ALLEVIANT MEDICAL, INC.
FINANCIAL CONFLICTS OF INTEREST POLICY

I. INTRODUCTION

Alleviant Medical, Inc. strives to create a research climate that promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of Public Health Service ("PHS") – which includes National Institutes of Health ("NIH") – Funded Research will be free from bias resulting from any financial conflict of interest ("FCOI").

This FCOI Policy implements U.S. federal requirements pertaining to "Objectivity in Research" promulgated by PHS. FCOI requirements related to PHS-Funded Research (which included NIH grants) are published in U.S. regulations 42 CFR Part 50, Subpart F and 45 CFR Part 94.

To apply for funding with PHS Organizations, Alleviant Medical Inc. ("Alleviant") must be able to certify, in each application for funding, that Alleviant:

- has in effect, an up-to-date, written and enforced process to identify and manage FCOI;
- will promote and enforce compliance with the regulation;
- will manage FCOI and provide initial and ongoing FCOI reports;
- will make FCOI and significant financial interest information available to the PHS Organization, promptly, upon request; and
- will fully comply with the regulatory requirements.

This Policy is applicable to each employee or contractor of Alleviant who is planning to or is participating in a research activity that is either partially or wholly supported by PHS funds.

II. DEFINITIONS

A) Covered Individual: Any Alleviant employee or contractor who is responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding, including any project director, principal investigator or any other key personnel.

B) Covered Individual Responsibilities: A Covered Individual's responsibilities performed on behalf of Alleviant.

C) Equity Interest: Any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

D) Financial Conflict of Interest ("FCOI"): A significant financial interest that could directly and significantly affect the design, conduct or reporting of PHS funded research.

E) Financial Interest: Anything of monetary value, regardless of whether the value is readily ascertainable.

F) Immediate Family: A Covered Individual's spouse or domestic partner and dependent children.

G) Non-Significant Financial Interests ("Non-SFI"): include the following:

   i) any Remuneration paid by Alleviant to the Covered Individual if the Covered Individual is currently employed or otherwise appointed by Alleviant; or

   ii) any ownership interest in and or income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual (or Covered Individual's Immediate Family) does not directly control the investment decisions made in these vehicles; or

   iii) income from seminars, lectures or teaching engagements sponsored by a US 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

iv) income from service on advisory committees or review panels for a US 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

v) Travel reimbursement or sponsorship by a US 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.

H) PHS: Public Health Service of the U.S. Department of Health and Human Services ("HHS"), and any components of the PHS to which the authority involved may be delegated, including among others, the NIH. A listing of the PHS agencies and their offices may be located on the HHS Organizational Chart.

I) PHS-Funded Research: Any research funded by way of a grant from, or a contract or cooperative agreement with, a PHS Organization.

J) PHS Organization: An agency that is part of the or an organization that has adopted the PHS Regulations, but not a non-governmental non-profit organization.

K) PHS Regulations: U.S. 42 CFR Part 50 Subpart F and 45 CFR Part 94.

L) Remuneration: Any payment for services including consulting fees and honoraria.

M) Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research, basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a medical device).

N) Significant Financial Interest ("SFI"): A Financial Interest consisting of one or more of the following interests of a Covered Individual (and those of the Covered Individual's Immediate Family) that reasonably appear to be related to the Covered Individual's Responsibilities, but specifically excluding any Non-SFI:

i) any Remuneration received from any publicly traded entity in the 12 months preceding the disclosure, and the value of any Equity Interest in such entity as of the date of disclosure, that exceeds $5,000 when aggregated; or

ii) any Remuneration received from any non-publicly traded entity in the 12 months preceding the disclosure that exceeds $5,000 when aggregated or any Equity Interest in such entity of any value as of the date of disclosure; or

iii) income related to intellectual property rights and interests (e.g. patents, copyrights) that exceed $5,000 in the aggregate, upon receipt of such income; or

iv) any travel reimbursement or sponsorship.

III. TRAINING REQUIREMENTS

Each Covered Individual is required to complete training on Alleviant's FCOI Policy prior to engaging in PHS-Funded Research, at least every 4 years, and immediately, if (a) Alleviant revises the FCOI Policy that affects requirements of Covered Individuals or (b) a Covered Individual is not in compliance with the FCOI Policy.

IV. DISCLOSURE, REVIEW AND MONITORING REQUIREMENTS

Each Covered Individual is required to disclose SFIs (and those of the Covered Individual's Immediate Family) that meet or exceed the definition of SFI. This disclosure must occur before any payment by

Alleviant is made to a Covered Individual, at least annually during the period of the PHS-Funded Research, and within 30 days of discovering or acquiring a new SFI.
For any Covered Individual anticipated to conduct activities on a particular project involving PHS-Funded Research, Alleviant will also require each such Covered Individual to disclose SFIs before the date of submission for Alleviant's proposal for the project if the Covered Individual's anticipated role in the project is known before proposal submission.
Alleviant will designate individual/s to review disclosures of SFIs of the Covered Individual (and those of the Covered Individual's Immediate Family). The designated individual/s will review all Covered Individual SFI disclosures, determine if any SFIs relate to PHS-Funded Research, determine if an FCOI exists and develop and implement management action plans, as needed, to manage FCOIs:

- before work on a particular PHS-Funded Research project begins for any Covered Individual that is known Alleviant prior to such time; and
- within 60 days whenever Alleviant identifies an SFI that was not disclosed by an Covered Individual or not previously reviewed by Alleviant.

The designated individual/s must establish a process to monitor a Covered Individual's compliance with management action plans until completion of the PHS-Funded Research project. For any report of an SFI involving travel reimbursement or sponsorship, the designated individual/s must be provided information relating to the purpose, destination, and duration of each trip and the identity of the relevant sponsor or organizer. If requested by the designated individual/s, additional information, including the monetary value of the trip, must be disclosed to determine whether the reimbursement or sponsorship constitutes an FCOI.

V. REPORTING REQUIREMENTS

Alleviant will send initial, annual and revised reports listing FCOI of Covered Individuals ("FCOI Reports") to the relevant PHS Organization:

- prior to expenditure of funds for PHS-Funded Research; and
- within 60 days of identification of a FCOI for a Covered Individual who is newly participating in an on-going project; and
- at least annually to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and
- following a retrospective review to update a previously submitted report, if appropriate.

Whenever Alleviant identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, Alleviant's designated individual/s will, within 60 days, review and make the determination of whether an FCOI exists, and report the FCOI if it exists to the relevant PHS Organization:

- if an FCOI exists, Alleviant will within 120 days of the Alleviant's determination of noncompliance/nondisclosure complete a retrospective review of the Covered Individual's activities and PHS-Funded Research to determine whether any of the PHS-Funded Research conducted during the time period of the noncompliance/nondisclosure biased the design, conduct or reporting of such Research.
- Alleviant will document the retrospective review as required by PHS Regulations.
- Subsequent to the retrospective review, if applicable, Alleviant will update the existing FCOI report and, if bias is found, Alleviant will notify the relevant PHS Organization promptly and submit a mitigation action plan with details required by PHS Regulations.

Alleviant will notify the relevant PHS Organization promptly if a Covered Individual fails to comply with the FCOI Policy or an FCOI management plan and inform the relevant PHS Organization of the corrective action taken or to be taken.

VI. PUBLIC ACCESS

Before expending funds on a particular PHS-Funded Research project, Alleviant will establish procedures for public access to information concerning any SFI that is disclosed to Alleviant and (a) continues to be held by key personnel for a particular project, (b) is determined by Alleviant to be related to the project, and (c) is determined by Alleviant to constitute an FCOI.

Alleviant will make this information available within 5 business days of receiving a written request for at least 3 years after the information was most recently updated. Alleviant will include details specified in PHS Regulations when responding to any such request. Alleviant will also make this FCOI Policy available on a publicly accessible website.

VII. MAINTENANCE OF RECORDS

Alleviant will maintain all FCOI-related records:

- for at least 3 years from the date on which, for grants and cooperative agreements, the final expenditure report is submitted to the relevant PHS Organization or, for contracts, final payment is made; or
- for the time periods specified in 45 CFR 75.361 or 48 CFR Part 4, Subpart 4.7, as applicable.

During the applicable period identified above, Alleviant will also make all FCOI-related records available to each relevant PHS Organization upon request.

VIII. ENFORCEMENT MECHANISM AND REMEDIES FOR NONCOMPLIANCE

Alleviant will maintain adequate enforcement mechanisms and provide for corrective action to promote Covered Individual compliance.

In any case in which the HHS determines that a PHS-Funded Research project of clinical research, whose purpose is to evaluate the safety or effectiveness of a medical device, treatment (or drug), has been designed, conducted or reported by a Covered Individual with an FCOI that was not managed or reported by Alleviant as required, Alleviant will require the Covered Individual to disclose the FCOI in each public presentation of the results of the PHS-Funded Research, and request a similar addendum to previously published presentations and publications.

IX. THIRD PARTY REQUIREMENTS

Alleviant will by agreement require that any contractor or collaborator who carries out PHS-Funded Research with Alleviant (“Subcontractor”) certifies, via written agreement, that it will follow (a) this FCOI Policy or (b) the Subcontractor’s own FCOI policy, if the Subcontractor certifies that its policy complies with PHS Regulations.

Alleviant will require all disclosures and reports by a Subcontractor’s Covered Individual under either policy to be made to Alleviant at least 15 days before any corresponding disclosure or report is due to the U.S. Government.

If the Subcontractor certifies that it will comply with its own FCOI policy, the written agreement with the Subcontractor shall include:

- a copy of the Subcontractor FCOI policy; and
- a certification by the Subcontractor that its policy complies with all applicable laws, regulations, and rules (including, but not limited to the PHS Regulations; and

- list the 15 days reporting window of any identified FCOI before any corresponding disclosure or report is due to the U.S. Government.