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PURPOSE

To establish the Intelligent Hearing Systems' position in regard to the conflicts of interest of researchers and research teams.

Conflict of interest arise from an individual's opportunities to benefit financially from the outcome of his/her research or other activities conducted as an IHS researcher or as part of an IHS research team. This policy is designed to promote objectivity in research, scholarly, and educational activities, including those funded under external grants, contracts or cooperative agreements. By requiring the review of disclosures of interests made by our investigators relating to their institutional responsibilities, the policy establishes standards that provide a reasonable expectation that the design, conduct, and reporting of such activities will be free from bias resulting from individual financial and obligatory conflicts of interest.

The President of Intelligent Hearing Systems is responsible for the overall coordination of research at Intelligent Hearing Systems. The President is responsible for soliciting and reviewing disclosures of potential conflicts of interest related to research, scholarly, and educational activities at IHS.

This policy supplements the existing IHS policy contained in the Intelligent Hearing Systems Personnel Manual and other IHS policies and procedures on this subject. In the event of conflict as it relates to funded research funded under external grants, contracts or cooperative agreements, the provisions of this policy will apply.

DEFINITIONS

Conflict of interest (COI) means an actual or potential interest that could *directly and substantially* (as determined by the President and/or his/her designees), affect, or be affected by the design, conduct, or reporting of funded research, or of scholarly or educational activities funded under external grants, contracts or cooperative agreements. COIs can be financial (FCOI) or obligatory (OCOI) in nature.

Contractor means an entity providing property or services under contract for the direct benefit or use of an awarding component.

Disclosure of financial interests means an Investigator's disclosure of financial interests to IHS.

Financial interest means anything of monetary value, whether or not the quantitative value is readily ascertainable.

- A. With regard to any publicly traded entity, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure or the value of any equity interest in the entity as of the date of disclosure exceeds \$600. 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, travel); 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;

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- B. With regard to any non-publicly traded entity, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure exceeds \$600, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock options (vested or unvested), or other ownership interest); or
- C. With regard to Intellectual property (IP) rights and interests (e.g., patents, copyrights), a financial interest is considered to be present as soon as protection is sought (e.g., filing an invention disclosure, patent application, etc.).

The term *financial interest* does not include the following types of interests: salary, royalties, or other remuneration paid by the Intelligent Hearing Systems to the Investigator if the Investigator is currently employed or otherwise appointed by Intelligent Hearing Systems, including intellectual property rights assigned to the Intelligent Hearing Systems and agreements to share in royalties related to such rights; 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, teaching engagements, service on advisory committees or review panels for, or sponsored by a United States 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.

Financial conflict of interest (FCOI) means a financial interest that could *directly and substantially* affect, or be affected by the design, conduct, or reporting of funded research or scholarly or educational activities funded under external grants, contracts or cooperative agreements.

FCOI report means IHS’ report of a financial conflict of interest to a funding component.

Governmental agency means any governmental agency that has promulgated regulations or policies requiring investigator financial disclosure or requiring institutional conflict of interest policies relating to award of grants or contracts.

Institutional responsibilities means an Investigator’s professional responsibilities on behalf of the Institution. Income from, or obligations arising from any outside activity that is related to the Investigator’s institutional responsibilities must be disclosed to IHS.

Intellectual Property means the filing of a thought or idea that could be protected.

Investigator means the project director (PD), principal investigator(s) (PIs), co-investigators, and any other person substantively contributing to the design, conduct, or reporting of

- A. sponsored research (funded under external grants, contracts or cooperative agreements)
- B. other human subject research, or
- C. sponsored scholarly and/or educational activities.

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“Investigator” is used for the purpose of this policy to collectively indicate individuals whose role could be described as that of a researcher or investigator. Where questions exist concerning whether an individual qualifies as an investigator, the decision will be made by the President.

This includes sub-awardees, sub-contractor(s), and consultants as well as any individual whose biographical sketch is included in the proposal or whose name appears in the proposal budget (including subcontract budgets). The Investigator, as referred to within this policy, includes the investigator’s spouse and dependent children. The phrase “team member” is used interchangeably with Investigator.

Manage means taking action 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.

Obligatory interest means a relationship (regardless of compensation) that involves a responsibility or commitment to an external entity, including but not limited to being a founding member of that entity, or holding scientific advisory or governing board membership.

Obligatory conflict of interest (OCOI) means a responsibility or commitment that could *directly and substantially* affect, or be affected by the design, conduct, or reporting of funded research, or of scholarly or educational activities funded under external grants, contracts or cooperative agreements.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic “bench,” human subject research, and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or device). The term also includes any scholarly or educational activity for which external funding is available through a contract, grant or cooperative agreement.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the funding agency by IHS.

Significant financial interest means:

- (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 (associated with a common idea or practice) 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 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, travel); 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;

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- B. 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
- C. Intellectual property rights and interests (e.g., patents, copyrights) become SFIs when an individual receives an aggregated income of \$5,000 or more from one entity for said rights and interests.

- (2) The term significant financial interest *does not include* the following types of interests: salary, travel, royalties, or other remuneration paid by the Intelligent Hearing Systems to the Investigator if the Investigator is currently employed or otherwise appointed by the Intelligent Hearing Systems, including intellectual property rights assigned to the Intelligent Hearing Systems and agreements to share in royalties related to such rights; 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, teaching engagements, service on advisory committees or review panels for or sponsored by a United States 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.
- (3) For PHS funded Investigators this also includes 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 an Investigator’s institutional responsibilities that the President and/or his/her designees determines constitutes an FCOI with the Investigator’s funded research.

POLICY

This policy is divided into sections to describe the responsibilities of the IHS Investigator; the Sub-awardee/subcontractor/consultant that is not an employee of Intelligent Hearing Systems; and those of IHS.

I. Investigator Responsibilities

Training Requirements

Each Investigator is required to complete conflict of interest training prior to engaging in externally funded research, scholarly activities, and educational activities, at least every four years, and immediately when any of the following circumstances apply:

- A. IHS revises its COI policies or procedures in any manner that affects the requirements of IHS Investigators;
- B. an Investigator is new to IHS; or

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- C. IHS finds that an IHS Investigator is not in compliance with IHS' COI policy or management plan;
or
- D. The Investigator is engaging in a NIH funded grant or contract for the first time.

Responsibility to Disclose

A. Financial and Obligatory Interests

All Investigators who could be involved in sponsored work must disclose to the President and/or his/her designees their institutional responsibilities and financial and obligatory interests that could be perceived to be related to any of their institutional responsibilities. In addition, the Investigator must list financial and obligatory interests of his/her spouse and dependent children that are related to the Investigators institutional responsibilities.

Such disclosures must be made, updated, or certified to the President and/or his/her designees:

- at least annually
- prior to an application, project or contract being submitted for proposed funding
- prior to expending funds for a new award (grant or contract)
- upon joining a project/award/contract team engaged in funded research or scholarly or educational activities funded under external grants, contracts or cooperative agreements
- if a new financial interest is discovered or acquired (e.g., through activity, purchase, marriage, or inheritance)
- upon transfer to IHS of an externally funded award, contract or cooperative agreement from another institution or entity.

During the pendency or the term of an award or contract, Investigators are required to update disclosures within **thirty (30) days** of discovering or acquiring new financial or obligatory interests (e.g., through activity, purchase, marriage, or inheritance).

For investigators who are not IHS employees, and whose research is sponsored by non-federal entities whose policies do not require disclosure of financial interests, the training and disclosure requirements may be waived by the President and/or his/her designees.

B. Reimbursed or sponsored travel

Investigators funded by, or involved in the design, conduct or reporting of PHS-funded research/activities must also disclose the occurrence of any reimbursed travel 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.

The details of this disclosure include:

- the purpose of the trip,
- the identity of the sponsor/organizer,

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- the monetary value,
- the destination, and
- the duration.

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 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.

The President and/or his/her designees 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 PHS-funded research.

During the pendency or the term of an award or contract, investigators are required to update disclosures regarding reimbursed or sponsored travel within **thirty (30) days** of the occurrence of the travel.

II. Subrecipient Responsibilities

Responsibility to Comply

Sub-awardees, sub-contractors, and consultants on sponsored awards, contracts or cooperative agreements are required to comply with all aspects of the PHS FCOI regulations. In instances that the sub-awardee, sub-contractor, or consultant's organization does not have a federally compliant COI program, they must comply with IHS' COI policies and procedures. Failure to comply with this policy or adhere to a COI Committee management plan may result in termination of participation in the associated project.

Methods of Compliance

IHS (as an awardee Institution) takes reasonable steps to ensure that any subrecipient Investigator complies with the PHS conflict of interest policy by written agreement with the subrecipient with terms that establish whether the FCOI policy of IHS or that of the subrecipient will apply to the subrecipient's Investigators.

- If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with the Federal Regulation on FCOI, specifically Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for grants or cooperative agreements and Title 45 CFR Part 94 for research contracts. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to IHS' FCOI policy for disclosing significant financial interests that are directly related to the subrecipient's work for IHS;
- Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, per the agreement referenced above the subrecipient will report all identified FCOI to the

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President of IHS and/or his/her designees within twenty (20) days. This time period is required to enable IHS to provide timely FCOI reports, as necessary, to the awarding component.

- C. Alternatively, if the subrecipient's Investigators must comply with IHS' COI policy, the agreement referenced above shall specify that the subrecipient must submit to the Intelligent Hearing Systems all disclosures of financial and obligatory interests related to the Investigator's institutional responsibilities within fifteen (15) business days of submission of the grant or contract proposal. Disclosures are to be submitted directly to the President and/or his/her designees. This time period is required to enable IHS to comply timely with its review, management, and reporting obligations.

III. IHS Responsibilities

Disclosure Review

Disclosures of financial and obligatory interests and level of significance will be reviewed by President and/or his/her designees to determine whether an actual or potential COI exists, and to determine what conditions or restrictions, if any, should be imposed by IHS to manage or eliminate such COIs. The President and/or his/her designees are responsible for assuring that determinations are the result of consistently applied guidelines, including, but not limited to, a review of

- A. the nature of the personal relationship between the Investigator and the research;
- B. a risk/benefit analysis for human subjects if involved in the research;
- C. the specific role (e.g. patient screening and enrollment; data acquisition, analysis and interpretation) of the Investigator and consideration of how that role can affect the outcome of the research; and
- D. the expertise of the Investigator and extenuating circumstances as to why he or she should be involved in the research.

An interest will be determined to be a COI if it exceeds the threshold limits put forth by this policy and it could directly and significantly affect, or be affected by the design, conduct, reporting or outcome of the funded research or scholarly or educational activities funded under external grants, contracts or cooperative agreements.

Management of Identified COI

Management of an identified COI (including those of subrecipient Investigators if applicable) requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report. Examples of conditions or restrictions that might be imposed to manage or eliminate actual or potential conflicts of interest include, but are not limited to:

- Public disclosure of COIs;
- Monitoring of research by independent reviewers;
- Modification of the research plan;

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- Disqualification from participation in specific portion (s) of the funded research that would be affected by the COI;
- Divestiture or reduction of significant financial interests; or
- Severance of relationships that create actual or potential conflicts.

The Investigator will affirm in writing that he/she agrees to comply with the condition (s) and/or restriction (s) imposed by the President and/or his/her designees within ten (10) days of receiving the determination letter or management plan.

The management plan shall include monitoring of Investigator compliance with the plan until completion of the PHS funded research at a minimum.

In addition, as required, IHS will notify the awarding component if the FCOI management plan appears to have biased the design, conduct, or reporting of the NIH funded research.

Appeals

If an Investigator does not agree with the decision of the President and/or his/her designees, the Investigator may appeal the decision once to the President. If the Investigator remains unsatisfied with the subsequent ruling, he or she can further appeal the determination to the Director and Co-Directors of Research, whose decision will be final. For an appeal to be valid, the Investigator must file each appeal with the President and/or his/her designees in writing within 10 business days of receiving the management plan.

Noncompliance and Retrospective Review

Whenever an interest related to funded research or scholarly or educational activities funded under external grants, contracts or cooperative agreements is not identified or managed in a timely manner including failure by the Investigator to disclose a financial or obligatory interest, or failure by IHS to review or manage an interest, the President and/or his/her designees has sixty (60) days to determine if the disclosure constitutes a COI.

If determined to be an FCOI related to PHS funding, or upon learning that an Investigator failed to comply with a prior FCOI management plan for PHS-funded research, IHS shall complete a retrospective review of the Investigator's activities within one hundred and twenty (**120**) days of the discovery of nondisclosure/ determination of noncompliance in order to determine whether the research or scholarly activity, or any portion thereof, conducted during the time period of noncompliance, was biased in design, conduct, or reporting.

Further, regardless of type of COI or origin of funding, IHS has the option to conduct a similar retrospective review in order to determine if the design, conduct, or reporting of the research or scholarly activity was biased.

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Depending on the nature of the interest, the President and/or his/her designees may determine that additional interim measures are necessary with regard to the Investigator's participation in the funded research project or scholarly activity until the completion of the Institution's review.

If bias is found, IHS will notify and submit a mitigation report to the awarding component as required. The mitigation report will include the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and IHS' plan of action or actions taken to eliminate or mitigate the effect of the bias (*e.g.*, impact on the PHS funded research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, IHS will submit FCOI reports **annually** for the duration of the funded project, including extensions with or without additional funding.

Further, if the NIH determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a 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, 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.

Enforcement Mechanisms and Remedies

Regardless of funding source, failure to comply with a determination of the President and/or his/her designees or failure to comply with this policy will be brought to the attention of the Investigator's supervisor. The President and/or his/her designees will have the option of taking appropriate action(s) including but not limited to withdrawal of pending proposals and/or placing a hold on, or terminating, an active award, contract or cooperative agreement. In addition, as required, IHS will notify the awarding component of the Investigator's failure to comply with the determination and/or policy.

Public Accessibility Requirements

IHS will maintain a website to ensure public accessibility to this policy and information concerning any significant financial interest disclosed to IHS that meets the following three criteria:

- A. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this policy;
- B. IHS determines that the significant financial interest is related to funded research or scholarly or educational activities funded under external grants, contracts or cooperative agreements; and
- C. IHS determines that the significant financial interest is a FCOI.

The information presented includes the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest, 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.

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This information will be provided on the website prior to IHS' expenditure of any funds under the relevant funded research or scholarly or educational activities funded under external grants, contracts or cooperative agreements.

IHS will update the website at least annually and within sixty (60) days of IHS' receipt or identification of information concerning:

- any additional significant financial interest that was not previously disclosed held by the senior/key personnel for the funded research or scholarly or educational activities funded under external grants, contracts or cooperative agreements project, or
- upon the disclosure of a significant financial interest of senior/ key personnel new to the funded research project or scholarly or educational activities funded under external grants, contracts or cooperative agreements.

The information will remain publicly available for three years from the date on which the information was most recently updated.

Advising External Funding Entity

The President and/or his/her designees will be responsible for advising an external funding entity regarding actual or potential conflicts of interest according to the policies/requirements of the external entity. IHS does not disclose information related to potential or actual conflicts of interest unless it is required by the awarding component.

Reporting Requirements to NIH

For NIH funded projects, FCOI reports shall be sent to NIH by the President and/or his/her designees if applicable, as required by regulation:

- Prior to the expenditure of funds for a new award (grant or contract)
- 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.
- Following a retrospective review to update a previously submitted report, if appropriate.

Maintenance of Records

Records of financial interests, significant financial interests, determinations of the President and/or his/her designees, appeals and compliance documents, and documents regarding all actions taken to resolve actual or potential conflicts of interest will be maintained by the President and/or his/her

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designees for at least three years following the submission of the final expenditures report, or where applicable, from other dates specified in 45 CFR 75.361, where applicable.

Compliance with Federal Regulations

Any regulations promulgated by a governmental agency on conflict of interests will be incorporated by reference in this policy.

References and Related Resources

PHS Grants Policy Statement and Code of Federal Regulations 42CFR50, 42CFR75.