date	Summary of Changes

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Appendix A. Examples of COIs

- HHEAR RP is mentee or mentor with an individual on an Application.
- HHEAR RP is an investigator or Co-PI on an Application.
- HHEAR RP has a collaboration (e.g. letters of support, co-investigator, or co-authorship, etc.) on **any** research with an individual on an Application.
- HHEAR RP has a relationship (paid or unpaid) with the same institution as an individual on an Application.
- HHEAR RP has funding on any research grants or projects with the same institution as an individual on an Application.
- HHEAR RP has a relationship with an individual or institution on an Application that could alter objectivity or contribute to bias or perception of bias in the HHEAR Application review process.

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Appendix B. Example of COIs with Compelling Circumstances

- The HHEAR RP has collaborated with the investigator on the parent study and wishes to continue the collaboration for the proposed project by providing services. In this situation, the EC may decide the RP should be recused from all proposal review activities and allow the RP's institution to provide services.
- The HHEAR RP has collaborated with the investigator on other research not related to the Application. The RP's expertise needed to evaluate the Application and he/she cannot be replaced. In this situation, the EC may decide that the RP will participate in the Application review process but should be recused from any decision making or voting processes and the institution will not provide services.
- The HHEAR RP is a co-investigator on the Application, and the RP's institution is the HHEAR component that can provide the requested services. In this situation, the EC may decide that RP will be recused from all Application review activities and the institution will provide the requested services.

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HHEAR COI Signature Page

Please record your name, indicate your affiliation with HHEAR and sign and date this signature page. Your signature indicates your agreement to declare any relationship that may be a COI and to ensure that any conflict arising from the relationship is documented and managed appropriately.

Name: _____

HHEAR Affiliation:

- National Institute of Environmental Health Sciences
- National Cancer Institute
- National Heart, Lung, and Blood Institute
- Environmental Influences on Child Health Outcomes
- HHEAR Data Center
- HHEAR Coordinating Center
- HHEAR Scientific Expert Panel
- Duke HHEAR Environmental Analysis Laboratory
- Minnesota HHEAR Targeted Analysis Laboratory
- Mount Sinai HHEAR Targeted Analysis Laboratory
- Mount Sinai HHEAR Untargeted Analysis Laboratory
- North Carolina HHEAR Untargeted Analysis Laboratory
- Wadsworth HHEAR Targeted Analysis Laboratory
- Other, please specify:

Signature: _____ Date: _____