Neurotype Inc. Financial Conflict of Interest (FCOI) Policy

Effective: April 20, 2026

1) Introduction

The purpose of this policy is to ensure that research funded by the National Institutes of Health (NIH) is designed, conducted, and reported objectively and without bias resulting from Investigator financial conflicts of interest (FCOI). The 2011 revised regulations are 42 CFR Part 50 Subpart F, "Promoting Objectivity in Research" and 45 CFR Part 94, "Responsible Prospective Contractors", which set requirements for promoting objectivity in Public Health Service (PHS)–funded research for grants, cooperative agreement, and research contracts, respectively. The regulations do not apply to SBIR or STTR Phase I applications or awards. This policy implements the regulatory requirements for PHS/NIH grants and cooperative agreements.

Neurotype Inc. ("Neurotype", "The Institution") adopts this policy for all Investigators (as defined below) engaged in PHS/NIH-funded research. It establishes processes to identify, disclose, and manage Investigator financial conflicts of interest to protect research integrity, ensure the safety of human and animal subjects, and maintain public trust in PHS/NIH-supported research.

2) Applicability

This policy implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for grants and cooperative agreements issued by the NIH. This policy applies to individuals who meet the regulatory definition of "Investigator" (as defined below) who are planning to participate in or who participate in PHS/NIH-funded research.

3) Definitions

For the purpose of these policies and procedures, the following definitions apply:

Financial Conflict Of Interest (FCOI): A significant financial interest that is related to the PHS/NIH- funded research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Interest: Anything of monetary value, whether or not its value is readily ascertainable.

Institutional Responsibilities: The professional activities or responsibilities an Investigator performs on behalf of Neurotype Inc., including research, product development and testing, publication and communication of research, consulting, clinical or regulatory activities, fundraising, and service on advisory panels or review boards.

Designated Official (DO): The individual appointed by Neurotype to solicit and review disclosures of significant financial interests, determine FCOIs in accordance with 42 CFR 50.604(f) and this policy, and develop management plans for identified FCOI.

Institution: Any public or private organization, domestic or foreign (excluding a federal agency) that is applying for or receives, PHS/NIH research funding.

Investigator: The Project Director (PD) or Principal Investigator (PI), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS/NIH or proposed for such funding, which may include, for example, collaborators or consultants. The institution determines who is responsible for the design, conduct, or reporting of PHS/NIH-funded research. The Institution will consider the individual's role, rather than the title (e.g., senior/key personnel, faculty, MD, PHD, etc.), of those individuals involved in the research and the degree of independence in carrying out the work when determining who is responsible for the design, conduct, or reporting of the PHS/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.

Research: means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). As used in the regulation, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

PHS-Funded Research: Any activity supported by a Public Health Service (PHS) Awarding Component through a grant, cooperative agreement, or contract, whether funded under the PHS Act or other statutory authority.

PHS: The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

NIH: The biomedical research agency within the Public Health Service (PHS) that funds and conducts research to improve health and advance scientific knowledge.

Senior/Key Personnel: The PD/PI and any other individual identified as senior/key personnel by the Institution in a grant application, progress report, or other submission to PHS/NIH. For this policy, the term applies specifically to the public accessibility requirement, which mandates disclosure only of financial conflicts of interest held by these senior/key personnel, as described in Section 9.

Significant Financial Interest (SFI):

1) A **domestic or foreign** financial interest consisting of one or more of the following interests of the Investigator, and those of the Investigator's spouse, domestic partner, and dependent children, that reasonably appears to be related to the Investigator's *institutional responsibilities* performed on behalf of Neurotype, and that consists of one or more of the following:

(i) **Publicly traded entity:** An SFI exists if the total of remuneration received from the entity in the previous 12 months and the value of any equity interest in the entity on the disclosure date exceeds $5,000. Remuneration includes salary and payments for services (e.g., consulting fees, honoraria, paid authorship). Equity interest includes stock, stock options, or other ownership interests measured by public prices or other reasonable market value.

(ii) **Non-publicly traded entity:** An SFI exists if the aggregated value of remuneration received from the entity in the 12 months preceding the disclosure exceeds $5,000, or if the Investigator (or their spouse or dependent children) holds any equity interest in the entity (e.g., stock, stock options, or other ownership interest).

(iii) **Intellectual property:** An SFI exists if receipt of income related to intellectual property rights or interests (e.g., patents, copyrights), exceeds $5,000 during the 12 months preceding the disclosure, related to such rights and interests.

2) Investigators must disclose any **reimbursed or sponsored travel** related to their institutional responsibilities with a value exceeding $5,000. Such travel includes trips paid on behalf of the Investigator rather than reimbursed directly, where the exact cost may not be known. The disclosure must cover the previous 12 months and include, at minimum, the purpose, sponsor or organizer, destination, and duration of each trip.

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 affiliated with a United States Institution of Higher Education

3) The term “significant financial interest” does not include, and therefore investigators are not required to disclose, the following types of financial interests:

- Salary, royalties, or other remuneration paid by Neurotype to the Investigator if the Investigator is currently employed or otherwise appointed by Neurotype, including intellectual property rights assigned to Neurotype and any agreements to share royalties related to those rights.
- Any ownership interest in Neurotype held by the Investigator, since Neurotype is a commercial or for-profit organization. This exclusion applies only if the applicant or recipient (including a sub- recipient) is a for-profit or commercial institution. • Income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions for those vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher

education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

- Income from service on advisory committees or review panels for a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

Foreign Financial Interests: Investigators must disclose all financial interests originating outside the United States, including income from seminars, lectures, teaching engagements, service on advisory committees or review panels, and reimbursed or sponsored travel, received from any foreign entity. This includes foreign institutions of higher education and foreign governments (including local or provincial governments). Disclosure is required when the aggregated amount of such income meets the threshold for disclosure (e.g., income in excess of $5,000).

4) Significant Financial Interest (SFI) Disclosure Requirements

Investigators will disclose their SFIs that are related to their "*institutional responsibilities*" as defined in the policy.

The disclosure will <u>not</u> be limited to an Investigator's research responsibilities or their funded research as this is too narrow in scope and not consistent with the 2011 regulation.

The Investigator SFI Disclosures will be retained by the Institution as part of the record maintenance requirements.

Investigators are required to disclose SFIs at the following times:

At the time of application: The PI and all other individuals who meet the definition of "Investigator" must disclose their SFIs to the DO(s). Any new Investigator who joins the project after the NIH application has been submitted or during the course of the research must also disclose their SFI(s) to the DO(s) promptly and before participating in the project, using the SFI Disclosure Form.

Annual disclosure: Each Investigator participating in research under an NIH award must submit an updated SFI disclosure at least annually (on or before April 1) during the award period. The annual disclosure must include: (1) any new information that was not previously disclosed to the DO under this policy, including SFIs associated with NIH-funded projects transferred from another institution; and (2) updated details for any previously disclosed SFI, such as changes in the value of an equity interest.

New SFIs during the award: Each Investigator participating in PHS/NIH-funded research must submit an updated SFI disclosure within 30 days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Updated disclosure of reimbursed or sponsored travel must also be submitted within 30 days of each occurrence.

5) Review of SFI Disclosures

The CEO serves as the Designated Official (DO) responsible for reviewing all SFI disclosures. Each SFI will be evaluated in relation to every PHS/NIH research application or award on which the Investigator is responsible for the design, conduct, or reporting of research, to determine whether the SFI is related to the funded research and, if so, whether it constitutes a Financial Conflict of Interest (FCOI).

The SFI disclosures will be reviewed as described below:

Prior to the issuance of a new award or before any expenditure of any awarded funds (e.g., during Just-in-Time stage): The DO will review the Investigator's SFIs before NIH issues a new award. If an FCOI is identified, an FCOI report will be submitted to NIH via the eRA Commons FCOI Module prior to any expenditure of funds.

Annual SFI disclosure: As part of the annual disclosure process, Investigators must provide updated information on any previously disclosed SFIs (e.g., revised value of an equity interest). The DO will review these updates to determine whether changes to an existing management plan are needed. Any modifications will be reflected in the next Annual FCOI report submitted to NIH, if applicable.

Ad hoc basis during award period: If a new Investigator joins a project or an existing Investigator acquires or discovers a new SFI during the project, the DO will, within 60 days:

(1) review the disclosure;
(2) determine whether the SFI is related to the PHS/NIH-funded research;
(3) determine whether an FCOI exists; and, if so,
(4) implement, on at least an interim basis, a management plan.

An FCOI report will be submitted to NIH within 60 days of identifying the FCOI.

6) Relatedness of SFIs to PHS/NIH-Funded Research and FCOI

The DO is responsible for assessing the relatedness of SFIs to NIH-funded research and determining when they constitute a FCOI.

Relatedness Test: The DO determines whether an Investigator's SFI is related to research under an NIH award. An SFI is considered "related" when the DO reasonably determines that:

- The SFI could be affected by the PHS/NIH-funded research, **or**
- The SFI is in an entity whose financial interests could be affected by the PHS/NIH-funded research.

INVESTIGATOR INVOLVEMENT: The DO may consult with the Investigator when assessing whether an SFI is related to the research.

Designated Official FCOI Determination: An FCOI exists when the DO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH- funded research ("significantly" meaning that the financial interest would have a material effect on the research).

7) Management of SFIs that Pose an FCOI

When an FCOI is identified, the DO will determine and implement management strategies to ensure the research is conducted objectively. Examples of management conditions include, but are not limited to:

1. Public disclosure of the FCOI (e.g., in publications or presentations, to study personnel, to the IRB, IACUC, or Data Safety Monitoring Board). While public posting of FCOIs is required only for senior/key personnel, the DO may require disclosure of any Investigator's FCOI as a condition of a management plan.
2. For human subjects research, disclosure of the FCOI to participants in the informed consent document
3. Appointment of an independent monitor to protect against bias in the design, conduct, and reporting of the research 4. Modification of the research plan
5. Change of personnel roles or removal from portions of the research
6. Reduction or elimination of the financial interest (e.g., divesting equity)
7. Severance of relationships creating the conflict

The DO will communicate the determination and the management plan in writing to the Investigator, the PD/PI, and the appropriate supervisor.

No expenditures on an NIH award may occur until the Investigator has met all disclosure requirements and agreed in writing to comply with the management plan. The DO will submit an FCOI report to NIH via the eRA Commons FCOI Module.

8) Monitoring Investigator Compliance

Neurotype will monitor Investigator compliance with the management plan for the duration of the NIH award.

FCOIs are made in publications, presentations, and other communications. Investigators must also disclose the FCOI in writing to study personnel and provide a copy of this disclosure to the DO for recordkeeping.

9) Public Accessibility of the FCOI Policy and FCOIs Held by Senior/Key Personnel

FCOI Policy: A copy of this FCOI policy is available on Neurotype's public website, as required by Section 4.1.10 Financial Conflict of Interest of the NIH Grants Policy Statement.

Identified FCOIs held by Senior/Key Personnel: Before any funds are spent under an NIH award, Neurotype will ensure public accessibility, by providing a written response within five

(5) business days to requests for information about any SFI that meets all three of the following criteria:

- The SFI was disclosed, is still held by Senior/Key Personnel (the PD/PI and any other individual identified by Neurotype as senior/key personnel in the application, progress report, or other NIH submission).
- Neurotype has determined that the SFI is related to the NIH-funded research.
- Neurotype has determined that the SFI constitutes an FCOI.

When applicable, Neurotype will make available at least the following information:

- Investigator's name
- Investigator's title and role with respect to the research project
- Name of the entity in which the SFI is held
- Nature of the SFI
- Approximate dollar value of the SFI in the following ranges: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000 and $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that the value cannot be readily determined by public prices or reasonable fair market value measures

The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of the institution's identification of a new FCOI, which should be requested subsequently by the requestor.

If Neurotype uses a publicly accessible website to meet this requirement, the information will be updated at least annually and within 60 days of:

- Receiving or identifying an additional SFI of Senior/Key Personnel related to the NIH-funded research that was not previously disclosed, or
- A new SFI being disclosed by Senior/Key Personnel joining the project and determined by the DO to be related and an FCOI.

Information on SFIs subject to public accessibility will remain available for at least three years from the most recent update.

10) Reporting Identified Financial Conflicts of Interest

Prior to spending any funds under an NIH-funded award, Neurotype will submit an identified FCOI report to NIH, in accordance with NIH regulations, for any Investigator's SFI determined to be an FCOI. Neurotype will also ensure that the Investigator has agreed to and begun implementing the associated management plan.

Neurotype will designate an institutional official to act as the FCOI Signing Official (FCOI SO) in the eRA Commons FCOI Module. The FCOI SO is authorized to submit FCOI reports to NIH. FCOI reports are submitted only when an award is active and an FCOI has been identified (i.e., no award means no FCOI report, and no FCOI means no FCOI report).

The NIH eRA Commons FCOI Module User Guide, available at the following location, provides instructions for preparing and submitting FCOI reports.

https://www.era.nih.gov/files/fcoi_user_guide.pdf

Initial (Original) FCOI Reports: The report must include all information required under 42 CFR 50.605(b)(3) or as outlined in the NIH FAQH.5.

- **Prior to the expenditure of funds:** If an FCOI is identified at the time a new NIH award is issued, the FCOI SO will submit an "Original" FCOI report (2011 FCOI) through the eRA Commons FCOI Module before any funds are spent.
- **Within 60 days during the award:** If an FCOI is identified during the award period (e.g., a new SFI is disclosed or a new Investigator joins the project), the Institution must submit an Original FCOI report within 60 days of identifying the FCOI.

Annual FCOI Reports: For the duration of an award, including any extensions with or without funds, the Institution must submit an annual FCOI report to NIH. This report will indicate whether each previously reported FCOI is still being managed or no longer exists and describe any changes to the management plan, if applicable.

- The annual report must be submitted at the same time as the Research Performance Progress Report (RPPR) or multi-year progress report, and at the time of any grant extension, following NIH guidance (see NIH's FAQ H.2). NIH creates the opportunity for the FCOI SO to submit the Annual report 75 days prior to the next budget period start date for continuation awards. NIH will notify the Institution by an email when an annual report is due.
- Annual FCOI reports are not required at grant closeout.

Revision (or Mitigation) FCOI Reports: After completing a retrospective review, the Institution will submit a Revision report to NIH if new information about the FCOI is discovered, or a Mitigation report if the review finds that bias has occurred.

Types of FCOI Reports Summary Chart for NIH:

Required FCOI Reports to NIH via eRA Commons FCOI Module		
REPORT	**CONTENT**	**REQUIRED WHEN**
New FCOI Report (Initial submission)	Grant number; PI; name of entity with FCOI; nature of FCOI; value of the financial interest (in required increments); description of how the financial interest relates to the research; key elements of the management plan	Prior to the expenditure of funds on a new award; within 60 days of identifying any new FCOI during the award period.

Annual FCOI Report	Status of the FCOI (whether it is still being managed or no longer exists) and any changes to the management plan, if applicable.	Submitted annually at the same time as the annual progress report, multi-year progress report, or at the time of a grant extension.
Revised FCOI Report	If applicable, updates to a previously submitted FCOI report to describe actions that will be taken to manage the FCOI going forward or to revise the original report.	Following a retrospective review when noncompliance with the regulation is identified, if applicable.
Mitigation Report	Project number; project title; contact PI/PD; name of Investigator with FCOI; name of entity with FCOI; reason for review; detailed methodology, findings, and conclusions.	After a retrospective review when bias is found.

11) Training Requirements for Investigators

Each Investigator will be informed of Neurotype's FCOI Policy and trained on their responsibility to disclose foreign and domestic SFIs under this policy and the FCOI regulation at 42 CFR Part 50 Subpart F. Training must be completed before an Investigator engages in PHS/NIH-funded research, at least once every four years, and promptly (as described below) when any of the following occur:

- Neurotype revises this policy or related procedures in a way that affects Investigator requirements.
- An Investigator is new to Neurotype research under an NIH award (training must be completed before participating in the research).
- Neurotype determines that an Investigator has not complied with this policy or with a management plan issued under it (training must be completed within 30 days as directed by the DO).

To meet the NIH training requirement, Neurotype requires Investigators to complete the NIH FCOI Training Tutorial, print and retain the Completion Certificate for audit purposes. Certificate should be shared with the DO.

Neurotype also requires Investigators to review the NIH Virtual Seminar presentation on FCOI compliance from the following location: https://www.youtube.com/watch?v=D292YZ6BX24.

12) Noncompliance With FCOI Policy and Corrective Actions

If Neurotype identifies an SFI that was not disclosed, reviewed, or managed in a timely manner, the DO will, within 60 days: review the SFI; determine whether it is related to NIH-funded

research; determine whether it constitutes an FCOI; and, if so, implement an interim management plan describing actions that have been and will be taken to manage the FCOI going forward. Neurotype will also submit an FCOI report to NIH via the eRA Commons FCOI Module.

In cases of noncompliance, including:

- Failure by the Investigator to disclose an SFI that is later determined to constitute an FCOI
- Failure by the institution to review or manage an FCOI
- Failure by the Investigator to comply with an established management plan

Neurotype will, within 120 days of identifying noncompliance:

1. Conduct a retrospective review of the Investigator's activities and the NIH-funded research to determine whether the research, or any part of it, was biased in the design, conduct, or reporting.
2. Document the retrospective review in accordance with 42 CFR 50.605(a)(3)(ii)(B) or NIH's FAQ I.2.

If bias is found, Neurotype will promptly notify NIH and submit a mitigation report as required by 42 CFR 50.605(a)(3)(iii) or as described in NIH's FAQ I.3 to NIH via the FCOI Module.

The report will include:

- The impact of the bias on the research project, and
- The plan of action or corrective steps taken to eliminate or mitigate the effect of the bias.

Neurotype will thereafter submit FCOI reports annually to NIH as required by the regulations and the terms and conditions of the award. Depending on the circumstances, Neurotype may implement additional interim measures regarding the Investigator's participation in the research until the retrospective review is complete. If no bias is found, no further action is required.

13) Clinical Research Requirements

If HHS determines that a PHS-funded clinical research project evaluating the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with an unmanaged or unreported FCOI, Neurotype will require the Investigator to disclose the conflict in every public presentation of the research results and to request an addendum to previously published presentations.

14) Subrecipient Requirements

A subrecipient relationship exists when federal funds flow from or through Neurotype to another individual or entity that will carry out a substantive portion of a PHS-funded research project and is accountable to Neurotype for programmatic outcomes and compliance. Subrecipients (e.g. collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees) are subject to Neurotype's terms and conditions. Neurotype will take

reasonable steps to ensure that all subrecipient Investigators comply with the federal FCOI regulations at 42 CFR Part 50 Subpart F. Neurotype will include in each written agreement with a subrecipient terms specifying whether Neurotype's FCOI Policy or the subrecipient's own FCOI policy will apply to subrecipient Investigators (see NIH Grants Policy Statement Section 15.2.1 on Written Agreements).

- **If the subrecipient's FCOI policy applies:**
  The subrecipient institution must certify in the agreement that its policy complies with federal FCOI regulations. The agreement will specify the timeframe for the subrecipient to report identified FCOIs to Neurotype in time for Neurotype to meet NIH reporting deadlines (i.e., before funds are spent and within 60 days of the subrecipient identifying an FCOI). Typically, this means requiring subrecipients to report FCOIs to Neurotype within 50–55 days of identification. Neurotype's DO will then submit the subrecipient FCOI report to NIH through the eRA Commons FCOI Module.

- **If the subrecipient cannot certify compliance:**
  The agreement will specify that Neurotype's FCOI Policy applies. In this case, subrecipient Investigators must disclose their SFIs to Neurotype. The SFI disclosure must include SFIs that are directly related to the subrecipient's work for Neurotype. The agreement will allow sufficient time for Neurotype to review, manage, and report any resulting FCOIs. When an FCOI is identified, Neurotype will implement a management plan, monitor compliance by the subrecipient Investigator, and submit the required FCOI report to NIH via the eRA Commons FCOI Module.

15) Maintenance of Records

Neurotype will maintain records of all Investigator financial interest disclosures, Neurotype's review and response to those disclosures (whether or not they resulted in a determination of an FCOI), and any actions taken under this policy or through retrospective review. These records will be retained for at least three years from the date of submission of the final expenditures report, or for longer periods as specified in 2 CFR 200.334 for specific situations. Neurotype will retain these records for each competitive segment as required by regulation.

16) Enforcement Actions for Investigator Noncompliance

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Investigators who fail to comply may be subject to disciplinary action, which can include termination of employment or contract, formal warning letter or official notice of disciplinary action, restrictions on the use of research funds, and/or disqualification from further participation in any PHS/NIH-funded research, as deemed appropriate.

17) Useful FCOI and NIH Resources

- NIH e-mail address for FCOI-related inquiries: fcoicompliance@mail.nih.gov
- FCOI Regulation 42 CFR Part 50 Subpart F - Promoting Objectivity in Research
- Financial Conflict of Interest
- FCOI Training
- Frequently Asked Questions (FAQs)
- NIH "Welcome Wagon" Letter: Information for New Recipient Organizations

18) Point Of Contact

If you have a question related to the FCOI Policy of Neurotype, or would like to disclose a financial interest, contact us using the information below:

Contact:

Scott Burwell, PhD
Chief Executive Officer
Neurotype Inc.
scott@neurotype.io