NewHaptics Corp. Financial Conflict of Interest (FCOI) Policy

PURPOSE

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of NewHaptics Corp. (NHC: Company) research, and to comply with federal regulations (42 CFR Part 50 Subpart F). While our collaborations may be governed by the FCOI policies and processes of our collaborative research institution, if any, the purpose of this policy is to ensure when there is no institutional FCOI to rely upon, Company research will still be in compliance with federal regulations. Specifically, our research agreements with subawardees/subrecipients will establish if they will follow the NHC FCOI or that of their institution of employment.

The Company must be able to certify, in each application for funding, that the Company:

(i) has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI;

(ii) promotes and enforces Investigator compliance with the regulation;

(iii) manages FCOI and provides initial and ongoing FCOI reports;

(iv) agrees to make FCOI and Significant Financial Interests (SFI) information (including related Institutional reviews and determinations) available to HHS, promptly, upon request; and

(v) fully complies with the regulation's requirements.

This policy has been developed to address and comply with the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F). This regulation was developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of research funded under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. An electronic version of the regulation is found at **http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf**.

KEY DEFINITIONS

The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI. A complete list of official definitions can be found at 42 CFR 50.603.

Institution – means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for or receiving NIH research funding.

Investigator – means the project director or principal investigator and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the NIH, which may include, for example, collaborators or consultants.

Institutional responsibilities – means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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

Financial conflict of interest (FCOI) – means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Manage – means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Senior/Key Personnel – means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the regulation.

Significant Financial Interest (SFI) – Includes any one or more of the following from any single entity OUTSIDE THE COMPANY for activity that is related to the investigators professional qualifications:

(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;
   (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) Upon receipt of income related to intellectual property rights and interests (e.g., patents, copyrights).

(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 excluded sources provided in regulation. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e., the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination and duration. The Company is required to determine if additional information is required (e.g., monetary value) and whether the travel constitutes a FCI with NIH-funded research.

(3) The term significant financial interest **does not** include the following types of financial interests:
   (i) salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
   (ii) intellectual property rights assigned to the Company and agreements to share in royalties related to such rights;
   (iii) any ownership interest in the Company held by the Investigator, if the Company is a commercial or for-profit organization;
   (iv) 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;
   (v) 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
   (vi) income from service on advisory committees or review panels for a federal, state or local government agency, 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.

(4) For simplicity, a Significant Financial Interest of Conflict would exist in the following (non-exclusive) examples:

(i) the Investigator (or spouse/dependent) has a Significant Financial Interest in an entity that sponsors their research project;
(ii) the Investigator (or spouse/dependent) has a Significant Financial Interest in an entity that produces products (equipment, software, compounds, drugs, devices, etc.) or services used in their research project;
(iii) the Investigator (or spouse/dependent) has a Significant Financial Interest in an entity that develops product or services their research project intends to evaluate or develop; or
(iv) the Investigator (or spouse/dependent) has a Significant Financial Interest in an entity with whom they are consulting in an area that overlaps with or is the main subject of his/her research.

Significant Financial Interest Disclosure Form (SFIDF) – Company form by which the required person provides an itemized disclosure statement with regard to SFI categories. One SFIDF covers all of a person's funded projects: it lists each project they work on, and the Financial Administrator determines which disclosed interests relate to which project. The form is submitted to the Financial Administrator upon assignment of work sponsored by a federal, state, or local government grant, yearly thereafter, and when any occurrences of a new SFI arise. Training is required to be completed upon first submission, and every four (4) years unless further education is required.

SUMMARY OF PROCESS

Significant Financial Interests (SFI) (as defined below) shall be disclosed on the Significant Financial Interest Disclosure Form (SFIDF) by an Investigator requesting government-sponsored or company-sponsored funds for a research project or by an Investigator when a Significant Financial Interest arises during the course of research. Regardless of whether a SFI exists, all Investigators and key personnel are required to submit a SFIDF annually.

It is the Principal Investigator's responsibility to ensure those with financial interests in research are identified and make the required disclosures in conjunction with submission of a research proposal or application for approval of experiments involving human subjects.

The SFIDF and supporting materials are forwarded to the Financial Administrator for review. The Financial Administrator will be responsible for (in consultation with the CEO or Board of Directors) evaluating and instituting a plan for managing any disclosed financial interests, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

Advance approval by the Financial Administrator is required prior to engaging in government-sponsored research. An SFI review must be completed before any expenses are incurred under an award. Typically, the CEO provides approval as signatory of the research agreement, simple agreement, or engagement contract, or provides written approval for the Financial Administrator (an AOR) or Company signatory to sign in their stead.

Annual updates are required of all Investigators and key personnel participating in research. Any Investigator who has acquired a new or increased financial interest during the course of a research project shall report it immediately to the Financial Administrator. Annual updates and newly acquired interests are reported using the SFIDF.

TRAINING

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH funded project, which includes all Investigators, consultants and employees of NewHaptics Corp. engaged in NIH-funded research or its compliance.

The course is accessible at **https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html**. Upon completion of the training, a certificate of completion must be turned into the Financial Administrator. You should retain a copy for your records. This

training is required prior to engaging in research relating to any NIH-funded grant or as deemed necessary by the Company due to changes in the FCOI policy, non-compliance of the Investigator/Key Personnel or new to the Company. At a minimum, the FCOI training shall be taken every four (4) years.

PROCEDURES

A. **Identification of Persons Required to Disclose a Significant Financial Interest** - It shall be the responsibility of the Principal Investigator of a Research project to identify all Investigators who have a SFI requiring disclosure under this policy and to ensure that a SFIDF is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed. To assist PIs with this responsibility, the Financial Administrator will send out reporting reminders, SFIDF forms, and receive completed SFIDFs. This will occur yearly and just prior to application submissions. PIs are responsible for reporting SFIs that occur between these reporting timelines.

- This process is established to require each Investigator to disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigators institutional responsibilities that meets or exceeds the regulatory definition of SFI (42 CFR 50.03): (i) no later than at the time of application for PHS-funded research; (ii) at least annually during the period of award; and (iii) within 30 days of discovering or acquiring a new SFI (42 CFR 50.604(e)(1)-(3)).

B. **Submission and Review of SFIDF** - Every individual having a SFI requiring disclosure under this policy shall prepare a fully completed SFIDF that shall be submitted to the Financial Administrator. An initial review of the SFIDF will be conducted by the Financial Administrator to determine whether a potential for conflict of interest exists. The Financial Administrator will utilize the Review of Conflicts Form (RCF) to consider if a potential financial conflict of interest exists. This form compares the focus, contractual involvements, and research goals of each research project listed on the SFIDF against the interests the researcher disclosed. If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFI identified in the SFIDF. A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to these actions) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

a. Public disclosure of significant financial interests;
b. Review of research protocols by independent reviewers;
c. Monitoring of research by independent reviewers;
d. Modification of research plan;
e. Disqualification from participation in all or a portion of the research funded;
f. Divestiture of significant financial interests;
g. Severance of relationships that create actual or potential conflicts.

All management plans are required to be signed by the Investigator and the Financial Administrator (in consultation with the CEO or Board of Directors). Compliance of the management plan shall be monitored by the Financial Administrator and implemented within 60 days of identified FCOI.

C. **Annual Reporting and After-Acquired Significant Financial Interests** – All Investigators shall provide annual SFIDFs or more frequently if required by the management plan or acquired interests. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFIDF within 30 days of discovering or acquiring the new SFI. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research project submits the required SFIDF to the Finance Administrator. The Finance Administrator must report to NIH any FCOIs within ten (10) days of notification of new SFIs identified by the PI on either notification report, or annual report, and immediately upon review and determination of any bias found with the design, conduct, or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with the regulation, and including the following NIH FCOI reporting items:

a. The name of the Investigator with the FCOI
b. The name of the entity with which the Investigator has an FCOI

c. The nature of the Significant Financial Interest (SFI)
d. The value of the financial interest
e. Description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research
f. Description of the key elements of the Company's management plan, including other required information

D. **Violations of Conflict of Interest Policy** – Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the Financial Administrator shall make recommendations to the CEO regarding the impositions of sanctions or disciplinary proceedings against the violating individual. The Financial Administrator and CEO will review together with the employee or Investigator the specific behaviors and consequences that are determined relevant based upon review, and any other administrative actions to assure Investigator compliance, including but not limited to supervised research activities. The Financial Administrator and either the CEO or Board of Directors must conduct retrospective reviews within 120 days of the Institution determining noncompliance for SFIs not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation.

In addition, the Company shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy.

E. **Record Keeping** – Records of Investigator SFIDFs, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Finance Administrator for three (3) years from the date the final expenditure report is submitted to the NIH, or as required by 45 CFR 74.53(b) and 92.42(b) for different situations.

F. **Sub-recipient Requirements** – Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F) and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. Prior to Notification of Award, Company and sub-awards will establish in written agreement which FCOI policy will be followed by which Investigator, and if applicable, certification that the sub-award policy complies with the regulations, requirement to report identified FCOIs in a timeframe that permits Company to report identified FCOIs to NIH as required by regulation, or that Company will solicit and review subrecipient Investigator disclosures to enable identification, management and reporting of FCOIs as required by NIH. If an SFI is identified by the subaward recipient, they are required to notify the Financial Administrator of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations.

G. **Federal Reporting** – The Financial Administrator is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:
   i. Initial report – prior to the Company's expenditure of any funds under a NIH-funded research project, the Company must provide to the NIH an FCOI report regarding any Investigator SFI found by the Company to be a financial conflict of interest in accordance with the regulation.
   ii. During on-going NIH-funded research projects – the Company shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, the Company shall submit a FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.
   iii. Annual FCOI report – For any FCOI previously reported to the NIH, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

H. **Public Accessibility Requirements** – The Company will provide public access to this policy on the publicly accessible page of www.newhaptics.com. The Financial Administrator will ensure that any updated versions of this policy are provided for updated posting immediately upon implementation. In addition, an FCOI determined to exist for any Investigator or Senior Key Personnel will be posted to this same webpage in compliance with regulation, including the date of posting and (i) the minimum elements as provided in the regulation; (ii) posting within 5 days of a written request; (iii) annual updates, unless written requests are made which should continue to be available; (iv) any updates within 60 days of newly identified FCOI; and (v) remain available for three years from the date the information was most recently updated.