Ceretype Neuromedicine

Financial Conflict of Interest (FCOI) Policy

Pursuant to 42 CFR Part 50, Subpart F

I. Purpose

This policy establishes standards to ensure that the design, conduct, and reporting of research funded under grants, cooperative agreements, and contracts from the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies will be free from bias resulting from Investigator financial conflicts of interest. This policy is adopted pursuant to the requirements of 42 CFR Part 50, Subpart F (Promoting Objectivity in Research).
Ceretype Neuromedicine provides advanced functional MRI Software as a Medical Device (SaMD) and services for clinical trials and therapeutic applications in neuropsychiatry.

Ceretype recognizes the heightened importance of transparency and objectivity in its research activities. This policy applies to all Investigators involved in PHS-funded research and establishes a framework for identifying, disclosing, reviewing, managing, and reporting financial conflicts of interest.

II. Scope and Applicability

This policy applies to:

- All Investigators (as defined below) who are responsible for the design, conduct, or reporting of research funded by NIH or other PHS agencies, including grants, cooperative agreements, and contracts.
- All proposed and ongoing PHS-funded research activities conducted by Ceretype Neuromedicine.
- Subrecipients and collaborators as specified in Section XIV of this policy.

Note: Phase I SBIR/STTR applicants are generally exempt from the FCOI regulation. However, this policy applies to all other NIH-funded research conducted by Ceretype Neuromedicine.

III. Definitions

Designated Official: The individual within Ceretype Neuromedicine designated to solicit, review, and manage financial interest disclosures and determine whether any reported Significant Financial Interest constitutes a Financial Conflict of Interest. The Designated Official for Ceretype Neuromedicine is the Chief Operating Officer.

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

Institution: Ceretype Neuromedicine, a domestic entity that is applying for or that receives PHS research funding.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of Ceretype Neuromedicine, including but not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on advisory panels.

Investigator: The project director or principal investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research, or who applied for such funding. This includes any collaborators, consultants, and subrecipient investigators that meet this definition.

Manage: 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.

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).

PHS-Funded Research: Research proposed or funded by a PHS funding component through a grant, cooperative agreement, or contract. The term includes funded and proposed subprojects under a program project grant or center grant.

Research: 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.

Senior/Key Personnel: The PD/PI and any other person identified as senior/key personnel by Ceretype Neuromedicine in the grant application, progress report, or any other report submitted to the PHS by Ceretype Neuromedicine.

Significant Financial Interest (SFI): 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:

- **Publicly Traded Entity:** When the aggregate value of any remuneration received from a publicly traded 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.
- **Non-Publicly Traded Entity:** When any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, OR the Investigator (or spouse/dependent children) holds any equity interest in the entity (e.g., stock, stock option, or other ownership interest), regardless of value.
- **Intellectual Property Rights and Interests:** Income related to such rights and interests exceeding $5,000 upon receipt of income related to such rights and interests.
- **Reimbursed or Sponsored Travel:** 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 is not readily available) related to institutional responsibilities, with certain exclusions noted below. Investigators must disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

Exclusions from SFI: The following are NOT considered Significant Financial Interests:

- Salary, royalties, or other remuneration paid by Ceretype Neuromedicine to the Investigator if the Investigator is currently employed or otherwise appointed by Ceretype Neuromedicine.
- Income from investment vehicles, such as mutual funds and retirement accounts, where the Investigator does not directly control the investment decisions made in these vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency.

- Income from service on advisory committees or review panels for a Federal, state, or local government agency.
- Income from seminars, lectures, teaching, or service at an institution of higher education as defined at 20 U.S.C. 1001(a).
- Income from seminars, lectures, teaching, or service at an academic teaching hospital, medical center, or research institute affiliated with an institution of higher education.

IV. Investigator Disclosure Requirements

A. Timing of Disclosures

Each Investigator must submit a disclosure of all Significant Financial Interests (and those of the Investigator's spouse and dependent children) related to the Investigator's Institutional Responsibilities:

1. At the time of application for PHS-funded research (prior to submission of the proposal).
2. At least annually during the period of the award, in accordance with the schedule established by Ceretype Neuromedicine.
3. Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

B. Content of Disclosures

Disclosures must include sufficient information to enable the Designated Official to determine whether a SFI exists and whether it constitutes a FCOI, including:

- The name of the entity in which the SFI is held.
- The nature of the financial interest (e.g., equity, consulting fees, intellectual property income).
- The approximate dollar value or value range of the interest.
- A description of how the interest relates to PHS-funded research.
- For reimbursed or sponsored travel: the purpose, sponsor/organizer, destination, and duration.

C. Special Considerations for Medical Device Startups

Important: *Because Ceretype Neuromedicine is a medical device company, Investigators who hold equity interests in the company (including stock, stock options, or other ownership interests) and who are conducting research on the company's products will likely have Significant Financial Interests that require disclosure and management. Investigators must disclose any equity they hold in Ceretype Neuromedicine when they are involved in research on Ceretype's products or technology.*

V. Training Requirements

Each Investigator must complete FCOI training:

1. Prior to engaging in PHS-funded research.
2. At least every four (4) years.
3. Immediately when any of the following circumstances apply:
    - Ceretype Neuromedicine revises its FCOI policy in a manner that affects the requirements of Investigators.
    - An Investigator is new to Ceretype Neuromedicine.
    - An Investigator is found to be non-compliant with this policy or a related management plan.

Training must address the applicable FCOI regulations, Ceretype Neuromedicine's FCOI policy, Investigator disclosure responsibilities, and the consequences of non-compliance. Ceretype Neuromedicine may use the NIH FCOI Tutorial available at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html or develop equivalent internal training materials.

VI. Institutional Review and Determination Process

A. Review of Disclosures

The Designated Official shall review each SFI disclosure and determine whether any disclosed SFI is related to PHS-funded research and, if so, whether the SFI constitutes a Financial Conflict of Interest. A SFI is related to PHS-funded research when the Designated Official reasonably determines that the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research.

B. Determination of FCOI

A FCOI exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of PHS-funded research. The Designated Official will document the basis for each determination.

VII. Management of Financial Conflicts of Interest

A. Management Plan

When a FCOI is identified, the Designated Official shall develop and implement a management plan that specifies the actions taken to manage the FCOI. The management plan must be developed and implemented prior to the expenditure of any funds under the applicable PHS-funded research project.

B. Management Plan Elements

Management plans may include, but are not limited to, one or more of the following:

- Public disclosure of the FCOI (e.g., in publications and presentations arising from the research).
- Disclosure of the FCOI directly to participants enrolled in human research.
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias.
- 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.
- Independent review of the research by qualified individuals.

C. Monitoring

The Designated Official will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

VIII. Reporting to NIH

A. Initial FCOI Report

Prior to the expenditure of any funds under a PHS-funded research project, Ceretype Neuromedicine shall submit an initial FCOI report to the PHS Awarding Component (NIH) via the eRA Commons FCOI Module for each Investigator who has an identified FCOI.

B. Subsequent Reports

Ceretype Neuromedicine shall submit a FCOI report to NIH:

- Within sixty (60) days of identifying a new FCOI for an Investigator during an ongoing PHS-funded research project (e.g., new Investigator, new SFI, or existing SFI newly determined to be a FCOI).
- Annually, providing the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project.

C. Content of FCOI Reports

Each FCOI report must include:

- The grant number.
- PD/PI name.
- Name of the Investigator with the FCOI.
- Name of the entity with which the Investigator has the FCOI.
- Nature of the financial interest (e.g., equity, consulting fees, travel reimbursement, honoraria).
- Value of the financial interest (in dollar ranges: $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 a value cannot be readily determined).
- A description of how the financial interest relates to the PHS-funded research.
- Basis for the Institution's determination that the financial interest conflicts with the research.
- Key elements of the management plan.

IX. Retrospective Review and Mitigation

A. Retrospective Review

If Ceretype Neuromedicine identifies a SFI that was not disclosed in a timely manner by an Investigator, or was not previously reviewed by Ceretype Neuromedicine during an ongoing PHS-funded research project, the Designated Official shall, within sixty (60) days:

- Review the SFI.
- Determine whether it is related to PHS-funded research.
- Determine whether a FCOI existsand, if so
- Implement a management plan on at least an interim basis.

The retrospective review must be completed and documented within one hundred and twenty (120) days of the determination of noncompliance.

B. Mitigation Report

Whenever a retrospective review determines that PHS-funded research may have been biased in the design, conduct, or reporting, Ceretype Neuromedicine shall notify NIH promptly and submit a mitigation report that includes:

- The grant number.
- PD/PI name.
- Name of the Investigator with the FCOI.
- Name of the entity with which the Investigator has the FCOI.
- Reason(s) for the retrospective review.
- Detailed description of the financial interest.
- Basis for the Institution's determination that the financial interest is related to the research and why the financial interest is a conflict.
- Description of the impact of the bias on the research project.
- The Institution's plan of action to eliminate or manage the FCOI going forward.

X. Public Accessibility

A. Policy Availability

Ceretype Neuromedicine shall make this FCOI policy available via a publicly accessible website or upon request. If Ceretype Neuromedicine does not maintain a publicly accessible website, this policy shall be made available to any requestor within five (5) business days of a written request.

B. FCOI Information

Prior to the expenditure of funds under a PHS-funded research project, Ceretype Neuromedicine shall ensure public accessibility, via written response to any requestor within five (5) business days of information concerning any SFI that meets the following criteria:

- The SFI was disclosed and is still held by the Investigator.
- A determination was made that the SFI is related to the PHS-funded research. and
- A determination was made that the SFI is a Financial Conflict of Interest.

The information to be made available shall include:

- The Investigator's name.
- The Investigator's title and role with respect to the research project.
- The name of the entity in which the SFI is held.
- The nature of the SFI (e.g., equity, consulting fees, travel reimbursement) and
- The approximate dollar value of the SFI (dollar ranges may be used) 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.

XI. Subrecipient Requirements

When Ceretype Neuromedicine carries out PHS-funded research through a subrecipient (subcontractor or consortium member), Ceretype Neuromedicine shall take reasonable steps to ensure subrecipient Investigator compliance with the FCOI regulation. Specifically:

- A written agreement shall be established with each subrecipient that specifies whether the subrecipient's own FCOI policy or Ceretype Neuromedicine's FCOI policy will apply.

If the subrecipient's policy applies: The agreement shall specify time period(s) for the subrecipient to report all identified FCOIs to Ceretype Neuromedicine to enable timely reporting to NIH. The subrecipient must certify compliance with the FCOI regulation.

If Ceretype Neuromedicine's policy applies: The agreement shall specify that subrecipient Investigators must comply with Ceretype Neuromedicine's FCOI policy, including disclosure, training, and management plan requirements.

- Ceretype Neuromedicine shall report all subrecipient FCOIs to NIH in accordance with the reporting timelines and requirements described in Section VIII.

XII. Record Retention

Ceretype Neuromedicine shall maintain records relating to all Investigator disclosures of financial interests and Ceretype Neuromedicine's review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a FCOI) and all actions under this policy, for at least three (3) years from the date the final expenditure report is submitted to the PHS, or where applicable, from other dates specified in 45 CFR 75.361.

Records to be maintained include, but are not limited to:

- All financial interest disclosure forms submitted by Investigators.
- All documentation of the Designated Official's review and determination.
- All management plans and documentation of actions taken.
- All FCOI reports submitted to NIH.
- All retrospective reviews and mitigation reports.
- Training completion records for all Investigators.

XIII. Enforcement and Sanctions

A. Non-Compliance

Failure by an Investigator to comply with this policy may result in sanctions, which may include but are not limited to:

- Suspension or termination from participation in PHS-funded research.
- Letter of reprimand placed in the Investigator's personnel file.
- Imposition of conditions on future activities.
- Removal from the grant as senior/key personnel.
- Termination of employment.

B. Notification to NIH

If Ceretype Neuromedicine is unable to satisfactorily manage a FCOI, Ceretype Neuromedicine will promptly notify the NIH Awarding Component.

XIV. Certification

Ceretype Neuromedicine certifies, in each application for PHS funding, that it:

- Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS.
- Shall promote and enforce Investigator compliance with this policy and the FCOI regulation.
- Shall manage FCOIs and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with the regulation.
- Agrees to make information available, upon request, to the HHS relating to any Investigator disclosure of financial interests and Ceretype Neuromedicine's review of, and response to, such disclosure.

XV. Policy Submission to NIH

This policy shall be submitted to NIH via the eRA Commons Institution Profile (IPF) Module or the appropriate NIH designee in accordance with NIH Guide Notice NOT-OD-21-002. Ceretype Neuromedicine shall ensure that the policy submission status reflects "Certification Verified" in the IPF Module before submission of any NIH grant application subject to this regulation.

XVI. Regulatory References

- 42 CFR Part 50, Subpart F - Promoting Objectivity in Research
- 45 CFR Part 94 - Responsible Prospective Contractors
- NIH Grants Policy Statement (GPS), Section 4.1.10
- NIH Guide Notice NOT-OD-21-002 (September 30, 2020)
- NIH FCOI Policy Development Checklist

XVII. Contact Information

Questions regarding this policy should be directed to:
Designated Official: Niraj Doshi
Title: Chief Operating Officer
Email: ndoshi@ceretype.com

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