
THE LIEBER INSTITUTE FOR BRAIN DEVELOPMENT

POLICY ON CONFLICT OF COMMITMENT AND CONFLICT OF INTEREST

This Policy on Conflict of Commitment and Conflict of Interest (the “Policy”) covers the Institute Staff of The Lieber Institute for Brain Development (the “Institute”), except as noted below.

“Definitions” apply to the entire Agreement unless specifically defined in another part, subpart, section, provision, or clause. Words or terms defined in a specific part, subpart, section, provision, or clause have that meaning when used in that part, subpart, section, provision, or clause. Undefined words retain their common dictionary meaning.

DEFINITIONS

A *Conflict of Interest* is a 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 are determined by considerations of personal gain, financial gain or otherwise.

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 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. 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.

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.

Research (or research) is defined as a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. Includes basic and applied research and product development. Includes, but is not limited to, any such activity for which research funding is available from a PHS Awarding Component 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.

Financial Interest (FI) means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, 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) Incomes 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.

Outside Commitments includes all services to entities other than the Institute. For Institute Staff with concurrent faculty appointments at JHU, services provided to JHU in connection with such appointments are not considered outside commitments for purposes of this Policy.

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.

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.

Committee is a standing body consisting of senior members of the research staff of the Institute as well as senior members of the Institute administration, serving ex officio and legal counsel.

SUMMARY

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.¹ Compliance with this Policy does not relieve an Institute Staff member from any obligation under such other policy or under any applicable law.

This Policy is not an employment contract and all Institute employees are employed "at will" which means that either the Institute or its employees can terminate the employment relationship at any time, with or without cause, and with or without notice.

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

¹ 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.

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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 before undertaking any commitment that may conflict or appear to conflict with

the primary commitment to the Institute. The written report should be made as described in Sections I.C and I.D below.

A full written report is the best preventive measure to avoid any real or apparent conflict between the obligations of Institute Staff to the Institute and to his or her personal interests and other competing commitments.

C. SITUATIONS IN WHICH A WRITTEN REPORT MUST BE MADE²

Trust, good faith, and open discussion of controversial issues among colleagues are central to the life of the Institute. The activities of Institute Staff members must be governed by thoughtful and shared consideration of individual circumstances, rather than rigid rules. The requirement for 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 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 activities. 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. In addition, Institute Staff members must consider the impact of secondary commitments on their ability to fulfill the criteria for promotion.

Individual lectureships, conferences and scientific or professional meetings need not be included in the 26-day threshold unless those activities otherwise constitute or include activities described elsewhere in this Policy. On the other hand, 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.

2. Whenever outside activities require a written agreement.

With the exception of agreements for Institute Staff to provide occasional guest lectures or for the publication of Institute Staff writings, all written agreements relating to outside activities must be reviewed with the Conflicts Officer before they are signed by the Institute Staff to ensure that they do not conflict with the Institute's policies and procedures. Review is required regardless of duration of the activity. The written report

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

should be made in accordance with the reporting procedures described in Section I.D below.

3. In special circumstances.

A complete written report of all outside activities may be requested by the Conflicts Officer in special circumstances such as in connection with appointments, promotions 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.

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

Since a relationship with the Institute can be of great value to an outside organization, opportunities for outside activities may be offered to Institute Staff in part because of their association with the Institute. It must be remembered that there is no way to divorce the Institute Staff member completely from association with the Institute. A written report and disclosure to the Conflicts Officer prior to undertaking a secondary commitment serves to protect the Institute Staff member, the Institute, or both from possible discredit or embarrassment. Thus, Institute Staff members must be discriminating in the selection of secondary commitments, regardless of whether they are professional or non-professional in character, and regardless of whether the obligation is to be discharged in “off hours” or during vacation. If an outside organization wishes to use the Institute’s name, symbols or logos, written approval must be obtained prior to such use. To obtain a copy of the Institute’s statement on the use of its name, symbols or logos or to request approval, contact the Conflicts Officer.

5. Whenever a proposed agreement involves the use of facilities or resources belonging to or utilized by the Institute.

A written report must be made if the Institute will be investing its resources and sharing in the risks of a venture or in any other way subsidizing the activity, whether or not sharing in any revenues generated by the activity. The Institute’s Intellectual Property Policy governs an Institute Staff member’s participation in any agreement under which an outside entity will use or benefit from the resources, including information, of the Institute.

6. Whenever an outside commitment provides for intellectual or tangible property rights in the way of patent ownership or licensing to an organization other than the Institute.

Institute Staff must report in writing any relationship they are considering or are engaged in with another organization when the organization anticipates providing financial or other support for the Institute Staff member’s work or when the organization 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. See the Institute's Intellectual Property Policy for a full description of these matters.

7. 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.

In the case of a relationship with a commercial organization, the Institute Staff member must report in writing upon receiving, and prior to signing, any agreement which includes requirements for confidentiality that might compromise the Institute's research mission or the rights of the Institute Staff member, other Institute Staff or the Institute.

8. Whenever an Institute Staff member's relationship to an outside party might appear to influence either the conduct of the Institute's business with the outside party or the conduct of research within the Institute.

A written report must be made before engaging in a relationship with an organization when the organization proposes to conduct business with the Institute (or an affiliated organization) wherein the Institute Staff member may influence or may appear to influence the decision-making process on behalf of either party.

Consideration must be given to whether there is a perception of outside financial incentives being used to direct research activity away from avenues that might lead to more substantial scientific discoveries or to the accomplishment of research goals. Conflicts of interest may arise when an Institute Staff member has a relationship (*e.g.*, as consultant, advisor, owner, or shareholder) to an outside organization that is conducting business with the Institute on behalf of either that Institute Staff member or a subordinate Institute Staff member. See also Section II for activities that must be reported to the Committee on Outside Interests.

Consulting arrangements between Institute Staff members and outside institutions are distinct from research projects. Research projects require a contract with the Institute. In the latter case, payment for the Institute Staff member's effort is part of the Institute budget and is used as a source of an appropriate proportion of the Institute Staff member's Institute salary support. The Conflicts Officer must be made aware of compensation provided under a consulting agreement which will co-exist with a research grant or contract from the same industrial sponsor.

D. REPORTING PROCEDURES

An Institute Staff member must provide a written report, as described in the following paragraph, when any of the situations outlined above in Sections I.A.1 - I.C.8 arises. Disclosure must be made prior to any agreement to undertake the outside commitment or prior to exceeding the 26-day annual threshold. However, disclosure is a continuing obligation, as it also must be made if a possible conflict becomes evident when a faculty member's ongoing relationship with an outside party changes.

In situations covered by Sections I.A.1 to I.C.8, the Institute Staff member must submit a written statement of the activity and any proposed written agreement to the Conflicts Officer. If the Conflicts Officer approves the reported activity, the report and notice of

approval must then be forwarded to the Chief Operating Officer and any other individual designated by the Institute.

The purpose of these reviews is to ensure that the proposed activity and any agreement(s) comply with policies of the Institute. After the review is completed by the Conflicts Officer, and in the event the proposed activity and agreement is found to comply with all relevant policies, a written statement of approval will be sent to the Institute Staff member with a copy to any applicable supervisor.

E. PROHIBITED ACTIVITIES

Arrangements with outside organizations that have not received approval in accordance with Section I.D above or Section II are prohibited as well as other arrangements or activities that violate this Policy.

F. 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. (See attached forms).

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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.³ 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

³ The welfare of animal subjects is also a mission of the Institute; animal welfare is the subject of separate, related policies that are implemented and approved by the Animal Care and Use Committee of JHU. (See Handbook on Use of Experimental Animals at Johns Hopkins University.)

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 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 F⁴ 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 on Outside Interests (the "Committee"), do not involve research. An example of such activity would be procurement. Accordingly, although conflict of interest in research is the focus of the Committee, the Conflicts Officer may request that the Committee review and advise him/her concerning financial interests related to other activities.

B. APPLICABILITY

This Policy applies to all Institute employees and students who serve as investigators in proposals submitted to external sponsors. In accordance with U.S. Department of Health and Human Services (USDHHS) Public Health Service (PHS) regulations (42 CFR Part 50 § F and 45 CFR Part 94), this Policy also covers all Institute employees and students applying for or receiving PHS funding from a grant, cooperative agreement, or contract on or after 24 August 2012. 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 and fiduciary interests related to research activities⁷ 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.

⁴ "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors."

3. The Committee may recommend either prohibition of the proposed research activity or procedures for management of the conflict of interest.

4. Institute Staff may not participate in research projects 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.

5. Institute Staff are additionally responsible for complying with the all of the requirements set forth in Section I of this Policy. The provisions in this Section II are to be interpreted by the Committee consisting of a standing body consisting of senior members of the research staff of the Institute as well as senior members of the Institute administration, serving ex officio and legal counsel in a manner consistent with the Section I.

D. OBLIGATIONS OF INSTITUTE STAFF

1. Disclosure to Institution

Institute Staff must make disclosures to the Institute of financial interests as outlined in the policy 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 activities funded or proposed for funding, and
- b. all financial interests in entities whose financial position would reasonably appear to be affected by activities funded or proposed for funding.

2. Completion of conflict of interest training

All covered parties must complete Johns Hopkins University conflict of interest training.

- a. When training must be completed
 - i. Prior to engaging in research related to any PHS-funded project
 - ii. At least every four years
- b. Training also must be completed when any of the following occur:
 - i. The Institute revises this Policy;
 - ii. A covered party is new to the Institute; or
 - iii. The Institute determines that an Investigator is not in compliance with this Policy or his/her assigned management plan
- c. How training should be completed
 - i. 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).

3. Compliance with Institutional Management and Related Requirements

Covered parties are required to comply with institutional conflict of interest management requirements and administrative conditions associated with financial interests related to research.

E. FINANCIAL INTERESTS REQUIRING DISCLOSURE AND REVIEW BY THE COMMITTEE ON OUTSIDE INTERESTS

The arrangements described below must be disclosed to the Institute via a Financial Disclosure Form and must be reviewed by the Committee prior to proposal submission to an 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. For additional procedures related to human subjects research proposals, see Section H below. Review is required regardless of the value of the financial interest in question; there is no “de minimus” level below which review is not required. Financial 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.

1. Royalties

a. Proposals to conduct research (regardless of the source of external research support, if any) when the research will be performed by an Institute Staff member who receives, or is entitled to receive, royalty from the sale of products, the value of which may reasonably appear to be materially affected by the research. This includes arrangements involving licensing-related payments, royalty, or future royalty, whether such payments are received by the Institute and distributed to the inventor or received by the inventor from another source.⁵

b. Institute proposals to license inventions to outside entities.

2. Equity

a. Any proposal for licensing an Institute Staff member’s invention when the Institute Staff member, either directly or through the Institute, holds equity or will hold equity (*e.g.*, stock, options) in the licensee. Equity also applies to equity instruments such as stock options and warrants, as well as to ownership interests.

⁵ 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. The eventual recognition of value of an invention to the public may, in the judgment of the Committee, constitute compelling justification to permit a potential future financial interest concurrent with human subjects’ research, subject to appropriate and extensive management conditions. The foregoing may not be interpreted so as to eliminate reporting obligations, limit the Committee’s ability to restrict or prohibit these arrangements, or to determine what constitutes a compelling justification. See Section H below for Special Considerations for Review and Management of Conflicts of Interest in Human Subjects Research.

b. Any proposal to conduct research (regardless of the source of research support, if any) involving an Institute Staff member who, either directly or through the Institute, holds equity (*e.g.*, stock, options) or will hold equity in: (i) a company supporting the research, or (ii) a company whose technology is a subject of the research. This includes equity received or to be received by any means, including but not limited to the following: for consulting or advisory services, through an Institute-based or personal licensing agreement, through inheritance, or as the result of an arms-length purchase.

c. Any proposal by an Institute Staff member to acquire equity in the sponsor of an ongoing research project or in a company that controls technology that is the subject of ongoing research, where the technology may reasonably appear to be materially affected by the research.

d. Diversified financial holdings that are not controlled, influenced, or managed by an Institute Staff member (*e.g.*, mutual funds) are not considered a relevant financial interest and need not be reported.

3. Income/Payments

Any proposal to conduct research that may affect the value of a company or entity from which an Institute Staff member receives or is entitled to receive income, including, but not limited to, income for consulting, advisory or lecturing services, honoraria, and in-kind support. This does not include payment to the Institute to support the cost of specific research projects (*e.g.*, grants or contracts).

4. Other

a. Any proposal by an Institute Staff member to have a management position, board of directors seat, or other fiduciary role in any organization (non-profit or for profit) whose activities could reasonably be interpreted as related to the Institute role or activities of the Institute Staff member.

b. Any proposal to conduct research when an Institute Staff member's spouse, domestic partner, or minor dependents have a financial interest that may be affected by the research.

F. MECHANISMS FOR REQUIRED REPORTING TO THE COMMITTEE ON OUTSIDE INTERESTS

Institute Staff have an affirmative duty to disclose all relevant financial interests on an ongoing basis as they arise, as described in Section E above, to the Conflicts Officer. Updated Financial Interest Disclosure Forms must be submitted as financial interests change within 15 days of discovering or acquiring a new FI as well as annually during the period of an award. Reports of the arrangements also are required in connection with specific activities described below.

1. Proposals for Outside Support

Disclosures are required to be filed with the Conflicts Officer in conjunction with all applications for outside funding. If an Institute Staff member has a relevant financial interest, as described in Section II.E above, such financial interest must be fully disclosed in

the Financial Interest Disclosure Form and described in the proposal to the external sponsor. All disclosures will be referred to the Committee for review.

2. Human Subjects Research

Proposals for all research protocols involving human subjects research shall be submitted to a JHU IRB for review; provided, however, that the principal investigator under any such proposal must obtain Committee review by submitting the proposed protocol directly to the Committee prior to submitting it to a JHU IRB. All approvals and subsequently the approved IRB protocols must be filed with the Institutes Office of Legal and Research Administration. Proposals must include a statement concerning relevant financial interests of any Institute Staff member, as described in Section II.E above. Procedural questions relating to the review of protocols for human subject research should be directed to the Conflicts Officer.

3. Written Agreements with Outside Entities

As outlined in Section I of this Policy, all proposed written agreements with outside entities must be submitted to the Conflicts Officer. All written agreements must be reviewed, regardless of the level of compensation to the Institute Staff member, prior to being signed by Institute Staff. If an Institute Staff member serving as a consultant or scientific advisor proposes to participate in research that is sponsored by the consulting client or involves a product of the consulting client, the proposed consulting activity requires Committee review.

4. Technology Transfer

When an outside entity proposes a technology transfer arrangement with the Institute involving an Institute Staff member, the Institute technology transfer office will control the negotiation of such arrangement. Any such arrangement will be subject to review under this Policy, the Institute's Intellectual Property Policy and other applicable policies law and regulations. The Institute Staff member will be responsible for submit to the technology transfer office and the Committee the relevant Invention Disclosure Application and any federal filing records to aid in the review. In connection with review under this Policy, the Institute technology transfer office will report the proposed financial interests of the Institute Staff member and the Institute to the Committee. 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. Appointment Letters

Institute Staff receiving annual appointment letters must confirm in writing that they reported all applicable outside commitments as required in this policy. Such reports must be updated as information changes.

6. 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.

G. REVIEW AND MANAGEMENT OF CONFLICTS OF INTEREST

1. Committee on Outside Interests

The Committee is a standing body consisting of senior members of the research staff of the Institute as well as senior members of the Institute administration, serving ex officio and legal counsel.

2. Obligations of the Committee on Outside Interests

Prior to expenditure of PHS funds the Committee must:

- a. Review all Investigator FI disclosures
- b. Determine if any FI's relate to PHS-funded research
- c. Determine if any FCOI exists
- d. Develop and implement management plans, as needed to manage FCOIs
- e. Monitor Investigator compliance with management plans until completion of the project

3. Review

The Committee reviews information related to all financial and/or fiduciary arrangements in light of related research activity. For clarity, the Committee does not review financial and/or fiduciary arrangements that do not appear to present a conflict of interest related to research activity. In its review, the Committee considers the following factors:

- a. impact on the integrity of research data;
- b. risks to the rights and safety of human research subjects (see Section H);
- c. risks to the rights and obligations of students and trainees participating in research; and
- d. appearance of a conflict of interest.⁶

4. Determination/Management

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.

⁶ 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.

For proposed arrangements involving human subjects research, the Committee will make a recommendation to the Conflicts Officer and to the appropriate IRB. This procedure is described more fully in Section H.

If the Committee determines that a conflict of interest may be permitted, it will recommend that management of the conflict of interest be implemented using, for example, one or more of the following:

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, presentations (whether or not academic presentations), including presentations at the level of the Institute Staff member's primary department or higher; (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.⁷

c. Limiting the Role of the Investigator with a Financial Interest: Requiring that the role of the Investigator with the financial interest 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 financial conflict of interest by a certain date.

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 financial or fiduciary conflict of interest.

⁷ 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.

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.

H. 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 financial interests provide the Committee with a *compelling justification*—consistent with the rights and welfare of human research subjects—for being permitted simultaneously to hold the financial interest 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 and the Institute Staff member has a financial interest, as defined below, 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 financial interests. Although the arrangements will not be presumptively prohibited, the research project will still be subject to review by the Committee.

1. Financial Interests

All financial interests are subject to reporting and review. *Financial interests below the thresholds listed below are not exempt from reporting.* Financial interests include:

- a. Fees, honoraria, gifts or other emoluments, or “in kind” compensation from a financially interested company (or entitlement to the same), whether for consulting, lecturing, or any other purpose, 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. This does not apply to diversified mutual funds or similar instruments in which the shareholder has no control over the equities held by the fund. 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.⁸

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.⁹

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. Review and Determination/Management

As described in Section H, the Committee will review reports of proposed financial interests in human subjects research projects. Recommendations concerning the Institute Staff member’s relationship to the outside entity will be communicated in writing to the Conflicts Officer and to the appropriate IRB. The Conflicts Officer will communicate his/her decision concerning the Institute Staff member’s relationship with the outside entity to the Institute Staff member in writing. Nevertheless, 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. Accordingly, the IRB will be instructed to communicate its decision concerning participation in the human subjects research protocol to the Institute Staff member and to provide a copy of that communication to the Committee.

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

⁸ 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.

⁹ 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.

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

a. Prohibition: If, upon reviewing specific evidence provided by the Institute Staff member with the relevant financial interest, the Committee believes that a 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 financial interest before beginning the project or be barred from participation in the research.

b. Management: In cases involving insignificant financial interests, 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 a limited number of cases involving significant financial interests, if the Committee concludes that the justification provided by the Institute Staff member is sufficiently compelling and that the conflict of interest can be managed, it will recommend specific project-related management measures to the appropriate IRB.

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 financial interest of any magnitude, a financial disclosure statement including the name of the financially interested individual and describing the source and nature of the relevant financial interests 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. Other project-related management measures, as detailed in Section II.G, may also be recommended.

The Committee's recommendation, accompanied by a description of the nature and magnitude of the potential conflict of interest, will be communicated in writing to the appropriate IRB. The IRB, which is responsible for ensuring the ethical acceptability of the research, 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.

I. 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.

J. 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 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 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.

K. 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 financial conflicts of interest with PHS-funded research¹⁰

- a. Investigator's name
- b. Investigator's title and role with respect to the research project
- c. Name of entity in which a FI is held
- d. Nature of the FI
- 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 financial conflicts of interest with PHS-funded research¹¹

- a. Project number

¹⁰ 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.

¹¹ 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).

- b. Program director/principal Investigator
- c. Name of Investigator with financial conflict of interest
- d. Name of entity in which a FI is held
- e. Nature of the FI
- 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
- g. Description of how the financial interest relates to the PHS-funded research and basis for the Institute's determination of a financial conflict of interest
- 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.

L. SANCTIONS FOR FAILURE TO COMPLY

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 within 120 of the determination of non-compliance to determine whether bias is present in the design, conduct or reporting of the research: failure to disclose in a timely manner financial interests that are determined to constitute an FCOI with PHS-funded research; failure by the Institution to review or manage an FCOI; or failure by a covered party to comply with a management plan. If bias is identified, the Institution will develop and implement a mitigation plan.¹²

¹² 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

If the failure of an Investigator to comply with this conflict of interest 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.

M. LEGAL OBLIGATIONS

Institute Staff should be aware that as a result of their financial interest or fiduciary role in a company 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)

Individuals who seek research funding from either PHS (including NIH) or NSF must comply with applicable regulations (e.g., Human Subjects Protection (45 C.F.R. Parts 46 and 690, respectively)) to ensure that the design, conduct, or reporting of research funded under PHS and NSF grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those Investigators responsible for the research. Under applicable regulations, Investigators are required to disclose to an official(s) designated by the Institute a listing of FI (as defined at 42 C.F.R. Part 50, Subpart F, for grants or cooperative agreements, and 45 C.F.R. Part 94 for research contracts) (and those of his/her spouse and dependent children) that would reasonably appear to be affected by the research proposed for funding by the PHS.”¹³ For a copy of the complete regulations, contact the Conflicts Officer.

2. U.S. Food and Drug Administration (FDA)¹⁴

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. For a copy of the complete policy, contact the Conflicts Officer. Individuals holding Investigational New Drug applications (“IND”) and Investigational Device Exemptions should consult FDA concerning applicable rules and regulations.

presentation of the results of the research and to request an addendum to previously published presentations if a disclosure was not made.

¹³ NIH, Objectivity in Research, available at <http://grants.nih.gov/grants/guide/notice-files/not95-179.html> and Frequently Asked Questions, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50 Subpart F, grants; and Responsible Prospective Contractors, 45 CFR Part 94, contracts), available at <http://grants.nih.gov/grants/policy/coifaq.html>.

¹⁴ FDA, Financial Disclosure by Clinical Investigators, Guidance for Industry, available at <http://www.fda.gov/oc/guidance/financialdis.html>.

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. 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

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

N. 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 Employee: _____ Date: _____

Printed Name: _____

Signature of Institute Officer: _____ Date: _____

Printed Name: _____

APPENDIX A

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.

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 on Outside Interests 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 Lieber) 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, 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. 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: _____