

SUBJECT: Financial Conflict of Interest in Research

PURPOSE

The purpose of this policy is to clearly state that financial Conflicts of Interest in research will not be tolerated at LIBR and to establish procedures for identifying, reporting, evaluating, and managing financial relationships that could affect the objectivity or integrity of research conducted by LIBR.

SCOPE

This policy on Financial Conflict of Interest in Research applies to all LIBR Associates, with specific requirements for investigators.

POLICY OBJECTIVES

LIBR encourages members of the LIBR Staff to engage in outside professional activities and relationships so long as such relationships and activities are consonant with the objectives of LIBR and are beneficial to both participants and society at large. LIBR Associates are also likely to engage in such activities and relationships. LIBR has an interest in protecting the integrity of research conducted at LIBR. Therefore, any activities or relationships of LIBR Associates that could appear to create a Conflict of Interest must be disclosed to LIBR so that an effective conflict management process can be invoked. While a Conflict of Interest also may exist at the institutional level, this policy focuses on Conflicts of Interest involving individual Investigators.

A Conflict of Interest can be either financial or non-financial, and may result in a conscious or subconscious bias in the conduct or interpretation of research. A Conflict of Interest can adversely impact the safety of human subjects or provide an incentive to breach a duty to human subjects or to society. A Conflict of Interest may compromise or appear to compromise an Investigator's professional judgment in conducting or reporting the results of research.

LIBR is committed to conducting safe, objective research that generates independent, high-quality, reproducible results. Because any Conflict of Interest can taint the objectivity and independence of research, LIBR aims to identify, manage, reduce or eliminate potential Conflicts of Interests. All LIBR Associates must recognize real or perceived conflicts and report them as required by this policy.

DEFINITIONS

For purposes of this policy, the following terms have the meanings ascribed to them below:

“Conflict of Interest” A Conflict of Interest exists when financial or other personal interests or considerations of the Investigator, or members of his immediate family, may directly and significantly affect, or have the appearance of directly and significantly affecting, the Investigator's professional judgment in exercising any duty or responsibility related to LIBR research, including the design, conduct, or reporting of research. Investigator financial Conflict of Interests occur when the Investigator or any member of that person's immediate family (spouse and dependent children) possesses a Financial Interest or a Significant Financial Interest in a research activity that involves his or her LIBR responsibilities.

“Conflict of Interests Committee” or **“Committee”** means the committee of the LIBR Board of Directors, composed of Board members, and as needed, Investigators and administrative personnel, which is charged with evaluating reports of financial Conflicts of Interest and determining an appropriate resolution, including the development of a management strategy.

“Financial Interest” means anything of monetary value, including salary or other payments for services (e.g., consulting fees, honoraria, paid authorship, reimbursed or sponsored travel, or payments for serving on a corporate board or scientific advisory board); equity interests (e.g., stocks, stock options, LLC membership interests, partnership interests, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights), but will not include (a) salary, royalties, or other remuneration originating from LIBR; (b) income from investment vehicles (such as mutual funds and retirement accounts) for which the individual does not directly control the investment decisions; (c) or certain other income derived from a federal, state or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an Institution of higher education. Note: Certain federal regulations provide specific guidance on exempt sources of financial interest; however, this policy intentionally takes a broader view of financial interest to simplify the analysis in the first instance. For purposes of reporting a financial Conflict of Interest to the IRB, the IRB may expand the definition of “Financial Interest” and require that other types of compensation arrangements or Financial Interests be reported.

“Financial Conflict of Interest” means a Conflict of Interest derived from a Financial Interest.

“Investigator” means any individual who is responsible for the design, conduct, or reporting of a research project, including but not limited to key personnel, co- or sub-investigators, medical investigators, students, trainees, and research coordinators.

“Significant Financial Interest” means a Financial Interest, as defined above, in which (a) the compensation aggregated for the Investigator and his immediate family exceeds \$5,000 in a 12-month period, or (b) with respect an equity interest, an interest valued at more than \$5,000 or which represents aggregate ownership by the Investigator and his immediate family of more than 5% of any single entity.

POLICY/PROCEDURE

1. Investigator Conflicts of Interests

An Investigator at LIBR may be considered to have a Conflict of Interest when he, or a member of his immediate family, possesses a Financial Interest in an activity that involves his LIBR responsibilities.

LIBR expects Investigators to avoid Conflicts of Interest that may, or may appear to, (a) compromise objectivity in carrying out research responsibilities; (b) adversely affect LIBR’s interests; or (c) otherwise compromise the performance of responsibilities, unless such conflicts are managed, reduced, or eliminated in accordance with this policy. Research responsibilities include research design and proposal writing, applying for research funding, performing research, reviewing research proposals and protocols, reporting intellectual property resulting from research activities, entrepreneurship, and new venture creation as they relate to the results of research, reporting research results in any form, and any other activities carried out for purposes of conducting or promoting research.

2. Regular Reporting by the Investigator

Each Investigator must complete Financial Conflict of Interest training prior to engaging in research and at least every four years or within 30 days of material changes to this policy or a finding of noncompliance with either this policy or a Conflict of Interest management plan established based on this policy.

The Principal Investigator (PI) and all other Investigators involved on a research project must submit an initial and annual Conflict of Interest report to the Compliance Manager disclosing all Financial Interests. The PI and all other Investigators must also submit a new Conflict of Interest report within 30 days whenever there is a change in status from the previously-submitted report. The Compliance Manager will solicit the Conflict of Interest report from Investigators on at least an annual basis, and will determine if any additional information or disclosure may be required of an Investigator. The Compliance Manager will review the completed reports and confer with the Chief Operating Officer and Director as necessary to determine if the financial interests disclosed represent Conflicts of Interest. In addition, the IRB requires the PI to disclose financial Conflicts of Interest as part of the protocol submission.

In the event an Investigator submits a marketing application for FDA approval, the applicant is responsible for submitting the appropriate certification and reporting statements to the FDA, in addition to those submitted to LIBR. The Compliance Manager will assist the Investigator in complying with these additional reporting requirements in accordance with 21 CFR Part 54.

3. Review by IRB – Human Subject Protection

In its review of an Investigator's disclosure of a financial Conflict of Interest, the IRB uses a "reasonable person" standard analysis and considers (i) whether the financial Conflict of Interest could challenge the integrity of a reasonable individual; and (ii) whether the financial Conflict of Interest would appear to a reasonable member of the general public to be a conflict that could challenge the integrity of the conflicted party. The IRB will make an independent finding regarding the Conflict of Interest as it pertains to human subject protection. The IRB may (a) determine that the Conflict of Interest is not likely to jeopardize subject safety or bias the Investigator's decision-making and no further action is required, (b) require that the Conflict of Interest be disclosed to subjects, (c) require controls (such as limiting the Investigator's role in the research), (d) find that the Conflict of Interest is unacceptable and must be eliminated before the research may proceed, or (e) make other findings.

LIBR will notify the PI of the IRB's findings and incorporate those findings in its conflict management plan, as described below.

4. Review and Referral to the Conflict of Interests Committee

If a real or apparent Conflict of Interest is reported by an Investigator, the Compliance Manager will review the conflict and confer with the Chief Operating Officer. The Compliance Manager and Chief Operating Officer will determine whether the conflict warrants review by the Committee. If the IRB finds that action must be taken, the Compliance Manager or Chief Operating

Officer will report the matter to the Committee. If the IRB finds that no further action is necessary, the Chief Operating Officer may accept the IRB's findings or may refer the matter to the Committee for review.

Once a conflict is referred to the Committee, the Investigator may not proceed in research without prior approval of the Committee if (a) the Investigator has any Financial Interest and the research involves human subjects or is being conducted for the purpose of regulatory approval, or (b) the Investigator has a Significant Financial Interest whether or not the research involves human subjects or is being conducted for the purpose of regulatory approval.

Members of the Committee who have a Financial Interest in a particular proposal or LIBR protocol must recuse themselves from review of such protocol.

5. Managing Conflicts of Interest

If a Significant Financial Interest exists that would reasonably appear to compromise the objectivity of the research, the Committee requires that a written management plan be adopted prior to (a) expenditure by LIBR of any part of any sponsored research award or contract, and (b) the commencement of the research. If the research project is funded by the NIH or other federal agency, certain information concerning the Conflict of Interest must be made available via a publicly accessible website or by a written response to any requestor within 5 business days of the request and the written management plan must be adopted within 60 days from the date the conflict was identified by the Investigator. The Investigator reporting a Significant Financial Interest may propose a written management plan for ensuring research objectivity for consideration by the Committee. The Committee will also consider the IRB's requirements with respect to management of a Conflict of Interest. The Committee may also require a written management plan for conflicts that do not involve Significant Financial Interests, but could directly and significantly affect the design, conduct, or reporting of a research project.

Possible strategies for management of Conflicts of Interest include:

- Public disclosure of the Financial Interest
- Written affirmation of this policy
- Monitoring of research by independent reviewers
- Modification of the research plan
- Disqualification of Investigator from participation in the research
- Limitation of the Investigator's role in the research
- Notifying human subjects of the conflict prior to enrollment
- Divestiture of the Financial Interest
- Severance of relationships that create Conflicts of Interest
- Declining the grant award

For management plans that require research monitoring, individuals reporting Conflicts of Interest in the project will not be assigned as independent reviewers. In circumstances where an Investigator has a Significant Financial Interest in a contract involving LIBR and research and development or commercialization of intellectual property or a business, the Committee may require additional consultation in dealing with the Conflict of Interest.

The Committee has the authority to modify, approve, or disapprove a management plan submitted by an Investigator. A final management plan developed by the Committee must be accepted in writing by the Investigator.

The signed copy of the Committee-approved management plan will be provided to the IRB that reviewed the Investigator's project. The Committee-approved management plan may not be altered by the IRB, but it may be augmented to ensure the optimal protection of research subjects, as required by the IRB. For example, the IRB may require disclosure in the informed consent form. The research protocol cannot be approved until the IRB has reviewed and approved the Committee-approved management plan. The Committee-approved management plan, together with any additional requirements by the IRB, will become part of the approved protocol record maintained by LIBR.

The Investigator must provide the Committee with an annual update on the fulfillment of the management plan. The Compliance Manager is responsible for monitoring the Investigator's compliance with the plan and providing periodic reports to the Committee.

6. Reporting Significant Financial Interests to Federal Agencies and Other Sponsors

Prior to any expenditure of any funds under a federal award, LIBR will report to the federal agency the existence of a Significant Financial Interest. The initial report shall include the name of the entity with which the Investigator has a Financial Conflict of Interest, the nature of the Financial Interest (e.g. equity, consulting fees, travel reimbursement, honoraria), the value of the Financial Interest, a description of how the Financial Interest relates to federally funded research and the basis of determination that the Financial Interest conflicts with such research and key elements of the management plan. Annually thereafter, LIBR will submit an updated report to the relevant federal agency detailing the status of the Financial Conflict of Interest and any changes to the management plan. If LIBR identifies a Significant Financial Interest subsequent to delivery of the initial report to the funding agency, LIBR will make a follow-up report to the federal funding agency promptly after identification of such Significant Financial Interest.

With respect to sponsors that are not federal agencies, LIBR will comply with the sponsor's specific requirements concerning Conflicts of Interest.

7. Records

Records relating to the Conflict of Interest Forms and management plans are to be maintained as follows: (a) in the case of grants or cooperative agreements, for a period of at least 5 years after submission of the final expenditures report, unless otherwise directed, or (b) in the case of research contracts, for at least 5 years after final payment, unless otherwise directed. These records are subject to review by federal agencies in accordance with applicable law.

8. Policy Implementation and Policy Breaches

The Board is responsible for the appointment of members to the Committee. The Compliance Manager is responsible for (a) implementing this policy and the process for reporting and managing conflicts, and (b) updating this policy if there is a change in applicable law related to the identification, reporting, or management of Conflicts of Interest. The Compliance Manager will investigate and evaluate all identified breaches of the reporting, review, and approval process, including (a) failure to comply with the process (e.g., failure of Investigators to report Conflicts of Interest, failing to respond to Committee or IRB inquiries, or responding with incomplete or knowingly inaccurate information), (b) failure to remedy conflicts, and (c) failure to comply with a prescribed monitoring plan.

With respect to any federally funded research, within 120 days of a breach of this policy, the Compliance Manager will (a) complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine any bias in the design, conduct or reporting of research, (b) document the retrospective review consistent with the regulation, (c) document LIBR's determination as to whether any federally funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this policy or a prescribed monitoring plan, was biased in the design, conduct or reporting of such research.

If an Investigator's failure to comply with this policy has biased the design, conduct, or reporting of federally funded research, LIBR will notify the federal agency promptly and submit a mitigation report to the federal agency that shall address (a) the impact of the bias on the research project and (b) LIBR's plan of action or actions taken to eliminate or mitigate the effect of the bias. The federal agency may determine that a Conflict of Interest will bias the objectivity of the research and may require that additional corrective action be taken (in addition to the written management plan). The federal agency may suspend funding until the matter is resolved.

If the federal agency determines that an Investigator did not disclose or manage a Conflict of Interest appropriately, LIBR will require that the Investigator disclose the Conflict of Interest in each public presentation of research. This requirement applies to research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment.

If an Investigator violates this policy or fails to comply with a written management plan, the Investigator will be subject to disciplinary action, up to and including termination, in accordance with LIBR policies and procedures.

REFERENCES

DHHS Guidance “Financial Relationships and Interests in Research Involving Human Subjects”

42 CFR Part 50, Subpart F (Objectivity in Research - Public Health Service Rules)

21 CFR Part 54 (FDA Rules)

45 CFR 94 (Responsible Prospective Contractors)

RESOURCES

NIH Guidance at <http://grants.nih.gov/grants/policy/coi/>

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