Financial Conflict of Interest Policy in Conduct of Research

Effective Date: 09/01/2019

Objective

Institutions engaged in research funded by the Public Health Service (PHS) are required to develop an FCOI policy that is maintained and enforced and meets or exceeds the current Federal regulatory requirements. Per applicable regulations, this policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. It applies to any SFI [as defined below] that could directly and significantly affect the design, conduct, or reporting of company research, including NIH-or other Government funded research.

This Policy does not apply to Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Phase I applications and grants.

Policy Statement

NeuroWave Systems Inc. (NeuroWave) requires Investigators on a sponsored project to disclose a listing of significant financial interests (and those of their spouse and dependent children) that could be reasonably expected to bias the design, conduct, or reporting of the project.

This policy applies to each Investigator, as defined by the regulation, who is planning to participate in or is participating in PHS funded research. All PIs, Co-PIs and Key Personnel listed in a proposal for external funding must complete a disclosure form before expenses can be charged to an award.

Covered Institution

NeuroWave Systems Inc., "Company" or "Institution", is covered under this policy. It is the responsibility of the Company to Promote Objectivity in all Research performed by or for the company including all research for which PHS, which includes the National Institutes of Health, funding is sought or obtained. Significant Financial Interest (SFI)s include financial interests that are related to an Investigator's institutional responsibilities. The Company is responsible for determining whether SFI relates to NIH-funded research and if it is a Financial Conflict of Interest (FCOI).

The Company shall maintain an up-to-date, written, enforced policy that complies with the FCOI regulation and make available via a publicly accessible Web site. The Company and all of its employees shall comply with this Policy and applicable regulations in all research.

HHS/NIH Authority

The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in NIH-funded research. The NIH and the Department of Health and Human Services (HHS) have authority that applies before, during, or after an award with regard to any Investigator disclosure of financial interests, regardless of whether or not the disclosure resulted in the Institution's determination of an FCOI.

Contact with the NIH Mailbox for inquiries: FCOICompliance@mail.nih.gov

OER FCOI Web Site: http://grants.nih.gov/grants/policy/coi/

FAQs posted on 9/30/2011. See NIH Guide Notice NOT-11-121:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-121.html

Applicable Regulations

42 CFR Part 50 Subpart F (grants and cooperative agreements)

45 CFR Part 94 (contracts)

Initial Regulation effective 10-1-95: http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

Revised Final Rule published on 8-25-11: http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf

Definitions

1. **Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or receives NIH research funding.
2. **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.
3. **PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS including the NIH. PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.
4. **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development (e.g., a diagnostic test or drug).
5. **Significant Financial Interest (SFI)** is a financial interest consisting of one or more of the interests listed in **Appendix A** 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.
6. **Financial Conflict of Interest (FCOI)** is an SFI that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.
7. **Senior/Key Personnel** are 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 PHS by the Institution under the regulation.

   Note: Different definition than the NIH Grants Policy Statement
8. **Small Business Innovative Research** (SBIR) and Small Business Technology Transfer (STTR) programs and/or awards. The revised 2011 regulation does not apply to Phase I SBIR/STTR applications, but the revised 2011 regulation does apply to Phase II SBIR/STTR applications/awards.
9. **Manage** means taking action to address an 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.
10. **Disclosure** refers to the Investigator's disclosure of Significant Financial Interests (SFI) to their Institution.
11. **Report** refers to the Institution's report of identified FCOIs to the NIH.

Institutional Responsibilities

1. Institutions must establish standards that provide a reasonable expectation that the design, conduct and reporting of NIH-funded research will be free from bias resulting from Investigator financial conflicts of interest.
2. Maintain an up-to-date, written, enforced policy that complies with the FCOI regulation and make available via a publicly accessible Web site.
3. See list of specific requirements in **Appendix B**.

Investigator Responsibility

1. Complete FCOI training and understand this Policy
    a. Prior to beginning of PHS funded research
    b. At least every 4 years thereafter
    c. When Institution changes policy or in cases of non-compliance of the investigator
2. The training must inform each Investigator of the:
    a. Regulation;
    b. Institution's policy on FCOI; and
    c. Investigator's responsibilities regarding disclosure of SFIs.
    d. (NIH has developed an interactive training module to help satisfy the requirement for investigators to complete training in financial conflict of interest (FCOI) regulations: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)
3. Complete FCOI disclosure form in a timely manner
4. Monitor Subrecipients' Investigators
5. Take necessary actions to eliminate or mitigate FCOIs of the Investigator's programs.
6. Incorporate language as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators and include a time period to meet disclosure requirements, if applicable, and FCOI reporting requirements to the awardee Institution.
    a. Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS/NIH Awarding Component (i.e., to NIH through the eRA Commons FCOI Module, see **Appendix B**, **Item 8.c**) to meet FCOI reporting obligations.

Duties of the Responsible Official

The Responsible Official for the Company is the President.

The Chairman, who will be trained on the policy, will review disclosure statements from the President and any Director of the Company to make determinations regarding their FCOI.

The Responsible Official will further be assisted by the Director of Quality and Regulatory and Accounting Representative at the Company. They will both be trained on the policy and will assist in matters of record keeping, auditing and reporting to the NIH.

Duties of the Responsible Official (with assistance from other designated personnel as indicated above) include the following:

1. Train Investigators and Company employees in the Policy
2. Document training
3. Obtain required documents from Investigators including disclosures at time of application, annually, and within 30 days of discovering an SFI. Review disclosures to determine whether any SFI disclosed to the Institution is an FCOI.
4. Communicate SFIs from the President and any Director of the Company to the Chairman, who will review their disclosure statements and make determinations regarding their FCOI.
5. Take necessary actions to manage FCOIs of the Company's Investigators, including those of subrecipient Investigators
6. Maintain Records
7. Provide Application Certification for each application for funding (see **Appendix B**, **Item 2**)
8. Communicate with the NIH
9. Submit reports in a timely manner (see **Appendix B**, **Item 8**)
10. Monitor compliance
11. Ensure public accessibility of FCOIs on the website (see **Appendix B**, **Item 11**)
12. Conduct an audit not less than every two years of contracts to subrecipients for FCOI language. Document the audit findings.
13. If an Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the Responsible Official shall within sixty (60) days review the SFI in coordination with the Chairman, determine if an FCOI exists and implement an interim management plan, if needed.
14. In cases of non-compliance, complete a Retrospective Review and submit a Mitigation Report if bias is found (see **Appendix C**).

Non-compliance

Retrospective Review

1. Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, failure by the Institution to review or manage an FCOI, or failure to comply with the management plan, the institution shall within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research.
2. Notify NIH promptly and submit a Mitigation Report when bias is found.
3. See **Appendix C** for report formats.

Enforcement

The Responsible Official, with the advice and consult of the Chairman, shall have the authority to enforce this Policy. Sanctions, administrative actions, and other actions up to and including termination may be taken to enforce this policy and ensure Investigator compliance.

The Responsible Official may require that one or more of the following actions be taken in order to manage, reduce, or eliminate a potential Conflict of Interest:

1. Disclosure of Significant Financial Interests, including to the public, human subjects, researchers and other participants and publishers;
2. Monitoring of PHS-funded Research by independent researchers and/or reviewers, disinterested individuals or committees;
3. Disqualification from participation in all or a portion of the PHS-funded Research;
4. Requiring that Significant Financial Interests be divested, restructured, or placed in blind trust;
5. Modification or severance of relationships that create a potential Conflict of Interest;
6. Changing terms of agreement relating to the PHS-funded Research;
7. Requiring that Investigator participation in the recruitment or consent of subjects in human subjects PHS-funded Research be prohibited or restricted;
8. Requiring additional disclosures or actions with respect to matters before the Responsible Official, Chairman and/or Company's Board of Directors; or
9. Requiring non-participation in any business transactions between the Company and parties to agreements involving sponsored PHS-funded Research.

Revision of Policies

This policy shall be reviewed upon changes to the Federal Regulation and revised as appropriate.

APPENDIX A

Significant Financial Interests (SFIs)

1. 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;
2. 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
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
4. 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.

SFI Exclusions:

1. **Salary, royalties, or other remuneration paid by the Institution** to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
2. **Intellectual Property Rights** assigned to the Institution and agreements to share in royalties related to such rights;
3. **Any ownership interest in the Institution** held by the Investigator, if the Institution is a commercial or for-profit organization;
4. **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;
5. **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
6. **Income from service on advisory committees or review panels** for a federal, state or local government agency, Institution of higher education as defied 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.

APPENDIX B

Institutional Responsibilities

1. Maintenance of Records
    a. Maintain records of all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of FCOI) and all actions under the Institution's policy or retrospective review, if applicable
        i. for at least three years from the date of submission of the final expenditures report or, where applicable,
        ii. from other dates specified in 45 C.F.R. 74.53(b) and 92.42 (b) for different situations.
2. Application Certification - certify in each application for funding that the Institution:
    a. Has in effect an up-to-date written and enforced administrative process to identify and manage FCOIs related to all PHS research projects
    b. Shall promote and enforce Investigator compliance with the regulation pertaining to disclosure of SFI
    c. Shall manage FCOIs and provide initial and ongoing FCOI reports to PHS/NIH
    d. Agrees to make information available upon request relating to any Investigator disclosure of financial interest and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI
    e. Fully comply with the requirements of the regulation
3. Designated Institutional Official(s)
    a. Designate an Institutional Official(s), the Responsible Official(s), to solicit & review disclosure statements from each Investigator planning to participate in, or is participating in, PHS/NIH-funded research.
        i. The Responsible Official for the Company is the President.
        ii. The Chairman, who will be trained on the policy, will review disclosure statements from the President and any Director of the Company to make determinations regarding their FCOI.
        iii. The Responsible Official will further be assisted by the Director of Quality and Regulatory and Accounting Representative at the Company. They will both be trained on the policy and will assist in matters of record keeping, auditing and reporting to the NIH.
    b. Provide guidelines to identify conflicting interests related to proposed or PHS/NIH-funded research. This policy provides those guidelines.
    c. Designated Institutional Official(s) develop management plans that specify the actions that have been, and shall be, taken to manage FCOI. This Policy provides that Management Plan. The person who shall update this Management Plan is the Responsible Official.
4. Inform Investigators
    a. Inform each Investigator of the Institution's policy and his or her "disclosure" reporting obligations, including SFIs and time frames
    b. Identify an Institutional official(s) to determine the existence of conflicting interests and to take actions to ensure that they will be managed, reduced, or eliminated research:

i. The Institutional Official who shall determine the existence of conflicting interests and take appropriate actions is the Responsible Official, i.e., the President.

ii. The Chairman will determine the existence of conflicting interests for the President and any Director of the Company. He will be trained on the policy, will review disclosure statements from the President and any Director of the Company, and will make determinations regarding related FCOI.

5. Investigator Training - Institutions must require that each Investigator complete FCOI training
    a. Prior to engaging in research related to any NIH funded project
    b. At least every four years, and immediately when any of the following circumstances apply:
        i. Institution revises its policy in a manner that affects the investigator;
        ii. When an investigator is new to the institution
        iii. When the institution finds an Investigator is not in compliance with the Institution's policy or management plan
6. Investigator Disclosure of SFIs (including subrecipient Investigators)
    a. Require that each Investigator planning to participate in PHS/NIH-funded research to disclose to the designated official(s) at time of application
    b. Require each Investigator to submit an updated disclosure of SFI at least annually during the period of the award
    c. Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI
7. Management of FCOIs
    a. Take necessary actions to manage any FCOIs of its Investigators, including those of subrecipient Investigators
    b. Develop a management plan(s) and monitor compliance
    c. If Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the designated official(s) shall within sixty (60) days review the SFI, determine if an FCOI exists and implement an interim management plan, if needed
    d. In cases of non-compliance, complete a retrospective review and submit a Mitigation Report if bias is found
8. FCOI Reporting
    a. Provide initial and ongoing FCOI reports to NIH
        i. Prior to the expenditure of funds
        ii. During the period of award - within 60 days of identifying a new FCOI

    b. Annually
        i. Report on the status of FCOI and any changes in management plan
        ii. Due at same time as when grantee submits annual progress report, including multiyear progress report, or at time of extension

    c. All FCOI reports are submitted to NIH through the eRA Commons FCOI Module
        i. System allows institutions to:

1. Initiate and send FCOI Reports to NIH electronically through the eRA Commons FCOI Module
2. Revise or update a previously submitted FCOI report (future enhancement)
3. Submit a Mitigation Report when bias is found (future enhancement)
4. Search previously created records
5. Edit a previously submitted record
6. Respond to a request for additional information
7. Rescind a previously submitted record
8. View history of actions
9. To prepare, Institutional Signing Officials must assign FCOI roles to users in eRA Commons
10. More information on the FCOI Module can be found at http://era.nih.gov/services_for_applicants/other/fcoi.cfm

ii. FCOI reports for NIH-funded research contracts should be sent to the NIH Office of Acquisition Management and Policy at fcoicontracts@mail.nih.gov

9. Elements of an FCOI Report
   a. Grant number
   b. PD/PI or contact PD/PI
   c. Name of Investigator with the FCOI
   d. Name of the entity with which the Investigator has an FCOI
   e. Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria)
   f. Value of the financial interest $0-4,999; $5K-9,999; $10K-19,999; amts between $20K-100K by increments of $20K; amts above $100K by increments of $50K or a statement that a value cannot be readily determined
   g. A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research
   h. Key elements of the Institution's management plan
10. Subrecipient Requirements
   a. Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators, and include time period(s) for submission of all disclosures of significant financial interests or identified FCOIs
      i. If the subrecipient's FCOI policy applies to subrecipient Investigators, the subrecipient shall certify as part of the agreement that its policy complies with the regulation. If the subrecipient cannot provide the certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

ii. If the subrecipient's FCOI policy applies to subrecipient Investigators, the agreement shall specify time period(s) for the subrecipient to report all identified FCOIs to the awardee Institution.

iii. If the subrecipient Investigator is subject to the awardee Institution's FCOI policy, the agreement shall specify time period(s) for the subrecipient to submit all SFI disclosures to the awardee Institution.

b. Such time period(s) shall be sufficient to enable the awardee Institution to comply with its review, management, and reporting obligations under the regulation so to provide timely FCOI reports (including those for subrecipient Investigators), as necessary, to the NIH through the eRA Commons FCOI Module.

c. In all cases, the awardee Institution is responsible for reporting all identified FCOIs for subrecipient investigators to the NIH through the eRA Commons FCOI Module.

11. Public Accessibility of FCOIs

a. Prior to expenditure of funds, make certain information (defined below in *Item b*) concerning FCOIs held by senior/key personnel publicly accessible via a Web site or provide written response within five business days of a request

i. Update the website annually and within 60 days of identifying any new FCOIs when posting FCOIs to website

ii. Retain information for three years

b. The information concerning any Significant Financial Interest (SFI) disclosed to the Institution that meets the following three criteria shall be made publicly accessible:

i. The SFI was disclosed and is still held by the Senior/Key Personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;

ii. The Institution determines that the SFI is related to the NIH-funded research; and

iii. The Institution determines that the SFI is an FCOI.

c. Information to be made publicly available includes the following:

i. Investigator's name;

ii. Investigator's title and role with respect to the research project;

iii. Name of the entity in which the SFI is held;

iv. Nature of the SFI; and

v. Approximate dollar value of the SFI (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value.

APPENDIX C

Retrospective Review Report

1. Documentation of the key elements of a retrospective review
    a. Project number;
    b. Project title;
    c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
    d. Name of the Investigator with the FCOI;
    e. Name of the entity with which the Investigator has an FCOI;
    f. Reason(s) for the retrospective review;
    g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
    h. Findings and conclusions of the review
2. If results of the retrospective review warrant, update previously submitted FCOI report

Mitigation Report

1. If bias is found through retrospective review, notify the NIH Awarding Component promptly (through the eRA Commons) and submit a Mitigation Report
2. Key Elements
    a. Key elements documented in retrospective review
    b. Description of the impact of the bias on the research project
    c. Plan of action(s) to eliminate or mitigate the effect of the bias
    d. Thereafter, submit FCOI reports annually