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# THE LIEBER INSTITUTE FOR BRAIN DEVELOPMENT

## POLICY ON CONFLICT OF COMMITMENT AND CONFLICT OF INTEREST (*Effective as of March 12, 2018*)

The Lieber Institute (the “Institute”) encourages its members to engage in the translation of research and scholarship for the benefit and well-being of the public. Institute Staff (as defined below) serve these goals through their primary commitment to research and collaborations with fellow Institute Staff. To the degree that is consistent with that commitment, it is also appropriate and often valuable for Institute Staff to engage in public and private professional and academic activities beyond their Institute responsibilities. Such activities may include public service, pro bono work and consulting activities that may benefit the Institute Staff, the Institute, and the greater public. A divergence can occur between the personal interests of Institute Staff and his or her professional obligations to the Institute, in which case a Conflict of Commitment or Conflict of Interest can arise. The purpose of this Policy on Conflict of Commitment and Conflict of Interest (the “Policy”), is to assist Institute Staff in determining whether and to what extent such other activities may conflict with their primary commitments to the Institute; to clarify expectations about disclosing interests and activities that might result in conflicts, and; to identify means to manage, reduce or eliminate such conflicts.

This Policy covers the Institute Staff of the Institute, except as noted below. The conflict of interest provisions of this Policy also apply to the Institute itself, insofar as specific financial or fiduciary interests of the Institute as an institution may represent a source of bias or perceived bias in the conduct and reporting of research. Such interests include, but are not limited to, royalties or equity obtained as a result of licensing technology to outside entities and income or other Financial Interests obtained in other ways.

This Policy will be interpreted in a manner consistent with the Institute’s Intellectual Property Policy, and consistent with applicable federal and state statutes and implementing regulations. In the event of a conflict with this Policy, such statutes and regulations shall supersede the provisions of this Policy. This Policy is separate and distinct from any other policy of the Institute, the Johns Hopkins University School of Medicine (“JHU”) and any other entity that may be applicable to an Institute Staff member.<sup>1</sup> Compliance with this Policy does not relieve an Institute Staff member from any obligation under such other policy or under any applicable law.

The Institute has the right to amend, modify, or revise this Policy at any time with or without notice to Institute Staff.

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<sup>1</sup> In particular, Institute Staff members with faculty appointments at JHU should be aware that they are also subject to JHU’s Conflict of Commitment and Conflict of Interest Policy.

## **POLICY DEFINITIONS**

A ***Conflict of Commitment*** occurs when an Institute Staff member's Outside Commitments compromise or may compromise his or her ability to meet the Institute Staff member's obligations to the Institute.

A ***Conflict of Interest*** is a potential or actual divergence between an individual's private interests and his or her professional obligations to the Institute such that an independent observer might reasonably question whether the individual's professional actions or decisions, including the ethical and objective conduct of scholarship or Research, are determined by considerations of personal gain, financial gain or otherwise.

***Committee*** is a body consisting of senior members of the research staff of the Institute as well as senior members of the Institute administration appointed by the Conflicts Officer, serving ex officio and legal counsel.

***Fiduciary Interest*** refers to a legal and/or ethical obligation on the part of an Institute Staff member to act in the best interests (*i.e.*, the financial success) of another. Examples of fiduciary roles include, but are not limited to, membership on a board of directors or a management role in a company or partnership.

***Financial Interest (FI)*** means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees, advisory, in-kind support, or honoraria); equity interests, either through the Institute or Institute Staff member (e.g., stocks, stock options, warrants or ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

Specifically ***excluded*** from the definition of Financial Interest are:

- (1) Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.
- (2) Income from service on advisory committees or review panels for public or non-profit entities.
- (3) Investments in mutual funds or retirement programs if the investigator has no practical control over the management of those investments.
- (4) Royalties paid by the Institute.

***Financially Interested Company*** is a commercial entity whose financial interests would reasonably appear to be affected by the conduct or outcome of the Research. Examples include, but are not limited to, companies that hold patent rights for discoveries, drugs or devices being studied in research protocols or companies that provide financial or in-kind support for Research projects. This term includes companies that compete with the sponsor of the Research or the manufacturer of the investigational product, if the Institute Staff member knows that the financial interests of such a company would reasonably appear to be affected by the Research. This term

also includes any entity acting as the agent of a financially interested company (e.g., a contract research organization).

***Human Subjects Research*** includes all research meeting the definition of “research” performed with “human subjects” as defined in the Federal Common Rule (45 C.F.R. Part 46 and 21 C.F.R. Part 56), regardless of the source of Research funding or whether the Research is otherwise subject to federal regulation. In the event that the Common Rule definitions of “human subject” or “research” are modified through rulemaking, any such revisions shall apply for the purposes of this Policy.

***Institute Staff*** includes investigators, members of the research staff (professors, scholars, and scientists with research titles), postdoctoral fellows, research associates and assistants (including full-time graduate students), as well as other professional and senior staff who are compensated or otherwise supported by the Institute for their services. It also applies to those who appear to act as agents of the Institute in using, controlling, or assigning to others the use of Institute facilities and resources in the conduct of Research. Institute Staff may include other individuals, pursuant to contractual arrangements, who participate in Research conducted under the auspices of the Institute and Investigators on sub-awards from the Institute. While the immediate family of Institute Staff are not covered by this Policy, compliance with this Policy and applicable federal regulations may require reporting of the financial and fiduciary interests of the immediate family of certain Institute Staff members. The immediate family of an Institute Staff member includes her or his spouse, domestic partner, and/or dependent children.

***Institutional Responsibilities*** means the responsibilities and roles an Institute Staff member is assigned in the course of their employment with the Institute. This includes for example, research, teaching and administrative obligations.

***Investigator*** refers to the Project Director/Principal Investigator, any other person identified as Senior/Key personnel in a grant application, progress report, or other report submitted to an external sponsor, and others who direct or can materially influence the Research, or who are responsible for the design, conduct, and reporting of such Research. This definition is independent of whether one is appointed or employed by the Institute.

***Outside Commitment(s)*** includes all services, consulting or other business activities and external professional or academic endeavors, public service or pro bono work, to, or on behalf of, Outside Entities. For clarity purposes, services provided to JHU in connection with an Institute Staff member’s concurrent faculty appointment at JHU, are not considered Outside Commitments for purposes of this Policy.

***Outside Commitment and/or Financial Interest*** is a scenario in which an Institute Staff member has an Outside Commitment and/or has a Financial Interest in an Outside Entity independent of an agreement between the Institute and the Outside Entity. Examples of Outside Commitments and/or Financial Interests include, but are not limited to: consulting or advising, serving on scientific advisory boards, speaking or lecturing, providing expert testimony or legal consulting, Financial Interest in or from an Outside Entity that has optioned or licensed Institute intellectual property or intellectual property developed by Institute Staff outside of the Institute, ownership

of stock, equity, stock options or other ownership stakes, fiduciary and/or management roles for an Outside Entity.

***Outside Entity(ies)*** is any for-profit or not-for-profit entity, whether private or governmental. This includes, for example, foundations, pharmaceutical companies, professional organizations, and academic societies.

***Research*** is defined as a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research and product development. Includes, but is not limited to, any such activity for which research funding is available from external sources through a grant or cooperative agreement; for example, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, and research resources awards.

***Significant Financial Interest (SFI) is***

(1) A Financial Interest consisting of one or more of the following interests of the Institute Staff member (and those of his/her spouse and dependent children) that reasonably appears to be related to the Institute Staff member'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 Outside Entity in the 12 months preceding the disclosure and the value of any equity interest in the Outside Entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the Outside Entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Institute Staff (or his or her spouse or dependent children) holds any equity interest (e.g., stock, stock option, 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.

(2) Institute Staff also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Institute Staff and not reimbursed to the Institute Staff so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education

## I. CONFLICT OF COMMITMENT

A.	PRIMARY COMMITMENT OF INSTITUTE STAFF.....	5
B.	NECESSITY FOR A WRITTEN REPORT OF POTENTIAL CONFLICTS .....	5
C.	SITUATIONS IN WHICH A WRITTEN REPORT MUST BE MADE.....	6
D.	REPORTING PROCEDURES.....	8
E.	ACTIVITIES SUBJECT TO HIGHTENED REVIEW.....	8
F.	RESEARCH AND PUBLICATIONS.....	9
G.	ANNUAL AND NEW HIRE CERTIFICATION REQUIREMENTS.....	9

### A. PRIMARY COMMITMENT OF INSTITUTE STAFF

Acceptance of a position at the Institute entails a commitment to assign first priority to the needs and goals of the Institute, consistent with the Institute’s affiliation with JHU. At the same time, it is recognized that participation of Institute Staff in activities of government, professional associations, industry, and other private institutions may serve the research mission of the Institute. The experience and enhanced national status that such participation brings to the Institute Staff member is shared indirectly by the Institute, and these outside activities often contribute to the richness and diversity of the research community. Moreover, as a result of such activities, society may benefit from the dissemination of knowledge and technology developed within the Institute.

A commitment to serve an institution, agency, or industrial organization other than the Institute should be made only after giving serious consideration to the amount of time and effort that can be given to another entity while satisfying the Institute Staff member’s primary commitment to the Institute. Any such commitment may be made only in compliance with this Policy.

In addition, Institute Staff members are expected to be discriminating in the selection of Outside Commitments in order to avoid impairment of the Institute’s reputation as a research institution. Institute Staff should avoid commitments that could compromise the research mission of the Institute. Where there is the possibility or appearance of a conflict between an Institute Staff member’s obligations to another organization and those to the Institute, the Institute Staff member must discuss and then report in writing his or her plans with the conflicts officer designated by the Institute (the “Conflicts Officer”) before making such commitment. The Conflicts Officer at the Institute is the Chief of Staff.

### B. NECESSITY FOR A WRITTEN REPORT OF POTENTIAL CONFLICTS

Determination of whether a Conflict of Commitment or Conflict of Interest exists in a particular instance will always be a matter of judgment by the Institute in its sole discretion, assessed after taking into consideration all the facts of the situation as per the report submitted to

the Conflicts Officer. While informal discussion with the Conflicts Officer or other Institute representatives may provide guidance for decisions, Institute Staff members must prepare a written report and obtain approval from the Conflicts Officer before undertaking any commitment that may conflict or appear to conflict with the primary commitment to the Institute. A full written report is the best preventative measure to avoid any real or apparent conflict between the obligations of Institute Staff to the Institute and his or her personal interests and other competing commitments. Written reports must be updated if a possible conflict becomes evident when an Institute Staff member's ongoing relationship with an Outside Entity changes. The written report should be made as described in Sections I.C and I.E below.

### **C. SITUATIONS IN WHICH A WRITTEN REPORT MUST BE MADE<sup>2</sup>**

Trust, good faith, and open discussion of controversial issues among colleagues are central to the life of the Institute. The requirement to submit a written report in the situations outlined below is meant to ensure that Conflicts of Commitment and Conflicts of Interest will be considered openly and fairly and that appropriate action will be taken to resolve those conflicts. A written report thus serves to protect individual Institute Staff members and the Institute and its research mission. A written report must be made promptly in any of the following circumstances:

- 1. Whenever Outside Commitments and/or Financial Interests reasonably appear to be related to an Institute Staff member's Institutional Responsibilities**
  - a. Regardless of whether compensation will be received;
  - b. In the event an Institute Staff member's spouse, domestic partner, or dependent is compensated for an Outside Commitment and/or Financial Interest that appears to be related to an Institute Staff member's Institutional Responsibilities

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<sup>2</sup> The purpose of this list is not to place specific restrictions on outside commitments or situations requiring disclosure; it indicates only when a report must be made.

**2. Whenever an Institute Staff member is an Investigator on Public Health Service (PHS) funded Research projects and the value of each occurrence of reimbursed or sponsored travel related to his/her Institutional Responsibilities occurring during the 12 months prior to the disclosure is \$5,000 or more when aggregated for a specific Outside Entity.**

Institute Staff must disclose each occurrence of such reimbursed or sponsored travel related to his/her Institutional Responsibilities. If applicable, the sponsored or reimbursed travel for an Institute Staff member's spouse, domestic partner, and dependent children should be included in the valuation. Such written reports must include the purpose, sponsor/organizer, destination and duration of each occurrence.

**3. Whenever the aggregate time for all Outside Commitments exceeds 26 days per year.**

The maximum amount of time spent on Outside Commitments which is compatible with fulfilling the primary responsibility to the Institute needs to be determined by the Conflicts Officer after discussion with the Institute Staff member. The 26-day level is considered to be a threshold for a written report and not necessarily a limit on Outside Commitments. Intermittent activities such as visiting lectureships are desirable and bring honor and credit to the Institute Staff member and to the Institute, but excessive time devoted to these activities can compromise the Institute Staff member's ability to meet his or her obligations to the Institute.

Examples of activities that must be reported include ongoing or repetitive arrangements with an outside organization for activities such as consultation, research, laboratory testing, teaching, writing or membership on advisory groups and councils.

**4. Special circumstances.**

A complete written report of all Outside Commitment and/or Financial Interests may be requested by the Conflicts Officer in special circumstances such as in connection with appointments, promotions, performance reviews, or administrative assignments.

The Conflicts Officer or his/her designees may also request a written report from Institute Staff members in connection with requests for institutional clearance or certification of research (*e.g.*, for research on animals or humans), application for support of Research activities or purchases of equipment, or similar requests.

**5. Whenever an Institute Staff member's relationship to an Outside Entity might appear to influence either the conduct of the Institute's business with the Outside Entity or the conduct of Research within the Institute.**

A scenario in which an Outside Entity proposes to conduct business with the Institute wherein the Institute Staff member may influence or may appear to influence the decision-making process on behalf of either party.

**6. Whenever an Outside Commitment provides for intellectual or tangible property rights in the way of patent ownership or licensing to an Outside Entity other than the Institute.**

Institute Staff must report in writing any relationship they are considering or are engaged in with an Outside Entity when the Outside Entity anticipates providing financial or other support for the Institute Staff member's work or when the Outside Entity anticipates utilization of intellectual property (*e.g.*, inventions, know-how) or tangible property (*e.g.*, research materials) or original works of authorship (*e.g.*, computer software but not textbooks) of that Institute Staff member's academic work or the work of a subordinate Institute Staff member.

**D. REPORTING PROCEDURES**

An Institute Staff member must provide a written report and any proposed written agreement to the Conflicts Officer when any of the situations in Sections I.C.1 – I.C.6 and I.E. arises. Disclosure must be made prior to any agreement to undertake the Outside Commitment, or within 30 days from the date of acquiring or discovering a new Financial Interest or a change in a Financial Interest, or within 30 days of travel if disclosure is required by Section I.C.2, or prior to exceeding the 26-day annual threshold.

The Conflicts Officer may place restrictions on the Outside Commitment and/or Financial Interest or deny the engagement altogether. If the Conflicts Officer approves the Outside Commitment and/or Financial Interest, the written report and notice of approval must then be forwarded to the Chief Operating Officer and any other individual designated by the Chief Operating Officer. In the event the proposed activity and agreement is found to comply with all relevant policies, a written statement of approval will be sent by the Conflicts Officer to the Institute Staff member with a copy to any applicable supervisor. The purpose of these reviews is to ensure that the proposed activity and any agreement(s) comply with policies of the Institute. Written reports will be maintained by the Institute for a period of 5 years.

An Outside Commitment and/or Financial Interest in a for-profit entity should generally be administered under a private agreement between the Institute Staff member and the Outside Entity. Any compensation associated with an Outside Commitment must be provided directly from the Outside Entity to the Institute Staff member and may not be directly deposited into any Institute account.

**E. ACTIVITIES SUBJECT TO HIGHTENED REVIEW**

The following Outside Commitments are ordinarily prohibited unless otherwise explicitly approved, in writing, by the Conflicts Officer and/or the Chief Operating Officer:

**1. Any Outside Commitment that could imply or constitute endorsement or promotion of any commercial product, technology, service, or company.**

This includes scenarios in which Institute Staff are expected to act as an agent or spokesperson for the purpose of disseminating organization-generated materials on behalf of the Outside Entity.

**2. Whenever the name of the Institute might be used by another party.**

If an Outside Entity wishes to use the Institute's name, symbols, logos, or brand marks, written approval from the Chief Operating Officer must be obtained prior to such use.

**3. Whenever a proposed agreement involves the use of facilities, resources or proprietary information belonging to or utilized by the Institute.**

Any Outside Commitment that involves the use of facilities, resources or proprietary information of the Institute are generally the subject of an Institute agreement with an Outside Entity.

**4. Whenever an agreement is being considered that restricts the Institute Staff member's public reporting of the existence of the agreement or information developed by the Institute Staff member under the agreement.**

Any agreement which includes requirements for confidentiality that might compromise the Institute's research mission, its scholarly independence, or the rights of the Institute Staff member, other Institute Staff or the Institute. This includes speaking engagements where the Outside Entity has the contractual right to dictate or control the content of the presentation or scenarios in which the Outside Entity creates the presentation materials with final approval of the content.

**F. RESEARCH AND PUBLICATIONS**

Institute Staff may consult with or advise an Outside Entity regarding the entity's research under a private agreement. However, when it is anticipated that the Institute Staff member's services for the entity will result in qualification as an author in accordance with International Committee of Medical Journal Editors (ICMJE) standards, it is expected that the Institute Staff member will provide the services under an institutional research agreement.

On occasion, when Institute Staff provide consulting or advising services under private agreements they may ultimately qualify for authorship of resulting research publications according to ICMJE standards. In these instances, the Institute Staff member must ensure the publication includes a disclaimer that states (a) he/she engaged in the research as a private consultant or advisor and not in his or her capacity as a Lieber Institute member and/or (b) he/she was compensated for the consulting or advising service in [income/stock/equity/other form of compensation]. Institute Staff members who qualify for authorship in the course of private consulting are expected to follow all ethical standards of the research community. The Institute Staff member should also update his/her existing consulting or advising disclosure to include the authorship role.

**G. ANNUAL AND NEW HIRE CERTIFICATION REQUIREMENTS**

All Institute Staff certify at the point of hire and annually thereafter that they understand their responsibilities under this Policy. All Institute Staff will receive a copy of this Policy and will be required to sign a certification upon hire. This certification will be renewed on an annual basis and signed by each Institute Staff member. (See attached forms).

## II. CONFLICT OF INTEREST

A.	INTRODUCTION.....	10
B.	APPLICABILITY .....	11
C.	GENERAL PRINCIPLES.....	11
D.	INSTITUTE STAFF CONFLICT OF INTEREST TRAINING.....	12
E.	FINANCIAL INTERESTS REQUIRING DISCLOSURE AND REVIEW BY THE COMMITTEE .....	12
F.	REVIEW AND MANAGEMENT OF CONFLICTS OF INTEREST.....	13
G.	SPECIAL CONSIDERATIONS FOR REVIEW AND MANAGEMENT OF CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH.....	15
H.	MONITORING .....	17
I.	APPEALS .....	17
J.	EXTERNAL REPORTING .....	18
K.	SANCTIONS FOR FAILURE TO COMPLY .....	19
L.	LEGAL OBLIGATIONS .....	20
M.	ANNUAL AND NEW HIRE CERTIFICATION REQUIREMENTS.....	21

### A. INTRODUCTION

The Institute is dedicated to the goal of developing novel treatments, diagnostic tests, and new insights into the etiology of behavioral disorders stemming from abnormalities in human brain development. Its research mission is to translate basic genetic and molecular mechanisms of schizophrenia and related developmental behavioral disorders into clinical advances that change the lives of affected individuals. To advance this mission, the Institute needs to ensure that Research is conducted with integrity and openness and that the rights and interests of human and animal subjects are protected. The Institute also has a goal of fostering creativity and facilitating the translation of discoveries into therapies that improve human welfare. Increasingly, the private, for-profit sector plays an important role in this process. Corporate and industry involvement can benefit Research and its translation into useful products. However, the financial incentives that accompany such involvement may lead to Conflicts of Interest with the Institute's research mission. Financial Conflicts of Interest have the potential to increase bias in research, thus affecting research integrity and placing human research subjects at additional risk. Such conflicts may also reduce public confidence in the research enterprise.

This Policy is designed to identify arrangements involving Institute Staff who have a Financial Interest or Fiduciary Interest in an Outside Entity where such arrangements may represent a source of conflict or an appearance of conflict in the conduct and reporting of all Research; the Policy specifically addresses protection of the rights and interests of human subjects in Research. All arrangements involving potential Conflicts of Interest must be

reported to and reviewed by the Institute. This Policy is designed to maintain the trust of the public, research volunteers, and the scientific community in the Institute's research enterprise and to support institutional compliance with PHS 42 CFR Part 50, Subpart F<sup>4</sup> and other applicable government regulations.

This Policy acknowledges that potential Conflicts of Interest may exist, for both Institute Staff and the Institute, with respect to activities that, in the determination of the Committee, do not involve Research. An example of such activity would be procurement. Accordingly, although Conflicts of Interest in Research is the focus of the Committee, the Conflicts Officer may request that the Committee review and advise him or her concerning Financial Interests related to other activities.

## **B. APPLICABILITY**

This Policy applies to all Institute Staff when they are acting in their Institute roles as Investigators in Research. Institute employees and students who serve as investigators in proposals submitted to external sponsors are required to adhere to this Policy. Sub-recipients and their personnel, as well as collaborators of other institutions (collectively "Sub-Recipients") must either comply with this policy or document that their institutions or organizations are in compliance with USDHHS PHS rules by certifying that: (a) their company or institution has a financial conflict of interest policy that is compliant with USDHHS PHS rules; and (b) they have received COI training; and (c) if necessary, they have made COI disclosures as required by their institution's or company's COI policy; or (d) **they cannot so certify and will be subject to the Institutes COI policy.**

## **C. GENERAL PRINCIPLES**

1. All Financial Interests and Fiduciary Interests related to Research activities must be reported to and reviewed by the Committee.
2. There is no "de minimus" level below which a Financial Interest is exempt from reporting.
3. The Committee may recommend either prohibition of the proposed Research activity or procedures for management of the Conflict of Interest if the disclosed interest has the potential to directly and significantly affect the design, conduct, or reporting of research funded by a PHS Awarding Component or other sponsor (FCOI). Institute Staff are obligated to comply with the Committee's management requirements in the event of an FCOI, and/or administrative conditions in cases where the Committee has determined that no FCOI exists. Updated Financial Interest Disclosure Forms must be submitted as interests change within 15 days of discovering or acquiring a new FI as well as annually during the period of an award.
4. Institute Staff may not participate in Research involving human subjects while having a Financial Interest in the Research project or in a Financially Interested Company. Exceptions may be granted if an Investigator provides the Committee with a compelling justification for participating in a specific Research project while maintaining certain Financial Interests. In addition, this restriction may not apply to projects that an institutional review board ("IRB")

determines to meet the definition of “no more than minimal risk” to research subjects or which the Committee considers to be low risk, such as conducting studies on tissue samples. For further details, see Section G below.

#### **D. INSTITUTE STAFF CONFLICT OF INTEREST TRAINING**

All Institute Staff must complete Conflict of Interest training.

1. Timeframe for completion of training:
  - a. Prior to engaging in Research related to any PHS-funded project, and
  - b. At least every 4 years
2. Additional trainings are required in the event:
  - a. The Institute revises this Policy;
  - b. An Institute Staff member is new to the Institute; or
  - c. The Institute determines that an Investigator is not in compliance with this Policy or his/her assigned management plan
3. Access to training:
  - a. Via MyLearning on the JHU Intranet (log into my.jhu.edu, select “Education”, select “myLearning”, select the course titled “Conflict of Interest and Commitment” provided by the Office of Policy Coordination, Division of Outside Interests, complete the course, and finally send certificate of course completion to Institute Grants Administrator).

#### **E. FINANCIAL INTERESTS REQUIRING DISCLOSURE AND REVIEW BY THE COMMITTEE**

Institute Staff must make disclosures to the Institute of Financial Interests or Fiduciary Interests in accordance with the disclosure requirements in Section I via a Financial Interest Disclosure Form (See Appendix A) with supporting documentation regarding:

- a. all Financial Interests that would reasonably appear to be affected by the Research activities funded or proposed for funding, and
- b. all Financial Interests in Outside Entities whose financial position would reasonably appear to be affected by Research activities funded or proposed for funding.

The following scenarios specifically require disclosure and review by the Committee:

##### **1. Proposals for Outside Support**

All relevant Financial Interests of an Institute Staff member must be fully disclosed in the Financial Interest Disclosure Form and described in the proposal to the external sponsor. The Committee will recommend to the Conflicts Officer whether the Conflicts Officer should approve or disapprove submission of the proposed application. If the Committee recommends approval, it will also recommend conditions for management of the Conflict of Interest.

## **2. Human Subjects Research**

Proposals for all Research protocols involving Human Subjects Research shall be submitted to an IRB for review; provided, however, that the Investigator under any such proposal must obtain Committee review by submitting the proposed protocol directly to the Committee. All approvals and subsequently, the approved IRB protocols, must be filed with the Conflicts Officer.

## **3. Written Agreements with Outside Entities**

All proposed written agreements with Outside Entities must be submitted to the Conflicts Officer regardless of the level of compensation, prior to being signed by Institute Staff.

## **4. Technology Transfer**

When an Outside Entity proposes a technology transfer arrangement with the Institute involving an Institute Staff member, the Institute's Legal Counsel will control the negotiation of such arrangement. To the extent other policies, laws or regulations are applicable to the arrangement, review under such policies, laws or regulations is separate and distinct from review under this Policy, and compliance with this Policy does not relieve the Institute Staff member or the Institute of any obligation under such other policies, laws or regulations.

## **5. Other**

If an Institute Staff member has a Financial Interest that is potentially a source of bias or perceived bias in Research and has not reported that interest through one of the mechanisms listed above, the Institute Staff member must make a written report to the Conflicts Officer.

Financial Interests or Fiduciary Interests of one's spouse, domestic partner, and dependents must be reported as though they were one's own. Individuals who are aware of Financial Interests of other family members (*e.g.*, parents, adult children, unmarried domestic partners or siblings) that might present the appearance of a Conflict of Interest should report such interests, but are not expected to inquire into the detailed personal matters of others.

## **F. REVIEW AND MANAGEMENT OF CONFLICTS OF INTEREST**

### **1. Committee Review**

The Committee reviews submitted disclosures in light of related Research activity. In its review, the Committee considers the following factors:

- a. Potential of disclosed interests to create a FCOI;
- b. Risks to the rights and safety of human research subjects;
- c. Impact on the integrity of research data;
- d. Risks to the rights and safety of human research subjects (see Section G);
- e. Risks to the rights and obligations of students and trainees participating in Research; and

- f. Appearance of a Conflict of Interest.<sup>3</sup>

## 2. Determination/Management Conditions

Upon completing its review, the Committee will recommend to the Conflicts Officer that the proposed arrangements be either (a) prohibited or (b) permitted, subject to specific management conditions. After reviewing the recommendation of the Committee, the Conflicts Officer will render a final decision and will communicate that decision, with a description of any specific management conditions, to the involved Institute Staff member in writing. The Conflicts Officer shall report his/her decision in each case to the Committee.

If the Committee determines that a Conflict of Interest may be permitted, the following management conditions may be implemented:

a. Disclosure: Disclosure is required in every case approved by the Conflicts Officer, including: (i) public disclosure of the Financial Interests of the Investigator and of the Institute, if applicable, in all relevant publications, grant applications, presentations (whether or not academic presentations); (ii) disclosure to the appropriate co-investigators, members of the laboratory or research group, and students or trainees; and (iii) disclosure on human subject consent forms.

b. Restriction on Equity: (i) Placement of stock in escrow until a trigger date specified by the Committee, as outlined in the Institute's Intellectual Property Policy and associated procedures, or (ii) requirement that options, warrants, and similar instruments not be exercised without the prior permission of the Committee.<sup>4</sup>

c. Limiting the Role of the Investigator with a Financial Interest: Requiring that the role of the Investigator with the FI be limited in some way. For example, the Investigator may not be allowed to (i) serve as principal Investigator, (ii) analyze data, (iii) determine whether potential subjects are eligible for enrollment, (iv) solicit consent, or (v) determine whether an adverse event report is required.

d. Oversight: Appointment of a disinterested individual or group to monitor the relevant Research activity. An oversight committee might be charged, at a minimum, with reviewing abstracts and manuscripts before they are submitted for publication to ensure that the Research is conducted and reported according to scientific and ethical standards and that Conflict of Interest management measures are observed. In other cases, an oversight committee might meet quarterly and review protocols, subject accrual, complications, and other issues as appropriate.

e. Divestiture: Allow arrangements to go forward contingent upon the sale or disposal of specified Financial Interests to eliminate or reduce the FCOI by a certain date.

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<sup>3</sup> In agreements and contracts related to the arrangements under review by the Committee, the Institute will require terms that uphold the rights and responsibilities of Institute Staff and the Institute, and ensure appropriate reporting of inventions and assignment of intellectual property rights.

<sup>4</sup> Institute Staff should be aware that separate Securities and Exchange Commission and other state and federal regulations may apply to their ownership of such equity. Obtaining the necessary information and complying with such regulations is the responsibility of the Institute Staff member.

f. Severance of Relationships that Heighten or Create Actual or Potential Conflicts: For example, relinquishing a seat on a board of directors or terminating a consulting arrangement with an Outside Entity in order to reduce the conflict.

The Committee may recommend other conditions or restrictions on the proposed arrangements if, in its view, such conditions or restrictions will contribute to the elimination, reduction, or management of the Conflict of Interest.

Each person judged to have a Conflict of Interest must sign an agreement certifying that he or she will adhere to all conditions or restrictions imposed by the Conflicts Officer and will cooperate fully with any individual(s) assigned responsibility for monitoring compliance. The Institute will not accept an award until the signed management plan for all project personnel judged to have a Conflict of Interest is received.

## **G. SPECIAL CONSIDERATIONS FOR REVIEW AND MANAGEMENT OF CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH**

Financial Interests in Human Subjects Research require additional scrutiny. Such interests may present real or perceived risks to the welfare and rights of human subjects, in addition to presenting risks to research integrity.

Institute Staff are required to report all Financial Interests in Human Subjects Research. It is presumed that individuals (faculty, staff, trainees, students, administrators, and researchers) may not participate in Research projects involving human subjects while they have a FI in the Research project or in a Financially Interested Company.

Exceptions may be made in specific cases when, in the judgment of the Committee, individuals holding conflicting FIs provide the Committee with a *compelling justification*—consistent with the rights and welfare of human research subjects—for being permitted simultaneously to hold the FI and to participate in the Human Subjects Research project. If an Institute Staff member proposes to conduct Research which is determined by the responsible IRB (in accordance with 45 C.F.R. § 46.110) to entail “no more than minimal risk” to subjects, the Research project will be not presumed to be prohibited. Such a determination by the IRB may be judged by the Committee a “*compelling justification*” for permitting participation in a Human Subjects Research project by Institute Staff with FIs. Although the FI will not be presumptively prohibited, the Committee will furnish the approved management plan to the responsible IRB.

### **1. The following FIs involving Human Subjects Research are presumed prohibited:**

a. Fees, honoraria, gifts or other emoluments, or “in kind” compensation from a Financially Interested Company (or entitlement to the same), that in the aggregate exceed \$25,000 in a given twelve month period, excluding reimbursement of expenses such as travel expenses incurred as a direct result of performing consulting services.

b. An equity interest of any amount, including stock options or warrants, in a non-publicly-traded Financially Interested Company (or entitlement to the same).

c. An equity interest, including stock options or warrants, in a publicly-traded Financially Interested Company (or entitlement to the same) that exceeds \$25,000 in value as determined through reference to current prices. Should the value of the equity interest increase to more than \$25,000 during the conduct of the research project, the Institute Staff member must immediately notify the IRB. Equity holdings worth less than \$25,000 and rights to acquire additional equity will nevertheless be subject to restrictions.

d. Royalty income or the right to receive future royalties from commercialization of Research results, including entitlement to any “milestone” payments conditioned upon specified research-related dates or events, whether such payments are received from a Financially Interested Company or via the Institute.<sup>5</sup>

e. Any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the Research (as specified in the applicable research agreement). This includes any bonus or milestone payments (other than those addressed in paragraph d above) to the investigators in excess of reasonable costs incurred, whether such payments are received from a Financially Interested Company or from the Institute.

f. Service as an officer, director, or in any other fiduciary role for a Financially Interested Company, whether or not remuneration is received for such service.<sup>6</sup>

g. Royalty income and the right to receive future royalties as a result of traditional academic publishing activity, such as the publication of textbooks, are excluded.

## **2. Management and Administrative Conditions when situations involve Human Subjects Research**

For proposed arrangements involving Human Subjects Research, the Committee will make a written recommendation, accompanied by a description of the nature and magnitude of the potential Conflict of Interest, to the Conflicts Officer and to the appropriate IRB. The IRB will be responsible for evaluating the recommendations of the Committee and deciding whether to: (a) accept the recommendations, (b) accept the recommendations with additional management measures prescribed by the IRB, or (c) conclude that the Human Subjects Research cannot proceed. It will then be instructed to communicate its determination to the Institute Staff member in writing. Upon concluding its evaluation, the IRB will inform the Conflicts Officer and the Committee of its determination, and the IRB’s decision will be final. To ensure the primacy of the welfare and rights of human subjects, the IRB will have the full and final authority for implementing the decision concerning the role of the involved Institute Staff member in the Human Subjects Research protocol.

If the IRB deems a specific Research project involving human subjects to be exempt from IRB review, the Conflict of Interest issues associated with that project will remain subject

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<sup>5</sup> Royalty interests arising from post-marketing sales of approved products are an example of a financial interest that promotes translational research and may be amenable to successful management.

<sup>6</sup> An Institute Staff member’s time-limited service as an officer or director of a company formed to obtain a grant under the federal Small Business Innovation Development Act or the Small Business Technology Transfer Program may be treated analogously to royalty interests arising from post-marketing sales of approved products.

to Committee review and the Committee may review the project as if it were “human subjects research” for the purposes of this Section.

The Committee’s recommendation may involve either prohibition or management. These options are described below.

a. Prohibition: If the Committee believes that the Conflict of Interest is incompatible with Human Subjects Research, it will recommend to the appropriate IRB that the involved Institute Staff member be required to eliminate the relevant FI before beginning the project or be barred from participation in the Research.

b. Management: In cases involving insignificant FIs, the Committee will generally recommend that the Institute Staff member be permitted to participate in a given Human Subjects Research project, subject to certain specified management conditions.

In all cases involving Human Subjects Research where a research consent form is required and in which an involved Institute Staff member has a relevant FI of any magnitude, a financial disclosure statement including the name of the financially interested individual and describing the source and nature of the relevant FI must be included in the consent form.

Additional project-related management measures may include, for example, one or more of the following: the Institute Staff member may not be allowed to (i) serve as principal Investigator, (ii) analyze data, (iii) determine whether potential subjects are eligible for enrollment, (iv) solicit consent, or (v) determine whether an adverse event report is required.

## **H. MONITORING**

Whenever the Institute implements a management plan, the Institute will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the Research project.

## **I. APPEALS**

If an Institute Staff member believes that a determination made by the Committee in a specific case and adopted by the Conflicts Officer or an IRB is not appropriate or is based on erroneous information, the Institute Staff member may request additional Committee review by submitting a written request to the Conflicts Officer’s supervisor. If, after a second review by the Committee and second determination by the Conflicts Officer’s supervisor, the Institute Staff member still wishes to appeal, the Institute Staff member may appeal to the Board of Directors of the Institute (the “Board”). The decision of the Board, in consultation with Legal Counsel, shall be final.

In the event the Conflicts Officer or the Conflicts Officer’s supervisor decides not to adopt a Committee recommendation and the Committee wishes to appeal that decision, it may appeal to the Board. The decision of the Board, in consultation with Legal Counsel, shall be final.

Institute Staff who believe that the Conflict of Interest management measures adopted by an IRB are not appropriate or are based on erroneous information must follow applicable IRB procedures for requesting additional review.

## **J. EXTERNAL REPORTING**

1. To comply with federal regulations, the Institute will make available to the public within 5 days of a request the following information with respect to FCOIs with PHS-funded research<sup>7</sup>

- a. Investigator's name
- b. Investigator's title and role with respect to the research project
- c. Name of entity in which a SFI is held
- d. Nature of the SFI
- e. Approximate dollar value of the FI within ranges (e.g., \$0-\$4,999; \$5,000-9,999; \$10,000-19,999; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000), or a statement that the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value

2. To comply with federal regulations, prior to the expenditure of funds the Institute will report to the PHS Awarding Component the following information with respect to FCOIs with PHS-funded research<sup>8</sup>

- a. Project number
- b. Program director/principal Investigator
- c. Name of Investigator with FCOI
- d. Name of entity in which a SFI is held
- e. Nature of the SFI
- f. Approximate dollar value of the FI within ranges (e.g., \$0-\$4,999; \$5,000-9,999; \$10,000-19,999; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000), or a statement that the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value

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<sup>7</sup> Information regarding these financial conflicts of interest will remain available for response to written requests for at least three years from the date that the final expenditures report is submitted to the PHS agency.

<sup>8</sup> These reports will be made prior to the Institution's expenditure of any funds under a PHS-funded research project, within sixty days of identifying a financial conflict of interest during an ongoing PHS-funded research project subsequent to the initial report, and on an annual basis for the duration of the project or until the financial conflict of interest ceases to exist for any previous reported financial conflict of interest (annual reporting will be done at the same time as when the Investigator is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension).

- g. Description of how the FI relates to the PHS-funded research and basis for the Institute's determination of a FCOI
- h. Description of key elements of the Institute's management plan, including:
  - i. Role and principal duties of the conflicted Investigator in the Research project
  - ii. Conditions of the management plan
  - iii. How the management plan is designed to safeguard objectivity in the Research project
  - iv. Confirmation of the Investigator's agreement to the management plan
  - v. How the management plan will be monitored
  - vi. Other information as needed

Investigators must abide by other disclosure requirements and standards, such as for journals and professional societies; in publications, presentations, and to colleagues, students and trainees -- even if an interest is not identified as a FCOI with Research.

#### **K. SANCTIONS FOR FAILURE TO COMPLY TO SECTIONS I AND II**

Potential sanctions range from placement of a warning letter in the Institute Staff member's file, to suspension for a specified period of time, to termination.

In the event of any of the following, an interim management plan will be implemented and a retrospective review of ongoing Research will be undertaken to determine whether bias is present in the design, conduct or reporting of the Research: failure to disclose in a timely manner FIs that are determined to constitute an FCOI with PHS-funded research; failure by the Institution to review or manage an FCOI; or failure by an Institute Staff member to comply with a management plan. If bias is identified, the Institution will develop and implement a mitigation plan.<sup>9</sup>

If the failure of an Investigator to comply with this Policy has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, in accordance with PHS regulations, the Institution must promptly notify the PHS Awarding Component of the findings and corrective action(s) taken or to be taken. The PHS Awarding Component will consider the situation and take appropriate action or refer the matter to the Institution for further action, potentially including directions on how to maintain appropriate objectivity in the funded project.

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<sup>9</sup> In the event that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment was been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by this regulation, the Institution will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations if a disclosure was not made.

## **L. LEGAL OBLIGATIONS**

Institute Staff should be aware that as a result of their FI or Fiduciary Interest in an Outside Entity they might have obligations under various federal or state laws separate and distinct from their obligations under this Policy. Several examples of such obligations are described below, this list is not exhaustive and includes, but is not limited to:

### **1. Public Health Service (PHS)/National Science Foundation (NSF)**

This Policy is intended to comply with and should be interpreted in accordance with 42 CFE Part 50 Subpart F, 45 CFR Part 94 and other applicable NSF regulations.

### **2. U.S. Food and Drug Administration (FDA)<sup>10</sup>**

The FDA requires applicants, under various regulations (e.g., 21 C.F.R. Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860), to submit to FDA a list of clinical Investigators who conducted covered clinical studies and to certify the absence of and/or disclose the existence of certain financial arrangements. Individuals holding Investigational New Drug applications (“IND”) and Investigational Device Exemptions should consult FDA concerning applicable rules and regulations.

### **3. Securities and Exchange Commission (“SEC”)**

The SEC enforces regulations concerning equity ownership and insider trading, which may affect Institute Staff. For additional information, Institute Staff should seek advice from personal counsel. It is the obligation of the financially interested individual to ensure compliance with applicable SEC regulations.

### **4. U.S. Federal Tax Law**

Section 4958 of the Internal Revenue Code imposes an excise tax on certain transactions in which an economic benefit is provided by an applicable tax-exempt organization, directly or indirectly, to or for the use of any person who was in a position to exercise substantial influence over the affairs of the applicable tax-exempt organization. The person who benefits from such transactions may be liable for the excise tax. An organization manager may also be liable for an excise tax on such transactions. For additional information, Institute Staff should seek advice from qualified, personal tax counsel.

### **5. Requirements of Other Sponsors**

Outside sponsors may have specific requirements regarding the Financial Interests of Institute Staff. Any conflict between the provisions of this Policy and the requirements of any outside sponsors must be brought to the attention of the Committee and the Conflicts Officer.

### **6. US Patent and Trademark Office**

Under the U.S. Patent Act (found in Title 35 of the United States Code), Patents issued by the U.S. Patent and Trademark Office confer upon the patent holder the right to exclude others from making, using or selling the invention throughout the United States, as well

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<sup>10</sup> FDA, Financial Disclosure by Clinical Investigators, Guidance for Industry, *available at* <http://www.fda.gov/oc/guidance/financialdis.html>.

as the right to prevent others from importing the invention into the United States (see 35 U.S.C. 271).

**M. ANNUAL AND NEW HIRE CERTIFICATION REQUIREMENTS**

All Institute Staff certify at the point of hire and annually thereafter that they understand their responsibilities under this Policy. All Institute Staff will receive a copy of this Policy and will be required to sign a certification upon hire. This certification will be renewed on an annual basis and signed by each Institute Staff.

Signature of  
Institute Staff: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Signature of  
Conflicts Officer: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

APPENDIX A

Lieber Institute for Brain Development  
Conflict of Commitment Disclosure Form

CONFIDENTIAL

Institute Staff Name: \_\_\_\_\_

Department: \_\_\_\_\_ Email: \_\_\_\_\_

Phone: \_\_\_\_\_ Project/Engagement Title: \_\_\_\_\_  
\_\_\_\_\_

**Institute Staff's Disclosure**

I am attaching a disclosure of my conflict of commitment and enclosing an explanation of the nature of the potential conflict in compliance with the Conflict of Commitment and Conflict of Interest policy.

I, \_\_\_\_\_ hereby declare that this statement (including accompanying additional pages and statements) has been examined by me and that to the best of my knowledge and belief is a true, correct, accurate, and complete statement of all such interests required to be disclosed by law, regulation, or policy. I have read and agree to comply with the Lieber Institute for Brain Development's policy on Conflict of Commitment and Conflict of Interest. I have complied with Federal conflict of interest policies and regulations. Also, I understand that failure to file this statement as required, or intentionally filing a false statement, may result in disciplinary action. Any changes with regard to information provided on this statement will be reported when it becomes known to me.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

*Submit this form and all additional pages and statements to the Lieber Institute for Brain Development's Conflicts Officer for review and signature.*

**Verification:** I have reviewed the potential or actual Conflict(s) with the above named individual.

\_\_\_\_\_  
**Conflicts Officer – Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Printed Name**

**Lieber Institute for Brain Development**  
***Financial Interest Disclosure Form***

Institute Staff Name: \_\_\_\_\_

Department: \_\_\_\_\_ Email: \_\_\_\_\_

Phone: \_\_\_\_\_ Funding Agency: \_\_\_\_\_

Project Title: \_\_\_\_\_

**Institute Staff's Disclosure**

I have Financial Interest (as defined in the Lieber Institute for Brain Development's Policy on Conflict of Commitment and Conflict of Interest) in the project outcome. I am disclosing the following interest(s):

- Ownership Interests (Complete & Attach Section A)
- Receipt of Compensation (Complete & Attach Section B)
- Officer or Director of Organization or Business (Complete & Attach Section C)
- Receipt of Fees and Commissions (Complete & Attach Section D)
- Travel (Complete & Attach Section E)

I, \_\_\_\_\_ hereby declare that this statement of Financial Interest(s) (including accompanying additional pages and statements) has been examined by me and that to the best of my knowledge and belief is a true, correct, accurate, and complete statement of all such interests required to be disclosed by law, regulation, or policy. I have read and agree to comply with the Lieber Institute for Brain Development's policy on Conflict of Commitment and Conflict of Interest. I have complied with Federal conflict of interest policies and regulations. Also, I understand that failure to file this statement as required, or intentionally filing a false statement, may result in disciplinary action. Any changes with regard to information provided on this statement will be reported when it becomes known to me.

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

*Submit this form and all additional pages and statements to the Lieber Institute for Brain Development's  
Conflicts Officer for review and signature.*

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**Verification:** I have reviewed the potential or actual Conflicts of Interest with the above named individual. A copy of the signed Financial Disclosure of Interest Form will be/has been sent to the Committee for resolution.

\_\_\_\_\_  
**Conflicts Officer – Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Printed Name**

**Lieber Institute for Brain Development**  
***Financial Interest Disclosure Form***

**CONFIDENTIAL**

Institute Staff Name: \_\_\_\_\_

Project Title: \_\_\_\_\_

**SECTION A. Ownership Interests**

List any corporation, partnership, proprietorship, trust, joint venture, and any other business interest, including land used for income, in which either you or other members of your household own or have owned, within the preceding 12 months, that constitute a legal or equitable interest which **actually or potentially influences or conflicts with any of your Research** at the Lieber Institute for Brain Development. Ownership of intellectual property, e.g., patents, royalties, and copyrights, are also included and must be disclosed. If you or a member(s) of your household have an ownership interest in a business, you must disclose the percentage held.

*Please insert additional pages as necessary to complete this section.*

**Entity 1:**

Business Name: \_\_\_\_\_

Business Address: \_\_\_\_\_

Type of Business: \_\_\_\_\_

Description of Interest: \_\_\_\_\_

Held by:  You  Spouse  Other (Please List): \_\_\_\_\_

% Interest Held: \_\_\_\_\_

**Entity 2:**

Business Name: \_\_\_\_\_

Business Address: \_\_\_\_\_

Type of Business: \_\_\_\_\_

Description of Interest: \_\_\_\_\_

Held by:  You  Spouse  Other (Please List): \_\_\_\_\_

% Interest Held: \_\_\_\_\_

**Lieber Institute for Brain Development**  
***Financial Interest Disclosure Form***

**CONFIDENTIAL**

Institute Staff Name: \_\_\_\_\_

Project Title: \_\_\_\_\_

**SECTION B. Receipt of Compensation**

List all places of employment and other business (excluding the Institute) from which you or any member of your household expect to receive remuneration per year as to which an independent observer could reasonably conclude could **actually or potential influence or conflict with any of your Research activities** at the Lieber Institute for Brain Development. Consulting fees, honoraria, paid authorship, royalties, equity interests which includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value are considered, for purposes of this policy, remuneration.

*Please insert additional pages as necessary to complete this section.*

**Entity 1:**

Business Name: \_\_\_\_\_

Business Address: \_\_\_\_\_

Position Held: \_\_\_\_\_

Held by:  You  Spouse  Other (Please List): \_\_\_\_\_

**Entity 2:**

Business Name: \_\_\_\_\_

Business Address: \_\_\_\_\_

Position Held: \_\_\_\_\_

Held by:  You  Spouse  Other (Please List): \_\_\_\_\_

**Lieber Institute for Brain Development**  
***Financial Interest Disclosure Form***

**CONFIDENTIAL**

Institute Staff Name: \_\_\_\_\_

Project Title: \_\_\_\_\_

**SECTION C. Officer or Director of Organization or Business**

List any organization or business in which you, your spouse, or any other member of your household, hold the position of officer, director, partner, or proprietor which **significantly affects or will be affected by any of your Research activities** at the Lieber Institute for Brain Development

*Please insert additional pages as necessary to complete this section.*

**Entity 1:**

Business Name: \_\_\_\_\_

Business Address: \_\_\_\_\_

Position Held: \_\_\_\_\_

Held by:  You  Spouse  Other (Please List): \_\_\_\_\_

**Entity 2:**

Business Name: \_\_\_\_\_

Business Address: \_\_\_\_\_

Position Held: \_\_\_\_\_

Held by:  You  Spouse  Other (Please List): \_\_\_\_\_

**Lieber Institute for Brain Development**  
***Financial Interest Disclosure Form***

**CONFIDENTIAL**

Institute Staff Name: \_\_\_\_\_

Project Title: \_\_\_\_\_

**SECTION D. Receipt of Fees and Commissions**

List each client or customer from whom you, your spouse, or any household member receives any compensation which could constitute an **actual or potential Conflict of Interest with any of your Research activities** with the Lieber Institute for Brain Development. In the case of a partnership, it is the proportionate share of the fee or commission that is significant, without regard to the expenses of the partnership. An individual who receives a salary as opposed to portions of fees or commissions is generally not required to report in this section, but may be required to report in Section B, above.

*Please insert additional pages as necessary to complete this section.*

**Entity 1:**

Business Name: \_\_\_\_\_

Business Address: \_\_\_\_\_

Position Held: \_\_\_\_\_

Held by:  You  Spouse  Other (Please List): \_\_\_\_\_

**Entity 2:**

Business Name: \_\_\_\_\_

Business Address: \_\_\_\_\_

Position Held: \_\_\_\_\_

Held by:  You  Spouse  Other (Please List): \_\_\_\_\_

**Lieber Institute for Brain Development**  
***Financial Interest Disclosure Form***

**CONFIDENTIAL**

Institute Staff Name: \_\_\_\_\_

Project Title: \_\_\_\_\_

**SECTION E. Travel**

Disclose the occurrence of any reimbursed travel or sponsored travel related to Institutional Responsibilities over \$5,000 in a 12 month period. You are NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

*Please insert additional pages as necessary to complete this section.*

**Trip 1:**

Purpose: \_\_\_\_\_  
Sponsor/Organizer: \_\_\_\_\_  
Destination: \_\_\_\_\_  
Duration: \_\_\_\_\_

**Trip 2:**

Purpose: \_\_\_\_\_  
Sponsor/Organizer: \_\_\_\_\_  
Destination: \_\_\_\_\_  
Duration: \_\_\_\_\_