

**THE NARROWS INSTITUTE FOR BIOMEDICAL RESEARCH AND EDUCATION INC.  
(NIBRE)**

**The Non-Profit Research & Education Corporation for the VA N Y Harbor Healthcare System  
(VA NYHHS)**

**CONFLICT OF INTEREST – FINANCIAL CONFLICT OF INTEREST POLICY**

**I. Application of Policy**

This policy is intended to supplement, but not replace, federal and state laws governing conflicts of interest applicable to nonprofit corporations. It applies to board members and staff. Persons covered under this policy, as well as their relatives and associates, are hereinafter referred to as “interested parties.”

This policy can also be found: [www.NIBRE.org](http://www.NIBRE.org)

**II. Conflict of Interest**

A conflict of interest (actual or perceived) may exist when any financial or other arrangement, situation, or action affects or could be perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. Conflicts may be related to financial gain, reputation, promotion, or to the role of research investigator vs. health care provider, among others.

An interested party is required to disclose a significant financial interest when he or she, any of his or her family, or any associated entity possesses a significant financial interest in a research activity that is related to his or her responsibilities as a member of the Narrows Institute for Biomedical Research & Education, Inc. (NIBRE) conducting research at VA New York Harbor Healthcare System (VA NYHHS)

NIBRE members are also subject to the conflict-of-interest policies of the federal government and institutions such as the State University of New York, Downstate (SUNY Downstate) and the New York University Langone Medical Center (NYU Langone) with whom they may have an affiliation or appointment and have a responsibility to disclose financial interests in research according to the policies of those institutions.

This policy covers all NIBRE administered research projects or programs and closely adheres to the policy as promulgated in the 2011 revised Department of Health and Human Services (DHHS) Financial Conflict of Interest (FCOI) regulation. Research supported by U.S. Public Health Service (PHS) funding has additional requirements addressed in the section for Additional Requirements for PHS Awards and in definitions noted below.

### **III. Definitions**

*Investigator* means the principal investigator, co-investigators, and other individuals who are responsible for the design, conduct, or reporting of research. It is not intended to apply to individuals who provide primarily technical support or who are purely advisory and without direct access to the data (e.g., control over its collection or analysis), unless they are able to influence the study's design, reporting, or results or have privileged information as to the outcome. Senior or key personnel identified on a grant application or progress report, consultants and post-doctoral fellows may or may not be included as Investigators.

*Research* means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development.

*Significant Financial Interest* means a financial interest consisting of one or more of the following interests of the Investigator (or those of the Investigator's spouse or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

Regarding, any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Regarding, any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Royalties from and agreements to share in royalties related to intellectual property rights paid to an Investigator (or his/her spouse or dependent children) are covered by the regulation and are subject to the \$5,000 threshold as described in the preamble (page 53265). If the royalties paid to the Investigator (or his/her spouse and dependent children) satisfy the definition of "Significant Financial Interest," then they must be disclosed. However, if the royalties or agreement to share in royalties relate to intellectual property owned by the employing or appointing applicant or awardee Institution and are licensed or potentially licensed through the applicant or awardee Institution (i.e., they are not personally owned by

the Investigator), they are considered remuneration from the Institution and would not be considered a Significant Financial Interest of the Investigator.

The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements 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; or income from service on advisory committees or review panels for 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.”

#### **IV. Disclosure of Potential Conflicts of Interest**

For all research projects, Investigators must disclose financial interests prior to review and approval by the Research & Development (R&D) Committee.

For NIBRE Board members, each member must complete a financial disclosure annually for Board review.

For Investigators under the PHS policy, disclosure is additionally required at the time of application and at least annually thereafter as delineated in the Financial Conflict of Interest Guidelines for PHS Awards. Disclosure should include the relationship of the financial interest to their institutional duties.

Interested parties are under a continuing obligation to disclose any potential conflict of interest within 30 days of being known or when it reasonably should be known.

Retrospective reviews will be required for significant financial interests not disclosed in a timely manner. Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest.
- Failure by the Institution to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan.

the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

An interested party shall complete the Questionnaire attached as Appendix A to disclose the material facts fully and completely about any potential conflicts of interest. The disclosure statement and Affirmation of Compliance (Appendix B) shall be submitted upon his/her association with NIBRE and shall be reviewed annually thereafter. An additional disclosure statement shall be filed whenever a potential conflict arises.

Disclosure statements will be submitted as follows. For board members, the disclosure statements shall be provided to the Chair of the board. The Chair's disclosure statement shall be provided to the Secretary of the board or its equivalent. Copies also shall be provided to the Executive Director of NIBRE.

In the case of investigators, the disclosure statements shall be provided to the Executive Director of NIBRE. In the case of the Executive Director, the disclosure statement shall be provided to the Chair of the Board.

In all cases, the recipient is the designated reviewing official responsible for bringing potential conflicts to the attention of the appropriate authorities. The Secretary of the Board of Directors shall file copies of all disclosure statements with the official corporate records of NIBRE.

## **V. Procedures for Review of Potential Conflicts**

Whenever there is reason to believe that a potential conflict of interest exists between NIBRE and a Board member or the Executive Director, the Board of Directors shall determine the appropriate response. This shall include, but not necessarily be limited to, invoking the procedures described below with respect to a specific proposed action, policy, or transaction. The designated reviewing official has a responsibility to bring a potential conflict of interest to the attention of the board promptly for action at the next regular meeting of the board or during a special meeting called specifically to review the potential conflict of interest.

Where the potential conflict involves an employee of NIBRE other than the Executive Director, the Executive Director shall be responsible for reviewing the matter and may take appropriate action as necessary to protect the interests of NIBRE. The Executive Director shall report to the Chair the results of any review and the action taken. The Chair shall determine whether any further board review or action is required.

## **VI. Procedures for Addressing Conflicts of Interest**

Where a potential conflict exists between the interests of NIBRE and an interested party with respect to a specific proposed action, policy or transaction, the Board of Directors shall consider the matter during a meeting of the board. NIBRE shall refrain from acting until such time as the proposed action, policy or transaction has been approved by the disinterested members of the Board of Directors of NIBRE. The following procedures shall apply:

An interested party who has a potential conflict of interest with respect to a proposed action, policy or transaction of the corporation shall not participate in any way in, or be present during, the deliberations and decision-making vote of NIBRE with respect to such action, policy, or transaction. However, the interested party shall have an opportunity to provide information about the proposed conflict and/or action, policy, or transaction. Also, the board may request that the interested party be available to answer questions.

The disinterested members of the Board of Directors may approve the proposed action, policy, or transaction upon finding that it is in the best interests of NIBRE. The board shall consider whether the terms of the proposed action, transaction or policy are fair and reasonable to NIBRE and whether it would be possible, with reasonable effort, to find a more advantageous arrangement with a party or entity that is not an interested party.

Approval by the disinterested members of the Board of Directors shall be by majority vote of directors in attendance at a meeting at which a quorum is present. An interested party shall not be counted for purposes of determining whether a quorum is present, nor for purposes of determining what constitutes a majority vote of directors in attendance.

The minutes of the meeting shall reflect that the conflict disclosure was made to the board, the vote taken and, where applicable, the abstention from voting and participation by the interested party. Whenever possible, the minutes should frame the decision of the board in such a way that it provides guidance for consideration of future conflict of interest situations.

## **VII. Violations of Conflict-of-Interest Policy**

If the Board of Directors has reason to believe that an interested party has failed to disclose a potential conflict of interest, it shall inform the person of the basis for such belief and allow the person an opportunity to explain the alleged failure to disclose.

If the board decides that the interested party has in fact failed to disclose a possible conflict of interest, the board shall take such disciplinary and corrective action as the board shall determine to include but not limited to:

- Disclosure of significant financial interests to the public, human subjects, researchers and other participants, publishers, and/or conference organizers
- Requiring additional disclosures or actions with respect to IRB or IACUC applications or materials
- Monitoring of research by disinterested co-researchers or independent reviewers or committees capable of taking measures to protect research from bias
- Disqualification from participation in activity affecting or affected by a technology transfer transaction
- Requiring that investigator participation in the recruitment or consent of subjects be prohibited or restricted
- Requiring that the significant financial interest be divested, restructured, or placed in a blind trust
- Modification or severance of relationships that create potential conflicts of interest
- Changing terms of the grant agreement or CRADA relating to the research
- Requiring non-participation in any business transactions between the parties to agreements involving the research in question.

Conditions imposed by NIBRE, or the VA NYHHS R&D Committee must be met by the Investigator to receive approval to conduct a proposed research project. NIBRE will not expend funds in support of a research project until any significant financial interest has been reviewed and any conflict of interest has been satisfactorily managed or eliminated.

NIBRE will comply with sponsor requirements for ongoing reporting of FCOIs including management plans, retrospective reviews, and mitigation reports. Any violation of this policy may require reporting to a sponsoring entity and affiliated institutions as appropriate.

### **VIII. Record Retention**

All records relating to the disclosure of conflicts of interest and any action taken with respect thereto will be maintained for at least three years or as required by applicable government regulations, whichever is longer.

## **IX. Additional Requirements for PHS Awards**

Additional requirements for PHS awards are promulgated by the 2011 revised DHHS Financial Conflict of Interest (FCOI) regulation, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). Compliance with these regulations is delineated under the Financial Conflict of Interest Guidelines for PHS Awards found on the NIBRE website.

Investigators entering consortium arrangements should be aware that NIBRE will include a requirement that subrecipient institutions comply with the PHS policy on Financial Conflict of Interest.

The PHS policy requires travel disclosure and training as defined below:

The Final Rule does not impose a general requirement to apply the de minimis threshold to all reimbursed or sponsored travel disclosure. However, Institutions may, within the discretion afforded by the Final Rule, impose the \$5,000 de minimis threshold to reimbursed or sponsored travel disclosure in their institutional policies which specify the disclosure details. For example, consistent with the requirement for other types of financial interests within the regulatory definition of SFI, Institutions could apply the de minimis threshold when aggregated per entity.

Disclosure of reimbursed or sponsored travel extends to the Investigator's spouse and dependent children (although not likely to apply to the children). However, training requirements do not extend to Investigators' immediate family members (spouses and dependent children).

Investigators must disclose all significant financial interests as defined above and in addition include reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities. However, this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency; an Institution of higher education; as defined at 20 U.S.C. 1001(a), an academic teaching hospital; a medical center; or a research institute that is affiliated with an Institution of higher education.

An Investigator is required to disclose all financial interests received from a foreign Institution of higher education or the government of another country. [See the NIH Guide Notice NOT-OD-18-160 dated 3/30/2018 for more information]<sup>i</sup>.

The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further

information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes an FCOI with the PHS-funded research.

Disclosures are required: (1) at the time of application for PHS-funding; (2) at least annually during the period of award; (3) within 30 days of acquiring or learning of a newly acquired significant financial interest; (4) within 30 days of an Investigator newly participating in the project; and (5) within 30 days of travel.

#### **A. Mandatory Training**

Each Investigator (as defined by the regulation), including subrecipient Investigator(s), must complete training prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances:

- Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

Institutions may utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at <http://grants.nih.gov/grants/policy/coi/> to satisfy some of the training requirements. However, Institutions must also provide additional training regarding Investigator's responsibilities for disclosure of Significant Financial Interests and of the Institution's specific policy on financial conflicts of interests.

#### **B. Public Availability**

In accordance with PHS policy, NIBRE makes identified FCOIs held by Investigators available to requestors within five calendar days of the receipt date of a written request.

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<sup>i</sup> <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html>