

POLICY NAME: CONFLICT OF INTEREST	
MANUAL: REGULATORY OPERATIONS	RESPONSIBLE EXECUTIVE: ROBERT WEINSTEIN
DEPARTMENT: REGULATORY	DATE LAST REVIEWED: APRIL 29, 2021

I. PURPOSE:

The purpose of this Conflict of Interest Policy (the “Policy”) is to ensure Synaptogenix, Inc.’s (“Synaptogenix” or “Company”) compliance with federal regulations promoting objectivity in research (42 CFR Part 50 Subpart F). Robert Weinstein, the Company’s Chief Financial Officer (“Compliance Officer”), is responsible for ensuring implementation and enforcement of this policy. Violation of any part of this policy may constitute cause for disciplinary or other administrative action pursuant to Synaptogenix policy.

II. SCOPE:

This policy applies to all Synaptogenix investigators participating in Public Health Service (“PHS”) funded research, including investigators applying for federal funding (each, an “Investigator” collectively, “Investigators”) as well as employees who serve as study personnel, including sub-Investigators, research coordinators, statisticians, and anyone on the study team with a potential conflict of interest. Additionally, anyone who is responsible for or in a position to influence the design, review, conduct, or reporting of research must complete a Financial Conflict of Interest Disclosure Form, as attached to this Policy.

III. DEFINITIONS:

Clinical Trial means any sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or other clinical procedures.

Family means any member of the Investigator’s immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights).

Financial Interest does NOT include:

- A. salary, royalties, or other remuneration from Synaptogenix;
- B. income from the authorship of academic or scholarly works;
- C. equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her research responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator’s research responsibilities, and:

- A. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or
- B. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
- C. if with a non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or
- D. is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through Synaptogenix, or
- E. is reimbursed or sponsored travel related to their research responsibilities.

Financial Conflict of Interest means a Significant Financial Interest that Synaptogenix reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

Public Health Service or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated.

Research means a systematic investigation, study, or experiment designed to 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).

Sponsored Project means an internally or externally funded clinical trial, research or service project.

IV. GENERAL INFORMATION AND TRAINING

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest or circumstances creating the appearance of a conflict of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and Synaptogenix to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy.

Each Investigator will be trained on this policy prior to engaging in PHS-funded research, and in any event, at least every four(4) years. Investigators will receive immediate training if i) the Policy is revised; ii) an Investigator is new to the Company; or iii) an Investigator is not in compliance with the Policy or any Conflict of Interest management plan.

V. PROCEDURE

DISCLOSURE OF FINANCIAL INTERESTS

1. All Investigators are required to disclose their outside financial interests related to research as defined above to Synaptogenix on an annual and on an ad hoc basis, as described below. Investigator disclosures should be current at the time of any application for PHS-funded research and during the period of any award. The Compliance Officer is responsible for the distribution, receipt, processing, review and retention of disclosure forms. Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, the Company's general counsel ("Legal Counsel"), will assist with the review of disclosure forms and any necessary follow up.

- a. Annual Disclosures: All Investigators must disclose their Significant Financial Interests that are related to the investigator's research on an annual basis. All forms should be submitted to the Compliance Officer or designee by January 31.
- b. Ad hoc Disclosures: In addition to annual disclosure, certain situations require ad hoc disclosure. Prior to entering into Sponsored Projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit an updated disclosure of his or her Significant Financial Interests with the outside entity. In addition, all Investigators must submit an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.
- c. Travel: Investigators must also disclose reimbursed or sponsored travel related to their research responsibilities, as defined above. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Compliance Officer will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

DISCLOSURE REVIEW

1. If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Compliance Officer with the support of Legal Counsel for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, Synaptogenix will take action to manage, reduce or eliminate the conflict, as appropriate. A Financial Conflict of Interest will exist when Synaptogenix determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsored research. This determination is based on an analysis that includes, but is not limited to:
 - A. the nature of the science;
 - B. the nature of the overlapping interests;
 - C. how closely the interest is tied to the research;
 - D. the degree to which the interest may be affected by the research;
 - E. the degree of risk that the research poses to human subjects and the integrity of the research; and
 - F. the degree to which the conflict can be effectively managed.
2. If the Compliance Officer determines that there is a Financial Conflict of Interest that can be managed, a written management plan will be developed. No research may begin until the affected Investigator formally agrees to the proposed management plan and signs the written management plan. Management plans may include, but are not limited to the following actions:
 - A. Public disclosures of Significant Financial Interests in abstracts, publications, presentations, press releases, and applications of proposals for research funding;
 - B. Disclosure of financial conflicts of interests to participants
 - C. Monitoring of research by independent reviewers of an oversight committee
 - D. Selection of a non-conflicted Investigator
 - E. Change of personnel or personnel responsibilities, or disqualification of personnel from participating in all or a portion of the research;
 - F. Severance of relationships that create actual or potential conflicts;
 - G. Participation of non-conflicted person(s) in evaluation of the research data and/or development of manuscripts.

3. The Compliance Officer will oversee compliance with any implemented management plan.
4. The Compliance Officer will be responsible for making required reports to NIH, including regular progress reports and reports of conflicts that may have biased the design, conduct or reporting of PHS-funded research.
5. The Compliance Officer will maintain all Financial Conflict of Interest records in accordance with regulatory requirements.

VI. ATTACHMENTS

Financial Interests Report

**FINANCIAL CONFLICT OF INTEREST
DISCLOSURE FORM**

Financial Interests Report
(submitted pursuant to the requirements of the Conflict of Interest Policy)

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Conflict of Interest

Financial Conflict of Interest Disclosure Form
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Name: _____

I am reporting on activities: for the year _____
 as an addendum to my most recent report

<input type="checkbox"/> yes	<input type="checkbox"/> no	<p>1. Compensation. In the last twelve months (or as of the date of disclosure), have you or a member of your Family (any dependent children or your spouse) received compensation from an external entity for activities or services such as consulting, honoraria, advisory board membership, and the like? If yes, furnish information on Page 3 of 3.</p> <p>EXCEPTION: Do NOT include compensation received from U.S. Federal, state or local governmental agencies.</p>
<input type="checkbox"/> yes	<input type="checkbox"/> no	<p>2. Travel. In the last twelve months (or as of the date of disclosure), have you had any travel reimbursed or sponsored by an external entity? If yes, furnish information on Page 3 of 3.</p> <p>EXCEPTION: Do NOT include travel sponsored or reimbursed by U.S. Federal, state or local governmental agencies.</p>
<input type="checkbox"/> yes	<input type="checkbox"/> no	<p>3. Equity. In the last twelve months (or as of the date of disclosure), have you or a member of your Family held or acquired stock, stock options, or another ownership interest in a publicly-traded or privately-owned entity involved in the research? If yes, furnish information on Page 3 of 3.</p> <p>EXCEPTION: Do NOT include equity interests or income from investment vehicles, such as mutual funds and retirement accounts for which you do not directly control the investment decisions.</p>
<input type="checkbox"/> yes	<input type="checkbox"/> no	<p>4. Intellectual Property. In the last twelve months (or as of the date of disclosure), do you or a member of your family have rights to and/or receive royalties or other income from intellectual property (including, patents copyrights and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity involved in the research? If yes, furnish information on Page 3 of 3.</p>

Financial Conflict of Interest Disclosure Form
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Certification:

I have read and understand the organization's policy on Conflict of Interest and have completed this report to the best of knowledge and belief. If required, I will comply with any conditions or restrictions imposed by this organization to manage any real or perceived conflicts. Should my outside financial or managerial interests, or those of my Family, change in a way that results in different answers to any of the questions asked in this report, I agree to submit a revision.

(Signature)

(Date)

