

N8 Medical Inc. – Financial Conflict of Interest (FCOI) Policy, May 2022

Objective research is of paramount importance to N8 Medical Inc. to ensure public trust and meet scientific, programmatic and ethical goals of our National Institutes Health (NIH) grant efforts. To address the increasing complexities related to financial interests held by biomedical and behavioral researchers, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) have published their final rules. N8 Medical Inc. believes we have fully addressed the requirements (including those of our defined sub-level vendors) of this ruling although we will continue to update this policy as needed, particularly related to any changes in personnel FCOI issues or upon further HHS guidance.

N8 Medical Inc.'s policy requires that its investigators and collaborators affiliated with N8 Medical Inc., by NIH or any other applicable grant or contract, be in compliance with 42 CFR Part 50, Subpart F (2011 revision) for PHS grants and cooperative agreements (and 45 CFR Part 94 for contracts). In addition, this legislation spells out NIH's commitment to preserving the public's trust that the research supported by them is conducted without bias and with the highest scientific and ethical standards. N8 Medical Inc. intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

Definitions

The following are key term definitions and N8 Medical Inc.'s policy guidance for principal or program investigators, subrecipients, subgrantees and collaborators affiliated with N8 Medical Inc. This policy and all FCOI N8 Medical Inc. guidance are also available at <https://www.n8medical.com/technology/publications/> (and this document, the Financial Conflict of Interest (FCOI) Policy, May 2022, is available in N8 Medical's Quality Management System) so that all interested parties, including the general public have access to this company policy.

Investigator

An Investigator is any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of research funded by PHS.

Significant Financial Interest (SFI)

Significant Financial Interest is defined by the regulations as:

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 reasonable appears to be related to the Investigators 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 the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and 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 remunerations 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 interests (e.g., stock, stock options, 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, medical center, or research institute that is affiliated with an Institution of higher education. The Institution'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 the Institution's FCOI policy, the institutional 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 FCOI with the PHS-funded research.

3. The term significant financial interest does not include the following types of financial interests: salaries, royalties or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the investigator, if the Institution is a commercial or for profit organization; income from investment vehicles, such as mutual funds and retirements 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, 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 Conflict of Interest (FCOI)

A Financial conflict of interest exists when N8 Medical Inc. reasonably determines that a Significant Financial Interest (defined above) could directly and significantly affect the design, conduct or reporting of NIH-funded research.

PHS Awarding Component

The PHS awarding component is any sub-agency of the Public Health Service or Department of Health and Human Services.

Research

PHS research is any project governed by PHS regulation, but excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Processes

PHS regulations and guidance require specific processes for compliance, not simple recitation of requirements.

Training Requirements

N8 Medical Inc. is required to complete training of its Investigators related to Financial Conflict of Interest (FCOI): the regulations, our Policy, and the Investigator's disclosure responsibilities. The training must be given to each N8 Medical Inc. Investigator (i) upon the effective date of this Policy, (ii) for each new Investigator upon hire, (iii) each time we change requirements for Investigators in this Policy (to the extent required to train the investigators on the new material implemented), (iv) whenever an Investigator has been found not to be following this policy, and (v) no less than every four years or as designated based on grant or role circumstances. The training must be updated no-less than every four years or as designated based on grant or role circumstances. Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site, presently at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.

Disclosures/Reporting Process

If any financial conflicts of interest (FCOIs) are found or known, they must be disclosed.

Prior to application for a PHS grant, and not less than annually during grant performance, all N8 Medical Inc. Investigators will review their financial interests and disclose all Significant Financial Interests to N8 Medical Inc.'s designated official(s). Any Investigator who is new to participating in a research project will review the financial interests policy and disclose all Significant Financial Interests to N8 Medical Inc.'s designated official(s), prior to beginning effort on the grant. N8 Medical Inc.'s designated

official(s), will solicit a disclosure from any grant Investigator from whom a required disclosure has not been received.

Prior to beginning performance of a grant project, N8 Medical Inc.'s designated official(s) will review all disclosures and determine whether they contain any FCOI as defined above and in PHS regulations. All disclosure forms will be filed in a N8 Medical Inc. SFI file. If a FCOI is identified it will be put on the FCOI report through PHS's eRA Commons FCOI module as promptly as practicable, and prior to expending any grant funds.

If any interests are identified as conflicting subsequent to the initial report, they must be reported to N8 Medical Inc. within 30 days. N8 Medical Inc. will then report it to the PHS awarding component that has issued the award within 60 days. If a PHS-funded project is conducted by an investigator or Signing Official with a conflict that was not disclosed or managed, N8 Medical Inc. is required to disclose the conflict in each public presentation related to the results of the research.

Records Management

The records of all financial disclosures and all actions taken by N8 Medical Inc. will be maintained in an SFI binder or binders, for at least three years from the date of submission of the final expenditures report for each PHS research grant, and throughout the completion of any litigation, claim, negotiation, audit or other action involving the records, whichever date is later.

Management of a FCOI

N8 Medical Inc.'s designated official(s) will take case-by-case action to address each FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. Being a small company, this process must be adaptable, but in the event of any identified FCOI, must include either reducing or eliminating the FCOI, must include monitoring each Investigator to ensure compliance with management plan requirements, must include reporting promptly to NIH any discovery of noncompliance or other bias related to an enacted management plan, and must include reporting on the FCOI as described above and at least annually thereafter (during the grant performance) in time for the funding PHS Institution's annual report.

Publication of PHS Research Performed by an Investigator with an FCOI

If a PHS-funded project is conducted by an Investigator with a conflict that was not disclosed or managed, N8 Medical Inc. will disclose the conflict in each public presentation related to the results of the research and request an addendum to each previously published presentation. Any research that is performed despite an FCOI causes a requirement to publish details of the FCOI on the N8 Medical Inc. web page, and to update the details annually on the web page, within 60 days of newly discovered FCOI, and remaining for at least three years from the most recent update. Note that it is N8 Medical Inc. policy not to permit research to proceed with an FCOI; if FCOIs are avoided, such a publication requirement will not be triggered.

Compliance and Penalties for Non-Performance

If an investigator fails to comply with N8 Medical Inc.'s FCOI policy, within 120 days, N8 Medical Inc. shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, N8 Medical Inc. shall submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias. N8 Medical Inc. will work with the Investigator to set up an FCOI management plan to mitigate the situation. Companywide, N8 Medical Inc. is required to mandate the Investigator disclose the FCOI in each public presentation with research results if it was not reported up front. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding, and/or be terminated by N8 Medical Inc.

Subawards for PHS Research Effort

N8 Medical Inc.'s *Policies & Procedures for Federal Grant Subrecipients* apply to all subrecipient awards ("subawards") by N8 Medical Inc. In addition, subawards for research funded by a PHS Institution will establish in that written agreement that the subrecipient will have and follow its own FCOI policy, compliant with PHS

regulations, and will require the subrecipient to report FCOIs it has discovered for its Investigators (or those of its own subrecipients) to N8 Medical Inc., in a time frame that allows N8 Medical Inc. to timely report to NIH; each reporting time period above will therefore be shortened by at least 5 days in the written subrecipient agreement.

Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the N8 Medical Inc. Signing Official, Carl Genberg (carlgenberg@n8medical.com).