

Bose Financial Conflict of Interest (FCOI) in NIH Funded Research Policy

1. **Scope.** This policy applies to research conducted by Bose employees with the use of NIH funds ("**Covered Research**"). This policy does not apply to other Bose research.
2. **Purpose.** The purpose of this policy is to identify and manage any financial conflicts of interest (defined below) to comply with the requirements of 42 CFR Part 50 Subpart F.
3. **Training.** Each Investigator must review and understand this policy prior to engaging in research related to any NIH-funded grant and at least every four years, and immediately when any of the following circumstances apply: (1) Bose revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators, (2) an Investigator is new to Bose, or (3) Bose finds that an Investigator is not in compliance with this policy.
4. **Disclosure.** Prior to participation in Covered Research and prior to an application for funding for Covered Research if the Investigator intends to participate in such Covered Research, each Investigator must disclose to the Designated Official the Investigator's Significant Financial Interests (and those of the Investigator's spouse and dependent children). In addition, Investigators must update this disclosure at least annually and within thirty days of discovering or acquiring a new Significant Financial Interest.
5. **Designated Official.** The Chair of the Ethics Committee will be the Designated Official. The Designated Official will determine, in accordance with the definitions below, whether a Significant Financial Interest is a Financial Conflict of Interest. A **Financial Conflict of Interest** is a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Covered Research.
6. **Review.** The Designated Official will review all Significant Financial Interests prior to the expenditure of NIH funds to determine if a Financial Conflict of Interest exists, and if so, to develop and implement a management plan in compliance with the requirements of 42 CFR Part 50 Subpart F. Disclosures by new investigators and new disclosures by existing investigators will be reviewed promptly, and in fewer than sixty days.
7. **Review for Bias Due to Non-Compliance.** Whenever a Financial Conflict of Interest is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest that is determined by Bose to constitute a Financial Conflict of Interest; failure by Bose to review or manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a Financial Conflict of Interest management plan, Bose shall, within one hundred twenty days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the Covered Research to determine whether any Covered Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
8. **Conflict Reporting.** Prior to expenditure of any NIH funds under a Covered Research project, Bose shall provide to the NIH Awarding Component a Financial Conflict of Interest report in compliance with 42 CFR Part 50 Subpart F, and ensure that it has implemented a management plan in accordance with 42 CFR Part 50 Subpart F. Bose shall provide additional reports, if needed, to disclose any Financial Conflict of Interest that is newly discovered within sixty days. Bose shall provide an annual report with updates on previously disclosed Financial Conflicts of Interest, and will update reports following a retrospective review if appropriate.

9. **Bias Reporting.** If bias is found following a retrospective review, Bose shall notify the NIH Awarding Component promptly and submit a mitigation report to the NIH Awarding Component that complies with 42 CFR Part 50 Subpart F and shall notify the NIH Awarding Component of the corrective action taken (or to be taken).
10. **Records.** Bose will maintain records relating to all Investigator disclosures of financial interests and Bose's review of, and response to, such disclosures (whether or not a disclosure resulted in Bose's determination of a financial conflict of interest) and all actions under Bose's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the NIH Awarding Component.
11. **Violations.** Investigators who violate this policy will be subject to disciplinary action up to and including dismissal.
12. **Remedies.** In any case in which the HHS determines that a NIH-funded 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 a Financial Conflict of Interest that was not managed or reported by Bose as required by law, Bose shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.
13. **Subrecipient Requirements.** Where applicable, each subrecipient contract shall contain terms compliant with 42 CFR Part 50 Subpart F that address Financial Conflict of Interest disclosures and controls and enable Bose to fulfill its obligations.
14. **Public Accessibility.** This policy shall be posted on Bose's publically accessible website. Information regarding Financial Conflicts of Interest held by senior or key personnel will be made available as required by 42 CFR Part 50 Subpart F.

Definitions

Covered Research is defined in Section 1.

Designated Official is defined in Section 5.

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 to the Investigator's institutional responsibilities:

(i) 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); 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;

(ii) 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

(iii) 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 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 disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this policy, Bose official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest with the Covered Research.

(3) The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by Bose to the Investigator if the Investigator is currently employed or otherwise appointed by Bose, including intellectual property rights assigned to Bose 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, or teaching engagements 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; or income from service on advisory committees or review panels for 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.

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

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Investigator means 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 the NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

NIH means the National Institutes of Health (NIH).

Bose Corporation Financial Interest Disclosure Form for Federally Funded Research

Please list below any Significant Financial Interest:

(i) that would reasonably appear to be affected by research activities funded or proposed for funding by a federal government source, such as the NIH.

(ii) in entities whose financial interests would reasonably appear to be affected by such activities,

(iii) that would reasonably appear to be related to your responsibilities as a Bose employee.

(Name) _____

(Signature) _____

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(i) 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); 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;

(ii) 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

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(3) The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by Bose to the Investigator if the Investigator is currently employed or otherwise appointed by Bose, including intellectual property rights assigned to Bose 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, or teaching engagements 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; or income from service on advisory committees or review panels for 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.