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# **Conflict of Interest and Conflict of Commitment**

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# **Policy Statement**

The Lieber Institute (the "Institute" or "Institution") encourages its members to engage in the translation of research and scholarship for the benefit and well-being of the public. Covered Individuals (as defined below) serve these goals through their primary commitment to research and collaborations with fellow Covered Individuals. To the degree that is consistent with that commitment, it is also appropriate and often valuable for Covered Individuals 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 Covered Individual, the Institute, and the greater public. A divergence can occur between the personal interests of Covered Individual and his or her professional obligations to the Institute, in which case a Conflict of Commitment or Conflict of Interest can arise.

This Conflict of Interest and Conflict of Commitment Policy ("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 a Covered Individual. Compliance with this Policy does not relieve a Covered Individual 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 Covered Individuals.

This Policy covers Covered Individuals of the Institute, except as noted below.

# **Policy Purpose**

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 or Conflicts of Commitment to 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.

The purpose of this Policy is to assist Covered Individuals 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. All arrangements involving potential Conflicts of Interest and Conflicts of Commitment 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.

#### **Definitions**

A *Conflict of Commitment* occurs when a (i) Covered Individual's Outside Commitments compromise or may compromise his or her ability to meet the Covered Individual's obligations to the Institute or (ii) is of a nature that the Outside Commitment may only be performed through the Covered Individual's role at the Institute.

A *Conflict of Interest* is a Financial Interest or Outside Commitment 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. The fact that the individual has the Financial Interest or Outside Commitment alone is enough to create a Conflict of Interest if it could compromise or appear to compromise the integrity of the Covered Individual's decision making.

Covered Individual(s) includes Investigators, members of the research staff, postdoctoral fellows, research associates and assistants (including full-time graduate students at the Institute), as well as other staff who are compensated or otherwise supported by the Institute for their services. This Policy 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 Research 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 research member includes her or his spouse, domestic partner, and/or dependent children.

**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 as legal counsel.

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 Covered Individual (e.g., stocks, stock options, warrants or ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights) received by a Covered Individual or that Covered Individual's spouse, domestic partner, or dependent children that reasonably appears to be related to the Covered Individual's Institute responsibilities or activities. In addition, a Financial Interest exists when a Covered Individual or a Covered Individual's spouse, domestic partner, or dependent children maintain fiduciary obligations to an Outside Entity when those fiduciary obligations reasonably appear to be related to the Covered Individual's institutional responsibilities or activities.

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

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.

*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.

*Institutional Responsibilities* means the responsibilities and roles a Covered Individual 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) is the provision of services and time commitments for non-LIBD activities that (i) are based on the expertise and knowledge of the Covered Individual and reasonably appear to be related to the Covered Individual's LIBD responsibilities or activities; or (ii) may reasonably be deemed to significantly impact the Covered Individual's ability to satisfy her or his LIBD responsibilities and activities. Outside Commitments include, but are not limited to, all consulting, serving on governing boards of an Outside Entity, scientific advisory boards, outside speaking, professional or academic society work, outside administrative responsibilities such as serving as an officer or employee of an outside entity, expert witness activity and outside teaching. For clarity, services provided to JHU in connection with a Covered Individual's concurrent faculty appointment at JHU, are not considered Outside Commitments for purposes of this Policy. The following are not considered Outside Commitments: uncompensated, domestic, scholarly activities that are traditionally undertaken in the Covered Individual's academic field, including but not limited to service on academic journals – for clarity any compensation received for such traditional academic activity is a Financial Interest and must be disclosed under this Policy.

*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.

A *Startup Company* is a privately held company that (i) is based on intellectual property developed by Covered Individuals at the Institution, or (ii) is founded by Covered Individuals and relates to the Covered Individuals' Institutional responsibilities and activities. Startup Companies do not include small limited liability corporations or partnerships created for the sole purpose of facilitating faculty expert consulting.

# **Policy**

### Primary Commitment of Covered Individuals

Acceptance of a position at the Institute entails a commitment to assign first priority to the needs and goals of the Institute. 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 Covered Individual is shared indirectly by the Institute, and these Outside Commitments 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. Where there is the possibility or appearance of a conflict between a Covered Individual's obligations to another organization and those to the Institute, the Covered Individual 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 General Counsel.

# Specific Prohibited Activities

The following Financial Interests and Outside Commitments are ordinarily prohibited:

- 1. Any Outside Commitment that could imply or constitute endorsement or promotion of any commercial product, technology, service, or company.
  - a. This includes scenarios in which Covered Individuals 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.
  - a. 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, proprietary information, or intellectual property, belonging to or utilized by the Institute.
  - a. 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 Covered Individual's public reporting of the existence of the agreement or information developed by the Covered Individual under the agreement.
  - a. Any agreement which includes requirements for confidentiality that might compromise the Institute's research mission, its scholarly independence, or the rights of the Covered Individual, other Covered Individuals 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.
- 5. Whenever a Covered Individual is considering whether to serve as principal investigator of any Human Subjects Research protocol or as principal investigator or sponsor-investigator of an FDA-regulated clinical trial when a Covered Individual has a Financial Interest that is related to the Human Subjects Research.
- 6. Involvement by a Covered Individual in an Institute business decision (including but not limited to subaward, procurement, licensing, and sponsored research decisions) when the Covered Individual's Financial Interest or Outside Commitment may create the appearance of a conflict in that decision-making.
- 7. Conducting Research outside of the Institute.

# Special Areas of Focus

**Research and Publications** 

Covered Individuals may consult with or advise an Outside Entity regarding the entity's research under a private agreement. However, when it is anticipated that the Covered Individual'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 Covered Individual will provide the services under an institutional research agreement.

On occasion, when Covered Individual 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 Covered Individual must ensure the publication includes a disclaimer that states (a) they 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) they were compensated for the consulting or advising service in [income/stock/equity/other form of compensation]. Covered Individuals who qualify for authorship in the course of private consulting are expected to follow all ethical standards of the research community. The Covered Individual should also update his/her existing consulting or advising disclosure to include the authorship role.

#### **Human Subjects Research**

Financial Interests and Outside Commitments 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. Covered Individuals are required to report all Financial Interests and Outside Commitments in and related to Human Subjects Research. When Covered Individuals who have Financial Interests or Outside Commitments related to Human Subjects Research wish to participate in that Research, the applicable official shall either recommend a management plan, or if the Conflict of Interest cannot be adequately managed, shall prohibit the participation 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 Financial Interest in the Research project or in an Outside Entity.

Exceptions may be made in specific cases when, in the judgment of the Committee, individuals holding conflicting Financial Interests provide the Committee or Conflicts Officer 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 a Covered Individual 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 Covered Individuals with Financial Interests. Although the Financial Interest will not be presumptively prohibited, the Committee or Conflicts Officer will furnish the approved management plan to the responsible IRB.

The following Financial Interests involving Human Subjects Research are presumed prohibited:

- A. Fees, honoraria, gifts or in-kind compensation (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;
- B. An equity interest of any amount, (including ownership interests, options, or warrants) in a private entity (or entitlement to the same).
- C. An equity interest (including ownership interests, options, or warrants), in a publicly-traded entity (or entitlement to the same) that exceeds \$25,000 in value as determined through reference to current prices (this does not include diversified mutual funds or similar instruments in which the shareholder has no control over the equities held by the fund).
- D. Service as an officer, director, or in any other fiduciary role in a company that has an interest in the outcome of the Research.

# **Startup Companies**

Opportunities for development and commercialization of inventions are often born from relationships between Covered Individuals and Startup Companies, yet they may also create Conflicts of Interest and Conflicts of Commitment. Covered Individuals must comply with all Institution policies, including the Institute's Intellectual Property Policy, when founding or otherwise engaging with Startup Companies.

Covered Individuals may engage with Startup Companies in the following ways, provided such engagement is appropriately and timely disclosed and approved in compliance with the procedures outlined in this Policy:

- 1. Founder: Covered Individuals may generally be a founder of a Startup Company.
- 2. Equity Interests: Covered Individuals may generally hold equity in Startup Companies.
- 3. Membership on Boards of Directors: Covered Individuals may generally serve on the board of directors of a Startup Company.
- 4. Service as an Operating Officer: Service as an operating officer of any entity, including Startup Companies, is a time-intensive position. Covered Individuals who are employed full-time by the Institute may, upon appropriate review and approval as stated in this Policy, serve as an operating officer of a Startup Company for a period of time, subject to the Committee's approval.
- 5. Service as a Consultant: Covered Individuals may generally consult for Startup Companies.

#### Consulting

It is the responsibility of Covered Individuals to ensure that all Outside Commitments, including private consulting, comply with the Institute's policies. The Institute is not a party to private consulting agreements. In general, consulting activity for large, established companies when the compensation provided for the consulting is a flat or hourly fee is less likely to be problematic than consulting activities for Startup Companies or consulting when the compensation is tied directly to the success of the third-party entity or its products (i.e., compensation in equity, royalties, and other methods of deferred compensation). Proposed private consulting will be reviewed as specified under the Procedures of this Policy, and factors to be taken into account by the reviewing official shall include: (i) the remuneration provided to the Covered Individual; (ii) the relationship between the faculty and the third-party entity; and (iii) the potential for confusion regarding the Covered Individual's Institution activities and the private consulting activity.

#### **Procurement and Sub-awards**

Covered Individuals who are in a position to make or influence Institution purchasing, sourcing, procurement, or Institute Research subaward decisions must refrain from any activity related to the Institute's purchasing, sourcing, procurement, or granting of subawards that could create the appearance of a Conflict of Interest and must notify the applicable Institute research administration or procurement official of the Covered Individual's Financial Interest or Outside Commitment.

With respect to proposed procurement engagements, the Covered Individual is prohibited from (i) participating in the selection of the third-party entity to provide goods or services to the Institution, (ii) negotiating with the third party entity on behalf of the Institution, (iii) negotiating with the Institution on behalf of the third party entity, and (iv) actively attempting to influence the procurement or subaward decision.

If a Covered Individual desires to issue a subaward for a portion of the Institute's Research to a third party entity in which the Covered Individual has a Financial Interest or Outside Commitment, the Institute must conduct appropriate due diligence to confirm that the proposed subaward is scientifically appropriate and in the best interest of the Research. If the Institute makes that determination in favor of issuing the proposed subaward, the Covered Individual is prohibited from negotiating for either the Institute or third party in the subaward contracting and subsequent business discussions related to performance of the subaward. Additional management conditions related to the subaward may be issued by the applicable Institute official at his or her discretion.

# Covered Individuals with Responsibilities Related to Technology Transfer, Business Development, and Entrepreneurial Activities.

Covered Individuals who have Institutional responsibilities related to business development, technology transfer, procurement, or entrepreneurial activity ("Business Development Staff") must be especially careful to avoid Outside Commitments or Financial Interests that may create a Conflict of Interest with their Institution responsibilities. As with all staff, full-time Business Development Staff are prohibited from creating Conflicts of Interest or Conflicts of Commitment. Specific prohibited Outside Commitments and Financial Interests for Business Development Staff include holding any Financial Interest in or engaging in Outside Commitment with an outside entity (including a Startup Company) that has licensed, optioned, or entered into negotiations to license or option Institute intellectual property. Business Development Staff may be required to submit regular reports to their supervisor of their Outside Commitments and Financial Interests that may reasonably be deemed to relate to their Institution responsibilities.

#### **Procedures**

### **Training**

All Covered Individuals who engage in Institute Research shall complete the conflict of interest training (i) before engaging in any Research related to any PHS-funded project, (ii) at least every four years thereafter, (iii) whenever this Policy is substantively revised, (iv) a Covered Individual is new to the Institute, and (iv) when the Institute determines that an Investigator is not in compliance with this Policy or their assigned management plan.

Conflict of interest training can be found via MyLearning on the JHU Intranet. Additionally, all Covered Individuals who do not engage in Research must read this policy before engaging in any Outside Commitment or accepting a Financial Interest.

#### When to Disclose

Covered Individuals must timely disclose all Financial Interests and Outside Commitments in writing or through an established electronic disclosure system, as specified by the applicable policy or procedure.

Disclosures must be made:

- 1. Before a Covered Individual engages in an Outside Commitment or acquires a Financial Interest.
- 2. When a previously-disclosed Financial Interest or Outside Commitment changes or ends.
- 3. At the time a Covered Individual applies for funding from a Public Health Service agency.
- 4. Within 30 days of reimbursed or sponsored travel related to a Covered Individual's institutional responsibilities, for all Covered Individuals who are investigators on Public Health Service funded research if the value of the Covered Individual's (including his/her spouse, domestic partner, and dependent children) reimbursed travel from any third party exceeds \$5,000.00 in the previous 12 months.

In addition to these disclosure requirements, all Covered Individuals must complete an annual certification to ensure that their disclosures are accurate and up to date.

#### What to Disclose

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

- 1. Proposed Outside Commitments, whether or not they are compensated.
- 2. Proposed Financial Interests.

3. For Covered Individuals who engage in Public Health Service funded research, all reimbursed or sponsored travel related to the Covered Individual's institutional responsibilities, if the value of the Covered Individual's (including his/her spouse, domestic partner, and dependent children) reimbursed travel from any third party exceeds \$5,000 in the previous 12 months.

#### How to Disclose

Covered Individuals shall disclose via a written report submitted to the Conflicts Officer. Covered Individuals must obtain prior approval from the Conflicts Officer before undertaking any commitment that may conflict or appear to conflict with the primary commitment to the Institute.

#### Review of Disclosed Financial Interests and Outside Commitments

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. Depending upon the circumstances, the Conflicts Officer may enlist the Committee to review the disclosure. Additionally, disclosures may be reviewed by the Covered Individual's supervisor and/or Human Resources in determining whether a conflict exists.

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

- A. Potential of disclosed interests to create a Conflict of Interest or Conflict of Commitment or the appearance of one:
- B. Risks to the rights and safety of human research subjects;
- C. Impact on the integrity and objectivity of academic scholarship and research data;
- D. Risks to the rights and safety of human research subjects;
- E. Risks to the rights and obligations of students and trainees participating in Research;
- F. Impact on a Covered Individual's ability to devote time, energy and devotion to research and Institute responsibilities; and
- G. Risk to Institute independence and objectivity in business transactions.

#### Outcome of Review of Disclosed Financial Interests and Outside Commitment

Upon completing its review, the Committee and/or the Conflicts Officer will recommend that the proposed arrangements be either (a) prohibited or (b) permitted, subject to specific management conditions. If applicable, 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 Covered Individual in writing. The Conflicts Officer shall report their decision in each case where Committee members were involved.

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 Covered Individual 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. The Institute shall monitor compliance with such management plans until the completion of the related Institute Research.

# Management of Conflicts of Interest and Conflicts of Commitment

If the Committee determines that a Conflict of Interest may be permitted, the Committee may implement the following management conditions including, but not limited to:

- A. Disclosure of the conflict, which may include, (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.
- 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.
- E. Divestiture: Allow arrangements to go forward contingent upon the sale or disposal of specified Financial Interests, or severance or limitation of Financial Interests or Outside Commitments 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 conflict
- G. Limitation on Institute business activity such as: (i) negotiating on behalf of the Institute, and (ii) receiving certain confidential or proprietary data

Once a management plan has been created, that management plan shall be conveyed to the Covered Individual in writing.

# Management of Conflicts of Interest in 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 Covered Individual 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 Covered Individual 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 to Committee or the Conflicts Officer's review, which may review the project as if it were "human subjects research" for the purposes of this Section.

The Committee's recommendation may involve the following management plan conditions described below.

- 1. Prohibition: The involved Covered Individual may be required to eliminate the relevant conflict before beginning the project or be barred from participation in the Research.
- 2. Disclosure of the conflict will be recommended to the responsible IRB for inclusion in the consent form where research consent forms are required and the Covered Individual has a conflict.
- 3. Prohibition from Covered Individual with a conflict from seeking or obtaining consent from prospective research subjects.

4. Monitoring compliance with any management plan related to Human Subjects Research until Research is complete.

In cases involving insignificant Financial Interests, the Committee or Conflicts Officer will generally recommend that the Covered Individual be permitted to participate in a given Human Subjects Research project, subject to certain specified management conditions.

Additional project-related management measures may include, for example, one or more of the following: the Covered Individual 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.

## Monitoring of Conflicts of Interest

Each person judged to have a Conflict of Interest or Conflict of Commitment must sign an agreement certifying that they will adhere to all conditions 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.

Whenever the Institute implements a management plan, the Institute will monitor the Covered Individual's compliance with the management plan on an ongoing basis until the completion of the Research project or activity. All arrangements may be reviewed again if circumstances change or there is new information.

### External Reporting of Conflicts of Interest

To comply with federal regulation, prior to the expenditure of funds from certain federal awards, including Public Health Service (PHS) awards, the Institute will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS. The Institute will also provide the following information with respect to Financial Interests:

- A. Project number.
- B. Program director/principal investigator.
- C. Name of investigator with financial conflict of interest.
- D. Name of entity in which a Financial Interest is held.
- E. Nature of the Financial Interest.
- F. Approximate dollar value of the Financial Interest within ranges, 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 federally funded research and basis for the Institute's determination of a Conflict of Interest.
- H. Description of the key elements of the Institute's management plan with respect to the Conflict of Interest, 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; and (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.

#### Record Retention and Accessibility

All disclosures of Financial Interests related to Research shall be retained by the Institute for a period of at least three (3) years following the termination of the related Research, including Research funded by any awarding body of the federal government.

In accordance with 42 CFR 50.605(a)(5)(i)-(iv) for managed conflicts of interest in research following PHS regulations for financial conflicts of interest (at 42 CFR Part 50 Subpart F), please request information from the Institute's Legal Department regarding such financial conflicts of interest related to PHS-funded research and the Institute will respond within five (5) business days of the request.

#### **Appeals**

If a Covered Individual believes that a determination made by the Committee and/or Conflicts Officer in a specific case is not appropriate or is based on erroneous information, the Covered Individual 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 Covered Individual still wishes to appeal, the Covered Individual may appeal to the Board of Directors of the Institute (the "Board"). 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.

# **Policy Enforcement**

Failure to comply with this Policy shall be subject to Institute review. In the case of Human Subjects Research failure to comply with this Policy may also be subject to responsible IRB policies on noncompliance. Potential sanctions range from placement of a warning letter in the Covered Individual's file, to suspension for a specified period of time, to termination.

If certain compliance failures occur with respect to Conflicts of Interest involving Public Health Service agency funding, 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 the research. Those failures include: (i) failure to timely disclose Financial Interests; (ii) failure by the Institute to review or manage a Conflict of Interest related to Research; and (iii) failure of a Covered Individual to comply with a management plan. If, after a retrospective review, the Institute determines that bias in research has occurred, the applicable official will develop and implement a mitigation plan. The Conflicts Officer shall promptly notify the federal funding entity of the findings and corrective actions that the Institute has taken or will take.

#### **Contacts**

Subject Matter	Office Name	Contact Number	Contact email
Policy Development and Interpretation	Legal Department	410-502-6517	Rebecca.Freedman@libd.org