LA BioMed
Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center

**Primary Responsible Official:** CEO or delegate
**Primary Responsible Office:** Financial Conflict of Interest Committee
**Classification:** LA BioMed Policy

# FINANCIAL CONFLICT OF INTEREST POLICY AND PROCEDURES

## REASON FOR POLICY

This policy implements the 2011 Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (PHS regulations). PHS regulations are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct and reporting of PHS-funded research will be free from bias resulting from any Investigator's financial conflicts of interest.

This policy is applicable to all research funded by the PHS and other sponsors that adopt the PHS regulations with an award issue date of August 24, 2012, or later, and to proposals for research activities submitted on or after August 24, 2012. This policy applies to the Principal Investigator and to any individual responsible for the design, conduct, or reporting of PHS-funded research or research supported by entities adopting the PHS regulations.

## PURPOSE AND SCOPE

Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed) is committed to ensuring that LA BioMed Investigators and staff are provided an open and productive environment in which to conduct research and carry out administrative responsibilities. The concern with conflicts of interest reflects the complexity of our society, relations with each other and outside institutions, legal obligations and developments, and the significance of the issue to the public.

Conflicts of interest, which arise when a secondary objective could affect the performance of a person's primary mission, are a normal part of human existence. The potential for financial gain is one of many potential incentives that can lead to bias in a subjective activity, often subtle and unrecognized by the affected individual. LA BioMed is committed to advancing knowledge, including accelerating the translation of novel research ideas into medical practice. The application of knowledge, its dissemination and utilization, involves engagement with outside institutions and persons. Thus, LA BioMed must have policies that both encourage interaction with outside institutions and persons, and at the same time define ground rules so that individuals have clear boundaries within which to operate. There should be a balance between engagement with outside entities that may have economic incentives, and the academic and professional expectations of Investigator and staff at LA BioMed, In that way, research, education, and administrative responsibilities are performed in a manner that maintains the utmost in integrity and objectivity, with the public's interest and the protection of patients and human research volunteers always being the highest priorities.

LA BioMed adheres to the requirements of federal regulations regarding reporting requirements and is also mindful of the rules in the Affordable Care Act, which mandate public disclosure by pharmaceutical companies of payments to physicians.

This policy governing financial conflicts of interest applies to all Investigators of the institution. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies will constitute cause for disciplinary or other administrative action pursuant to institutional policy.

*Definitions are found below under DEFINITIONS section.*

## WHO NEEDS TO KNOW THIS POLICY

Investigators and Staff Members

## DEFINITIONS

*Clinical Trial* means any research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

*Individual:* Any person who is independently responsible for making decisions regarding research, education, purchasing, clinical care, or administrative responsibilities. For any one individual, the policy includes a financial interest of any immediate Family Member as if any financial interest of that Family Member were one of the individual.

*Family Member* means any individual in the Investigator's immediate family, specifically, any dependent children, spouse and/or domestic partner.

*Financial Conflict of Interest Committee of LA BioMed (Committee*) means the institution's committee or individual that advises the Institutional Official on conflict of interest matters.

*Financial Interest* means anything of monetary value received or held by an Investigator or an Investigator's Family Member, whether or not the value is readily ascertainable, including, but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works), equity interests (e.g., stocks, stock options, or other ownership interests), or intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) upon receipt of royalties or other income related to such intellectual property rights and interests.

*Financial Interest* does NOT include:

a) salary, royalties, or other remuneration from the institution,
b) income from the authorship of academic or scholarly works,
c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. federal, state or local governmental, or foreign agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers, or

d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her Institutional Responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

*Significant Financial Interest* (SFI) means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any interest during the 12-month period preceding or as of the date of disclosure, exceeds $5,000, or
b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds $5,000, or
c) if with a publicly or non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure, or
d) is income exceeding $5,000 related to intellectual property rights and interests not reimbursed through the institution, or
e) is reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities.

*Financial Conflict of Interest* means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of research, or the performance of duties and responsibilities on behalf of LA BioMed. A financial COI can exist in a variety of situations, including the following examples:

- *Clinical Care:* A financial interest that could directly and significantly affect decision-making in regard to clinical care, particularly with regard to the selection of medication or a device. Most typically, this financial interest will be the receipt of an honorarium (for speaking or consulting) or a royalty arrangement related to intellectual property. For the purpose of this policy, issues regarding fee-for-service medicine will not be included.

- *Education:* A financial interest that could directly and significantly affect a mentoring relationship or educational presentations. Examples of such presentations are lectures, web-based teaching, and review articles.

- *Purchasing:* A financial interest that could directly and significantly affect a purchasing decision. Examples of such decisions are purchases of equipment, supplies, and services.

- *Research:* A financial interest that could directly and significantly affect the design, conduct, or reporting of research. FCOI is present in a situation in which a primary interest or responsibility is affected, real or perceived, perhaps unduly, by a secondary interest or responsibility. This means that a subjective component of a primary interest (e.g. research) is affected, or potentially affected, by a financial secondary interest, either ongoing (e.g. consulting) or where there is the potential for increased valuation (of stock or an option). FCOI is present when the outcome of the research could affect future income or the value of an asset (including an option for equity).

*Institutional Official* means the individual within the institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family Member related to the Investigator's Institutional Responsibilities.

*Institutional Responsibilities* means the Investigator's professional responsibilities associated with his or her institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

*Investigator* means any individual who is responsible for the design, conduct, or reporting of research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants, as appropriate.

*Public Health Service* means the Public Health Service of the U.S. Department of Health and Human Services (PHS), and any components of the PHS to which its authority may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

*Research* means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

## POLICY/PROCEDURES

### *Investigator Responsibilities*

1. *Disclosure*. Every Investigator must disclose all of his or her Significant Financial Interests (SFIs), and those of the Investigator's Family Members that reasonably appear to be related to the Investigator's Institutional Responsibilities. The Investigator is not charged with making a determination as to whether the SFI constitutes a conflict of interest or could affect the design, conduct or reporting of the research. That determination is made by the LA BioMed Chief Executive Officer or his/her delegate (collectively CEO), as is further described below. Investigator disclosures are required as follows:

    a. *Upon Application*. Each Investigator who is planning to participate in research must disclose SFIs to the Financial Conflicts of Interest Committee of LA BioMed (Committee) no later than the time of application or submission of a formal proposal for the research. With respect to SFIs of reimbursed or sponsored travel, disclosures will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

    b. *Annually.* Each Investigator who is participating in research must submit an updated disclosure of SFIs at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially to the institution pursuant to

paragraph a above, or in any subsequent disclosure of SFIs, and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

c. *New SFI.* Each Investigator who is participating in research must submit a disclosure within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI.

### *Process for Reviewing Investigator Significant Financial Interests*

1. *Initial Review and Action.* Before LA BioMed disburses any funds for a research project, the CEO will:

    a. Solicit and review Investigator SFI disclosures and any other information deemed relevant (e.g., research proposal summary, IRB application, etc.). In connection with this review, the CEO may require the Investigator to provide additional information as deemed necessary to clarify issues;

    b. Using federal standards and best judgment, make an initial determination whether an Investigator's SFI is related to research and, if it is, invite the Investigator to propose a management plan for review by the Committee and refer the issue to the Committee for review and action, along with a recommended course of action, and any management plan that the Investigator may have developed.

2. *Review by the Committee.* The Committee will review the federal standards, the particular circumstances related to any individual research and the CEO's recommendation, along with any proposed management plan and determine whether the Investigator's SFI is related to research and, if it is, whether the SFI is an FCOI. Investigators may be required to provide additional information.

3. *Decision by the Committee.* If the Committee determines that an FCOI exists, it will submit a report of its determination and recommended management plan to the CEO. The CEO may return the report to the Committee for clarification or supplementation, and can accept, reject or modify the Committee's determination and recommendation. The CEO will make a final determination, in writing, and specify the conditions or restrictions, if any, to be imposed to manage the FCOI.

    The CEO or the Committee, will provide copies of the final decision to the Investigator, Chair of the Investigator's department and, if applicable, the Division Chief of the Investigator's division, the responsible Institutional Review Board (if human subjects research is involved), and the Office of Research Administration.

    Upon receipt of the decision, the Investigator must either acknowledge his/her agreement to comply with the management plan by signature or submit an appeal. Funding will be held (1) during the appeals process, and/or (2) until the Investigator agrees to comply with the management plan.

4. *Investigator Appeals.* The Investigator has thirty (30) days from receipt of the final decision to submit an appeal, in writing, to the CEO or the Committee. The appeal should include the specific provisions being challenged, the reason for the appeal, and the justification for a different outcome. The Investigator may also propose an alternative management plan and any supplemental information that might be helpful in making a final determination. The CEO and/or the Committee will review the appeal and issue a decision. This decision shall be final and not further appealable.

5. *Submission of the Research Application.* The institution will certify in the application that it has implemented and maintains an effective policy that is in full compliance with the federal regulations

at 42 CFR Part 50 and 45 CFR Part 94, as specifically enumerated in 42 CFR §50.604(k)(1)-(5) and 45 CFR §94.4(k) (1)-(5).

*6. Institutional Remedies.*

a. Investigators are required to comply with the final decision of the CEO. If an Investigator fails to comply, the CEO, with the aid of the Committee, will review the nature of the failure to comply, give the Investigator a deadline to achieve compliance and, in the event of a further failure to comply, will impose sanctions on the Investigator.

b. If an Investigator fails to comply with this policy or management plan, and if this failure to comply could have, or could have appeared to, bias the design, conduct, or reporting of research, the institution shall promptly notify the Sponsor awarding component of the corrective action taken or to be taken (e.g., a mitigation report for the research, as further described below), and implement corrective action.

c. The institution will impose sanctions for non-compliance including, but not limited to, suspension, or the denial of eligibility to engage in research. Such sanctions may require notice to professional bodies or journals, or the public. The final responsibility for imposing sanctions will rest with the LA BioMed Board of Directors.

## ***Management of Financial Conflict of Interests***

1. *Management Plans.* Each management plan shall specify the actions that have been, and shall be, taken to manage the FCOI.

2. *Conditions or Restrictions.* Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- Public disclosure of the FCOI (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of the FCOI directly to potential human subjects with language in the study consent form as approved by the Institutional Review Board;
- Disclosure of the FCOI to other study staff;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research. This could include, but not be limited to:
- Limitation of the direct involvement of the Investigator with the FCOI in recruiting or consenting potential subjects in human subjects research;
- Limitation of the direct involvement of the Investigator with the FCOI in management and analysis of data generated by the study;
- Reduction or elimination of a financial interest (e.g., sale of an equity interest); and

- Severance of relationships that create the FCOI.

3. *Clinical Research.* The existence of an FCOI related to a clinical research project creates a rebuttable presumption that stringent management of the FCOI is appropriate. In any case in which the U.S. Department of Health and Human Services determines that a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the institution as required, the institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research.

4. *Monitoring Compliance with the Management Plan.* The Committee will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the research. It may avail itself of external sources of information to verify the information provided by Investigators. Such external sources include, but may not be limited to, compilations of publicly disclosed data such as "Dollars for Docs" by non-profit organizations (http://projects.propublica.org/docdollars/), or databases maintained by government agencies such as the Center for Medicaid Services, under the terms of the Affordable Care Act (https://openpaymentsdata.cms.gov/).

### *New SFIs during ongoing Research*

Whenever, in the course of ongoing research, an Investigator who is new to participating in the research discloses an SFI or an existing Investigator discloses a new SFI, the CEO will, within sixty (60) days, take the following actions, directly or in conjunction with the Committee:

- review the SFI and determine whether it is related to research;

- determine whether an FCOI exists, and, if so, implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI.

### *Review of Existing SFIs and Retrospective Review during ongoing Research*

The CEO, acting directly or in conjunction with the Committee, will take the following actions with respect to an FCOI in ongoing research:

1. *Review of Existing SFIs.* Whenever LA BioMed identifies an SFI that was not disclosed in a timely fashion by an Investigator or, for whatever reason was not previously reviewed during ongoing research (e.g. was not reviewed in a timely fashion or reported by a subrecipient), the CEO will, within sixty (60) days, undertake the same review, determinations and management plan implementation set forth in ***New SFIs during ongoing Research***, above.

2. *Retrospective Review.* Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is determined by the institution to constitute an FCOI, failure by the institution to review or manage such an FCOI, or failure by the Investigator to comply with an FCOI management plan, the CEO will, within 120 days of the institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the research to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in design, conduct, or reporting of such research.

   The Office of Research Administration will document the retrospective review in accordance with federal requirements set in 42 CFR, Part 50, Subpart F, §50.605(a)(3)(ii)(B)(1)-(9), for research grants or cooperative agreements, or 45 CFR Part 94, §94.5(a)(3)(ii)(B)(1)-(9), for research

contracts, and if appropriate, will update the previously submitted FCOI report, describing the new management plan.

3. *Notification and Mitigation Report.* If the CEO finds bias in the design, conduct, or reporting of research, the Office of Research Administration will notify the sponsor awarding component promptly and submit a mitigation report, as required by and including all key elements specified in, 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5(a)(3)(iii), described further in section H(3), below.

4. *Interim Measures.* At any time, the CEO may determine that interim measures are necessary with regard to the Investigator's participation in the research.

### *Training*

Every Investigator will complete training (http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm) or (https://www.citiprogram.org/) on financial conflict of interest policies and responsibilities at the following times:

1. Prior to engaging in research and at least once every four (4) years thereafter;

2. When this policy is revised in any manner that affects the requirements of Investigators;

3. When an Investigator is new to LA BioMed, even if the research has already begun; and/or

4. When an Investigator is not in compliance with this policy or a management plan, as determined by the CEO.

### *Subrecipients*

If LA BioMed is the awardee and conducts research through a subrecipient (e.g. subcontractors or consortium members), the CEO will take reasonable steps to ensure that subrecipient Investigators comply with this policy, as follows:

1. *Determination of which institution's policies apply.* LA BioMed's written agreement with the subrecipient will establish whether this policy or the subrecipient's FCOI policy will apply to the subrecipient's Investigators. The written agreement will state either that:

    a. The subrecipient certifies that its FCOI policy complies with the applicable federal regulations, and that the subrecipient's Investigators will comply with the subrecipient's policy or,

    b. if the subrecipient cannot provide such certification, subrecipient Investigators are subject to this policy.

2. *If the subrecipient's policy applies.* The written agreement will specify the time period(s) for the subrecipient to report all identified FCOIs initially and annually thereafter to LA BioMed. The time period(s) will be sufficient to enable LA BioMed to provide FCOI reports to the Sponsor prior to the expenditure of funds and within 60 days of finding any additional FCOI.

3. *If LA BioMed's policy, as awardee, applies*. The subrecipient Investigators will disclose all SFIs that are directly related to the subrecipient's work for LA BioMed. The written agreement with the subrecipient will specify the time period in which to comply, sufficiently allowing LA BioMed enough time to comply timely with its review, management and reporting obligations, e.g., to provide FCOI

reports to the Sponsor prior to the expenditure of funds, within sixty (60) days of finding any additional FCOI and annually thereafter.

### ***Reporting of Financial Conflict of Interest***

1. *Initial Reporting of FCOI to Sponsor*. Prior to the institution's expenditure of any funds under research, the CEO shall provide to the Sponsor, as required, an FCOI report regarding any Investigator's FCOI (unless eliminated) and ensure that a management plan has been implemented. The report (FCOI Report) to sponsoring agency will contain all the information required under federal regulations at 42 CFR, Part 50, Subpart F, § 50.605(b)(3) and 45 CFR, Part 94, § 94.5(b)(3), as applicable.

2. *Newly acquired FCOIs.* If, during ongoing research, an Investigator reports a newly acquired SFI, as described in ***New SFIs during ongoing Research*** above, which constitutes an FCOI, the CEO shall provide to the sponsoring agency, within sixty (60) days, an FCOI Report ensuring that the institution has implemented a management plan.

3. *Previously undisclosed FCOIs*. If, during ongoing research, the institution becomes aware of, and reviews, a previously undisclosed SFI, as described in ***Review of Existing SFIs and Retrospective Review during ongoing Research*** above, which constitutes an FCOI, the CEO shall, if the retrospective review results in a finding of bias in the design, conduct or reporting of the research, promptly submit its mitigation report to the sponsoring agency. In accordance with 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5a)(3)(iii), the mitigation report shall include the key elements documented in the retrospective review and a description of the impact of the bias on the research and the institution's plan of action or actions taken to eliminate or mitigate the effects of the bias.

4. *Annual FCOI Reports*. After the submission of any initial FCOI report with regard to ongoing research, the CEO shall provide the sponsoring agency with annual FCOI reports that address the status of the FCOI and any changes to the management plan for the duration of the research (including extensions with or without funds) in the time and manner specified by the sponsoring agency.

5. *Cooperation with Sponsor Requests*. The Committee, on behalf of LA BioMed shall, upon request of the Sponsor, make information available to the sponsor relating to any Investigator's disclosure of financial interests and the institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the institution's determination of an FCOI.

### ***Maintenance of Records***

The Committee, in collaboration with the Office of Research Administration, shall maintain records relating to all Investigator SFI disclosures, including the review of and response to such disclosures (whether or not resulting in an FCOI finding), and any other action under this policy, for at least three years from the date the final expenditures report is submitted to the sponsoring agency or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b), relating to records retention.

### ***Public Accessibility***

1. *Public Accessibility*. Upon written request to LA BioMed's Office of Research Administration, information will be provided including, at a minimum, that specified in 42 CFR, Part 50, Subpart F, §50.605(a)(5)(ii) and 45 CFR, Part 94, § 94.5(a)(5)(ii), concerning a specific SFI disclosed to LA BioMed and meeting the following criteria:

a. The SFI was disclosed and is still held by the Investigator;

b. The institution has determined that the SFI is related to the research; and

c. The institution has determined that the SFI is an FCOI.

2. *Data Retention*. Information concerning the SFIs of Investigators shall remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated.

3. *Responsibilities of Subrecipients*. When the research is conducted by a subrecipient Investigator, and under the written agreement, the subrecipient is required to comply with the subrecipient's FCOI policy, the subrecipient will have the responsibility of making such information publicly accessible.

4. *Response Time*. Responses will be returned within five (5) business days from the date LA BioMed's Office of Research Administration receives the request.

## WEBSITE ADDRESS FOR THIS POLICY

http://grants.nih.gov/grants/policy/coi/

www.labiomed.org

## RELATED INFORMATION

- NIH Financial Conflict of Interest Policy - http://grants.nih.gov/grants/policy/coi/
- Code of Federal Regulations (CFR) http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl

## RESPONSIBLE PARTIES

LA BioMed's CEO is responsible for overseeing implementation of and ensuring compliance with this policy. The Financial Conflict of Interest Committee and the Offices of Research Administration and Compliance and Regulatory Affairs are responsible for supporting implementation and compliance.

## HISTORY/REVISION DATES

**Origination Date:** September 24, 2012

**Previous Amended Date:** February 19, 2015

Revisions: Adds ACA disclosures requirements on payments to physicians; clarifies CEO as final arbiter, the review process and sanctions for noncompliance.

**Last Amended Date:** April 17, 2017

Revisions: Clarifies that *Financial Interest* does NOT include income from seminars, lectures, or teaching engagements sponsored by or from foreign agencies.

Removes references to externally-sponsored research throughout the document.

Reviewed by COIC: March 6, 2017 and April 17, 2017

Approved by COIC April 17, 2017

Next Review Date: TBD