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Subject: Financial Conflict of Interest
Division: Grants Management
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Financial Conflict of Interest Policy and Procedures

Purpose of Policy

The purpose of the Hearing Loss Association of America (HLAA) Financial Conflict of Interest (FCOI) Policy is to comply with Federal Regulation 42 CFR Part 50 Subpart F and to protect HLAA, its employees, its clients, and its conference participants from potential or actual risks associated with any financial conflicts of interest related to PHS-funded conference conducted by investigators.

Purpose of Federal Regulation 42 CFR Part 50 Subpart F

The purpose of this regulation is to promote objectivity in conference by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of conference funded under PHS grants and cooperative agreements will be biased by any conflicting financial interest of an investigator.

Application of Policy

This policy applies to all investigators (including subrecipient investigators) and applicable staff who are planning to participate in or are participating in Public Health Service (PHS) funded conference. Compliance with this policy is a condition of employment and/or relationship with HLAA.

All covered persons (investigators and applicable staff) are hereinafter referred to as “investigator.”

An “investigator” is defined as 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 conference funded by PHS (e.g., National Institutes of Health (NIH)), or proposed for such funding, including persons who are subgrantees, contractors, consortium participants, collaborators or consultants. Note, that these responsibilities are not limited to the project director, principal investigator, or key personnel but rather, apply to all individuals who are responsible for the design, conduct, or reporting of conference. HLAA will consider the role, rather than the title, of those individuals involved in conference and the degree of independence with which they work.

Training Requirements

Investigators are required to complete FCOI training:

1. Prior to engaging in conference related to any PHS-funded grant,
2. At least every four years, and
3. Immediately, if:
 - a. HLAA revises its FCOI Policy and procedures in any manner that affects investigator requirements;
 - b. An investigator is new to HLAA; and/or
 - c. An investigator is not in compliance with the policy or management plan.

Please see FCOI required training at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Financial Conflict of Interest (FCOI)

An FCOI exists when HLAA, through its FCOI officer, reasonably determines that an investigator (including their spouse and dependent children) has a Significant Financial Interest (SFI) related to a NIH-funded conference that could directly and significantly affect the design, conduct, or reporting of NIH-funded conference.

Significant Financial Interest (SFI)

Investigators are required to disclose to HLAA a listing of SFIs (and those of his or her spouse and dependent children) that: 1) would reasonably appear to be affected by the conference for which funding is sought, and 2) includes those entities whose financial interests would reasonably appear to be affected by the conference.

PHS FCOI regulation defines a "Significant Financial Interest" as follows:

1. 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 institutional responsibilities:
 - a. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the 12 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 etc.); 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; 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 12 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
 - b. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. 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 institutional 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 as defined by 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. HLAA's FCOI Policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with HLAA's FCOI Policy, the FCOI officer 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 regarding the PHS-funded conference.

3. The term *significant financial interest* does not include the following types of financial interests:
 - a. salary, royalties, or other remuneration paid by HLAA to the investigator, if the investigator is currently employed or otherwise appointed by HLAA;
 - b. any ownership interests in HLAA, if HLAA is an applicant under the SBIR and STTR programs;
 - c. intellectual property rights assigned to HLAA and agreements to share in royalties related to such rights;
 - d. any ownership interest held by the investigator, if the institution is a commercial or for-profit organization;
 - e. 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;
 - f. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined by 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;
 - g. income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined by 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.

Disclosure of an SFI

An investigator is under a continuing obligation to disclose any SFI (and those of his or her spouse and dependent children), or the appearance of a financial conflict, as soon as it is known, or reasonably should have been known.

The SFI must be disclosed to HLAA: 1) by the time an application is submitted to NIH for funding; 2) within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; and 3) on an annual basis at intervals determined by HLAA.

An investigator shall complete the attached SFI disclosure form in order to fully disclose an SFI. The SFI disclosure form shall be completed upon first participation in a PHS award with HLAA and shall be updated annually. An additional SFI disclosure form shall be submitted to HLAA within 30 days of discovering or acquiring a new SFI.

All disclosures of SFI shall be sent to HLAA and will be reviewed by HLAA's FCOI officer. The HLAA FCOI officer shall send his or her personal SFI disclosure form to the board chair ("chair") of HLAA for review.

Procedures for Review of an Actual or Potential FCOI

When there is reason to believe that an actual or potential FCOI exists, or the appearance of an FCOI exists, between the interests of HLAA and that of an investigator, the chair shall ultimately be responsible for determining the appropriate response. This shall include, but not necessarily be limited to, invoking the procedures described below with respect to a specific proposed action.

Where the appearance of an SFI or an actual or potential SFI involves an investigator, the FCOI officer shall review the matter and determine whether an investigator's SFI is related to PHS-funded conference and if so related, whether the SFI is an FCOI. The FCOI officer will notify the chair, who will take appropriate action to protect the interests of HLAA, its employees, its clients, and its conference participants. The FCOI officer shall report his or her determinations and suggestions for management of the conflict to the chair for review and adjudication. The chair shall, at his or her discretion, determine if any further board review or action is required.

In addition, the chair will present a report of all FCOI cases at the board of directors meetings.

The chair of HLAA shall serve as the FCOI officer in reviewing actual or potential conflicts of interest in those cases in which the HLAA FCOI officer has a potential FCOI or there exists the appearance of an FCOI.

Procedures for Addressing an FCOI

Where an actual or potential FCOI exists or the appearance of an FCOI exists, HLAA shall refrain from making any decisions concerning the FCOI until the chair has reviewed the FCOI and approved the action, or has presented the FCOI to the board of directors. The following procedures shall also apply:

- An investigator who has an actual or potential FCOI or the appearance of an FCOI shall not participate in, or be present during, the deliberations and decision-making with respect to this action unless requested by the chair or board of directors, and then will be present only to answer questions, provide information about the alleged FCOI, or respond to proposed HLAA actions.
- The chair may approve the proposed actions for remediation or amelioration of the FCOI upon a finding that these actions are in the best interests of HLAA, its employees, its clients, and/or its conference participants.
- If a finding of an FCOI, or a decision about an FCOI, is to be determined by the board of directors, determination and/or approval by the members of the board shall be by a majority vote, at a convened meeting, at which a quorum is present. The investigator who is the subject of the FCOI shall not be present during the vote.
- The meeting minutes shall reflect that the FCOI was discussed, the nature of the board's decision, and that a vote was taken regarding that decision.
- Members of the board of directors must recuse themselves from any discussion and vote on issues in which they have an FCOI or appear to have an FCOI.

Management of FCOIs

HLAA will make every effort to ensure that FCOIs do not bias conference conducted by investigators and that do not place clients, conference participants, or others at risk.

If the chair determines that an FCOI exists or has the potential to exist, he or she shall determine what conditions or restrictions, if any, should be imposed by HLAA to manage these actual or potential conflicts.

Examples of conditions or restrictions that might be imposed by the chair of HLAA to manage FCOIs include, but are not limited to: 1) public disclosure of SFIs; 2) monitoring and management of the FCOI by the HLAA FCOI officer; 3) review of the conference protocol by independent reviewers; 4) monitoring of the conference by independent reviewers; 5) modifications of the conference plan; 6) disqualification of the investigator from participation in all or a portion of the conference funded by PHS or NIH; 7) divestiture of significant financial interests; and/or 8) severance of relationships that create actual or potential conflicts of interest.

If the chair of HLAA does impose conditions or restrictions upon an investigator with respect to managing an FCOI, a management plan shall be prepared that details the conditions or restrictions imposed upon the investigator in the conduct of the project or regarding their relationship with HLAA. The management plan shall be signed by the investigator and the chair of HLAA. Actual or potential conflicts of interests will be satisfactorily managed, reduced, or eliminated, and/or they will be disclosed to the sponsoring agency for action.

If the chair of HLAA determines that imposing the above-referenced conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from an SFI are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the chair of HLAA may determine that the conference should go forward without imposing such conditions or restrictions, although an investigator would still need to disclose the nature of the conflict on a yearly basis (see Disclosure of Actual or Potential FCOI, above).

Compliance monitoring of the SFI will occur through a yearly review of the management plan by the FCOI officer, resulting in subsequent recommendations to the chair. Based on investigator compliance, the chair may decide to maintain, reduce, or eliminate the ongoing compliance monitoring plan. Or, the chair may impose additional conditions or restrictions upon an investigator, as outlined above.

Reporting Requirements to NIH

Prior to HLAA's expenditure of any funds under an NIH-funded conference project, HLAA will provide to NIH an FCOI report regarding any investigator SFI found by HLAA to be an FCOI, in accordance with the regulation. HLAA will also provide an FCOI report to NIH whenever an investigator fails to timely disclose an SFI or whenever HLAA-designated staff, for whatever reason, fail to timely review and/or properly identify a disclosed SFI but then subsequently review and determine that an FCOI exists. HLAA must report all identified FCOIs to NIH.

HLAA will submit an FCOI report to NIH within 60 days after its determination that an FCOI exists for an investigator who is newly participating in the project or for an existing investigator who discloses a new SFI to the institution during the award period.

Whenever an investigator does not timely disclose a previously existing SFI or HLAA-designated staff fail to timely review and/or properly identify a previously existing SFI regarding an ongoing NIH-funded project, HLAA's designated staff shall, within 60 days: 1) review the SFI; 2) determine whether it is related to the NIH-funded conference; and 3) determine whether an FCOI exists. And, if so, HLAA will implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such an FCOI going forward and submit an FCOI report to NIH.

In addition to the FCOI report, the institution will, within 120 days of HLAA's determination of noncompliance, complete a retrospective review of the investigator's conference activities and the NIH-funded conference project to determine whether any NIH-funded conference, or portion thereof, conducted during the time period of noncompliance, was biased in the design, conduct or reporting of such conference.

Based on the results of the retrospective review, if appropriate, HLAA-designated staff will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, HLAA-designated staff will notify NIH officials promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the conference project and HLAA's action plan or actions taken to eliminate or mitigate the effects of the bias. Thereafter, HLAA will submit FCOI reports annually.

HLAA will notify NIH promptly if an investigator fails to comply with HLAA's FCOI Policy or if the FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded conference.

For any FCOI previously reported by HLAA, HLAA shall provide an annual FCOI report to NIH that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual FCOI reports will be submitted to NIH for the duration of the project period (including extensions with or without funds) at the same time as when HLAA is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in eRA Commons or submission of an NIH prior approval request, whichever is applicable.) An annual FCOI report is not to be submitted as part of the annual progress report. The annual FCOI report is submitted to NIH separately through the eRA Commons FCOI Module at the same time the annual progress report is submitted.

Violations of the FCOI Policy

If the chair has reason to believe that an investigator has failed to disclose an actual or potential FCOI, or the appearance of an FCOI, the chair shall inform that investigator of the basis for this belief and allow him or her an opportunity to respond.

If, after hearing the response of the investigator, documentation of the response, and after initiating further investigation (as required), the chair, in determining that the investigator has failed to disclose an actual or possible FCOI, or the appearance of an FCOI, shall take appropriate administrative, disciplinary and/or corrective actions, such as implementing employee sanctions to ensure investigator compliance.

In any case in which the Department of Health and Human Services (DHHS) determines that an NIH-funded clinical conference project, 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 in which there was a financial conflict of interest that was not managed or reported by the institution as required by the regulation, HLAA will require the investigator(s) involved to disclose the FCOI in each public presentation of the results of the conference and to request an addendum to previously published presentations.

Subrecipient Investigator Requirements

HLAA will incorporate language, as part of a written agreement with the subrecipient, that the FCOI Policy of the subrecipient will apply to the subrecipient's investigator. The subrecipient must provide HLAA with certification that the subrecipient investigator is in compliance with 42 CFR Part 50 Subpart F and must submit all investigator-reported SFIs to HLAA within 30 days of discovering or acquiring a new SFI or, at the very least, in sufficient time for HLAA to meet its FCOI reporting obligations. If a subrecipient does not have an FCOI Policy that complies with 42 CFR Part 50 Subpart F, a subrecipient investigator must follow HLAA's FCOI Policy in all aspects.

Maintenance of Records

All FCOI-related records will be retained for at least three years from the date the final expenditure report is submitted to PHS. Documents will also be retained from the dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

Public Accessibility

The HLAA FCOI Policy is publicly available on the HLAA website: hearingloss.org. Prior to HLAA's expenditure of any funds under an NIH-funded conference project, HLAA shall ensure public accessibility, via HLAA's publicly accessible website located at hearingloss.org or by a written response to any requestor within five business days of a request, of information concerning any SFI disclosed to HLAA that meets the following three criteria:

1. The SFI was disclosed and is still maintained by HLAA senior/key personnel regarding a NIH-funded conference project;
2. HLAA determines that the SFI is related to the NIH-funded conference; and
3. HLAA determines that the SFI is an FCOI.

The information that HLAA makes available via its publicly accessible website or written response to any requestor shall include, at a minimum, the information listed in the PHS regulations at 42 CFR 50.605(a)(5)(ii), including:

1. Investigator's name;
2. Investigator's title and role with respect to the conference project;
3. Name of the entity in which the SFI is held;
4. Nature of the SFI; and
5. Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$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 reference to public prices or other reasonable measures of fair market value.

HLAA Financial Conflict of Interest Officer

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