

NEUROSCOPE, INC.
PHS-FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

The purpose of this policy is to prevent potential bias resulting from any Financial Conflict of Interest (FCOI) by individuals who have direct influence in the allocation and use of public funding in the conduct of research. The following FCOI policy applies to research and initiatives funded by US Public Health Service (PHS) grants wherein “NeuroScope Inc.” is the recipient of public funding. The policy aligns to requirements within regulation 42 CFR Part 50 – Subpart F with the goal of promoting objectivity and transparency in research.

This FCOI policy defines the requirements and processes for investigators or individuals participating in PHS funded research to identify and properly disclose any FCOIs. In addition, it outlines activities related to management, enforcement, and reconciliation for all appropriate studies.

A) Definitions:

Investigator(s): The project director (PD) or principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, and/or reporting of research funded by award, or proposed for such funding, which may include, for example, collaborators or consultants. NeuroScope Inc.’s Principal Investigator/Project Director, upon consideration of the individual’s role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

Senior Key personnel: 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 this subpart.

Public Health Service Awarding Component: The Public Health Service (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.

Institutional responsibilities: A professional responsibility on behalf of NeuroScope Inc., and as defined by NeuroScope Inc., 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 for PHS funded research.

Significant Financial Interest (SFI):

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 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, when aggregated exceeds \$5,000.

2. Investigators must disclose the occurrence of any foreign or domestic reimbursed or sponsored travel in excess of \$5,000 (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 the Investigator's institutional responsibilities. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- A federal, state, or local government agency located in the United States,
- A United States Institution of higher education,
- An academic teaching hospital,
- A medical center, or
- A research institute that is affiliated with a United States Institution of higher education.

The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months.

3. The term significant financial interest **does not** include the following types of financial interests:

- (i) Salary, royalties, or other remuneration paid by NeuroScope Inc to the Investigator if the Investigator is currently employed or otherwise appointed by NeuroScope Inc, including intellectual property rights assigned to NeuroScope Inc and agreements to share in royalties related to such rights;
- (ii) 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;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education; or
- (iv) Income from service on advisory committees or review panels for a federal, state, or local government agency located in the U.S., a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.

4. Foreign Financial Interests: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any

foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

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

B) Disclosures

Prior to the submission of an application to the NIH Grantee for funding, the Principal Investigator, and all other Investigators at NeuroScope Inc. must have disclosed to NeuroScope Inc.'s designated official an up-to-date listing of their Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application to NIH for funding from NIH, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the designated official promptly and prior to participation in the project. Each Investigator who is participating in research under an award from NIH must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Each Investigator who is participating in research under an NIH award must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to NeuroScope Inc. pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on an NIH funded project directly as a NIH Grantee and/or indirectly through a subaward) that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Review by NeuroScope Inc.'s Designated Official: Dr. Jeiran Choupan, Chief Executive Officer, serves as NeuroScope Inc. designated official for FCOI. Dr. Choupan or the designated official will conduct reviews of disclosures. She will review any SFI that has been identified in a disclosure; these interests will be compared to each research award on which the Investigator is identified as responsible for the design, conduct, and/or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a FCOI related to that research award. Dr. Choupan will also self-assess and disclose her SFI in the same cadence mentioned above.

Guidelines for Determining "Relatedness" and Financial Conflict of Interest: The designated official will determine whether an Investigator's SFI is related to the research under a NIH award and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to the research under the NIH award when the designated official reasonably determines that the SFI: could be affected by the research conducted under the award; or is in an entity whose financial interest could be affected by the research. The designated official may involve the Investigator in the determination of whether a SFI is related to the research supported by the award.

A FCOI exists when the designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. In determining if an Investigator's SFI is related to the research under a NIH award, and if so, whether the relationship creates a FCOI, the designated official considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the designated official may also consider the following factors:

- Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or

- Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
- Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or Where the research involves human subjects, whether there are double-blind conditions or the involvement of a data and safety monitoring board; or
- Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on NeuroScope Inc.'s business or financial outlook (excluding Phase I SBIRs and STTRs); or
- The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
- The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
- Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
- Whether other scientific groups are independently pursuing similar questions; or
- Whether sufficient external review of the research conducted, and the reporting of research results exist to mitigate undue bias; or
- Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has an SFI; or Whether the project involves a subaward to an entity in which the Investigator has an SFI.

Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest: If a conflict of interest exists, the designated official will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the designated official will be guided by the principles discussed in this FCOI Policy the designated official will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the Institution Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts;
- For research projects involving human subjects research, use of a data and safety monitoring board;

- Double-blind conditions;
- Provisions to conduct the work simultaneously at multiple sites;
- Written disclosure of the conflict to all individuals working on the research project;
- Annual reports on the research progress to the designated official;
- Disclosure at any presentation of information related to the FCOI.

If the designated official determines that a conflict exists, the determination will be communicated and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The designated official will keep a record of the disclosure and other relevant information for at least three years. If the designated official prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on a NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated official necessary to manage the Conflict of Interest. The designated official will communicate, in writing, with the NIH Grantee to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the NIH Grantee has reported the FCOI to NIH. The NIH Grantee will notify NeuroScope Inc. when it may incur expenditures. The designated official will keep a record of Investigator disclosures of financial interests and the designated official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations.

C) Reporting of Financial Conflicts of Interest

FCOI manager 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 sponsor:

- **Initial report:** Prior to NeuroScope Inc.'s expenditure of any funds under a PHS/NIH-funded research project, NeuroScope Inc. will provide to the sponsor an FCOI report regarding any Investigator SFI, if found by NeuroScope Inc. to be a financial conflict of interest, in accordance with the regulation. In cases in which NeuroScope Inc. identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of NIH-awarded funds, NeuroScope Inc. shall not submit an FCOI report to the NIH.
- **During on-going PHS/NIH-funded research projects:** Whenever, during the research project, a new Investigator discloses SFI or an existing Investigator discloses a new SFI, NeuroScope Inc. will:
 - Review of disclosure of SFI
 - Determine whether it is related to research
 - Implement a management plan in interim
 - Submit a report of FCOI within 60 days after its determination that a new FCOI exists.
- **Annual report:** For any FCOI previously reported to the sponsor, NeuroScope Inc. shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan. Further, NeuroScope Inc. will notify the sponsor promptly:

- If bias is found NeuroScope Inc. will notify and submit a mitigation report to the sponsor. The mitigation report will include, at a minimum, the key elements documented in the retrospective review (discussed in section E) and a description of the impact of the bias on the research project and NeuroScope Inc.'s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, NeuroScope Inc. will submit FCOI reports annually.
- If an Investigator fails to comply with NeuroScope Inc.'s FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research NeuroScope Inc. will take corrective action.

D) Training Requirement

Each Investigator must complete training on NeuroScope Inc.'s Financial Conflict of Interest Policy Applicable to an Award Issued by Public Health Services prior to engaging in research related to any NIH award and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- (i) upon the effective date of this Policy,
- (ii) for each new Investigator upon hire,
- (iii) each time NeuroScope Inc. changes 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.

In fulfillment of the training requirement, NeuroScope Inc. requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> in accordance with the requirements and expectations of this Policy. All investigators must print a certification of completion at the end of training, provide it to NeuroScope Inc. for audit purposes, and retain a copy for a period of four years, the time point at which updated training is required to be completed.

E) Retrospective Review

In an event when there is a failure to Comply with NeuroScope Inc.'s Conflict of Interest Policy Applicable to Public Health Service Funded Award such that When an FCOI is not identified or managed in a timely manner, including, failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a FCOI; failure by the Institution to review or manage such a FCOI; and failure by the Investigator to comply with a management plan; then NeuroScope Inc. will within 120 days:

- Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct or reporting of research;
- Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B);
- Document NeuroScope Inc.'s determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's non-

compliance with this Policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research;

If bias is found, NeuroScope Inc. shall notify NIH promptly and submit a mitigation report to NIH via the eRA Commons FCOI Module that shall address the following:

- Impact of the bias on the research project and
- NeuroScope Inc.'s plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, NeuroScope Inc. shall submit FCOI reports annually to NIH, in accordance with the regulation and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest, NeuroScope Inc. may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of NeuroScope Inc.'s independent retrospective review.

Additionally, in any case in which the sponsor determines that a PHS-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 NeuroScope Inc. as required by this subpart, NeuroScope Inc. will require the investigator involved to disclose the FCOI in each public presentation of the results of the PHS funded research and to request an addendum to previously published presentations under PHS Funded research.

F) Subrecipient FCOI Compliance:

A subrecipient relationship is established when federal funds flow down from or through NeuroScope Inc. to another individual or entity and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to NeuroScope Inc. for programmatic outcomes and compliance matters.

Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors and subawardees, are subject to NeuroScope Inc.'s terms and conditions, and as such, NeuroScope Inc. will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation. NeuroScope Inc. will incorporate, as part of a written agreement with the subrecipient, terms that establish whether NeuroScope Inc.'s FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator.

If the subrecipient's FCOI policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with NeuroScope Inc. that it is in compliance with the federal FCOI regulation, and that the institution's portion of the project is in compliance with the FCOI policy. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigator is subject to NeuroScope Inc.'s FCOI Policy for disclosing SFI that are directly related to the subrecipient's work for NeuroScope Inc.. NeuroScope Inc. will, if applicable, submit a FCOI report to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to NeuroScope Inc.. Such time period must be sufficient to enable NeuroScope Inc. to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module.

If the subrecipient Investigator is subject to NeuroScope Inc.'s Investigator FCOI Policy, the agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of SFI to NeuroScope Inc.. Such time period shall be sufficient to enable NeuroScope Inc. to comply with its review, management, and reporting obligations under the regulation. NeuroScope Inc. will submit any NIH FCOI reports for a subrecipient Investigator through the eRA Commons FCOI Module.

G) Records Management/ Maintenance

Records of financial disclosures and any resulting actions by either NeuroScope Inc. and/or NIH will be maintained by NeuroScope Inc. for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations. NeuroScope Inc. will retain records for each activity as provided in the regulation.

H) Public Accessibility to Information Related to Financial Conflicts of Interest:

Prior to the expenditure of any funds under an NIH award, NeuroScope Inc. will ensure public accessibility, by written response to any requestor within five business days of a request of information concerning any SFI disclosed that meets the following three criteria:

- The SFI was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by NeuroScope Inc. in the award application, progress report or any other report submitted to the NIH Grantee;
- NeuroScope Inc. has determined that the SFI is related to the research funded through an award; and
- NeuroScope Inc. has determined that the SFI is a financial conflict of interest.

The information that NeuroScope Inc. will make available via a publicly accessible Web site or in a written response to any requestor within five days of request will include, at a minimum, the following:

- The Investigator's name;
- The Investigator's title and role with respect to the research project;
- The name of the entity in which the Significant Financial Interest is held;
- The nature of the Significant Financial Interest; and
- The approximate dollar value of the Significant Financial Interest in the following ranges: \$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 reference to public prices or other reasonable measures of fair market value.

If NeuroScope Inc. uses a publicly accessible Website to comply with the public disclosure requirements of the NIH regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the NIH-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the NIH-funded research project, if it is determined by the designated official that the Significant Financial Interest is related to the research and is a financial conflict of interest. Information concerning the SFI of an individual, as limited by this Policy, will remain available for responses to written requests or for posting via NeuroScope Inc.'s publicly accessible Website for at least three years from the date that the information was most recently updated.

I) References

The below table is a summary of key guidance and regulatory requirements related to this policy.

| REGULATORY REQUIREMENTS | Regulatory Citation and NIH Grants Policy Statement |
|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Training | 42 CFR 50.604(b) 42 CFR 50.604(b) |
| Disclosure, Review, Manage and Monitoring | 42 CFR 50.603 , 42 CFR 50.604(e)(1)-(3) , 42 CFR 50.604(d) , 42 CFR 50.604(f) , 42 CFR 50.605(a)(1) , 42 CFR 50.605(a)(1) , 42 CFR 50.605(a)(2) , 42 CFR 50.605(a)(3)(i)-(iii) , 42 CFR 50.604 (g) , 42 CFR 50.605(a)(1)-(6) |
| Reporting to NIH | 42 CFR 50.604(h) 42 CFR 50.605(b) , 42 CFR 50.605(a)(3)(iii) , 42 CFR 50.606(a) |
| Retrospective Review Requirements | 42 CFR 50.605(a)(3) |
| Enforcement Mechanisms and Remedies and Noncompliance | 42 CFR 50.604(j) , 42 CFR 50.605(a)(3)(ii)(A) , 42 CFR 50.605(a)(3)(ii)(B) , 42 CFR 50.606(c) |
| Subrecipient | 42 CFR 50.604(c) (also see NIH Grants Policy Statement 15.2.1), 42 CFR 50.604(c)(1)(i)-(iii) |
| Public Accessibility | 42 CFR 50.604(a) (also see NIH GPS 4.1.10), 42 CFR 50.605(a)(5)(i)-(iv) |
| Maintenance of Records | 42 CFR 50.604(i) , 45 CFR 75.361 |
| Clinical Research | 42 CFR 50.606(c) |

FCOI Officer: Jeiran Choupan PhD, CSEE - Chief Executive Officer, NeuroScope Inc.

Revision: **B**

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