LA JOLLA BIOENGINEERING INSTITUTE
FINANCIAL CONFLICT OF INTEREST POLICY

1.0 PURPOSE

La Jolla Bioengineering Institute ("LJBI") is committed to fostering and maintaining the highest standard of integrity and ethical conduct in all Institute activities. To that end, the Institute must have policies that both encourage interactions with outside entities, and at the same time define clear boundaries. Conflict of interest (COI) may become a concern as the number of interactions and complexity of relationships with outside entities increase. A conflict of interest occurs where there is a divergence between an individual’s private interests and his or her professional obligations to LJBI, such that an independent observer might reasonably question whether the individual’s professional actions or decisions for LJBI are determined or materially influenced by considerations of personal gain, financial or otherwise. The intent of this policy is to assure that the design, conduct, and reporting of research is free from bias.

This policy is intended to be consistent with federal and state law. Where there is a discrepancy, the applicable federal or state law or rule of the funding agency will take precedence, unless the law or rule is less restrictive than LJBI’s more stringent standard.

2.0 HISTORY/REVISIONS FROM PREVIOUS VERSIONS

This policy revises Conflict of Interest for Board Members and Staff, and Investigators, effective on January 27, 2012, which superseded the policy dated January 5, 2009.

3.0 DEFINITIONS

3.1 Financial Interest (FI): Anything of monetary value or potential monetary value received or owned by the individual, their spouse and their dependent children, that reasonably appears to be related to the individual’s duties and responsibilities, including but not limited to:

- Salary, commissions, consulting fees, or other payment for services (e.g., lecture payment, other honoraria);

- An equity interest (e.g., stock, stock option, security, or other ownership interest);

- An intellectual property right (e.g., a patent, copyright, or royalty from such right);
- Reimbursed or sponsored travel related to institutional responsibilities, except if funded by any U.S. government agency or institution of higher learning, including academic teaching hospitals;

- A gift (e.g., money, hospitality, or a physical item over $100);

- Income from, or ownership of, shares of a mutual fund, pension, or other investment fund where the individual exercises control over the management and investments of such fund.

The term does not include:

- Salary or other remuneration for services from LJBI, from a U.S. institution of higher education, or from a government agency within the U.S. Services can include, for example, giving seminars or lectures, teaching engagements, being on an advisory committee, or review panels.

3.2 Significant Financial Interest (SFI): A financial interest that exceeds the thresholds defined in 42 CFR 50.603:

- Any remuneration received from a publicly traded entity in the past 12 months and value of current equity exceeds $5,000;

- Any remuneration received from a non-publicly traded entity in the past 12 months and exceeds $5,000 OR an equity interest is held.

3.3 Financial Conflict of Interest (FCOI): A financial interest that could directly affect the design, conduct, or reporting of funded research or the performance of duties responsibilities on behalf of LJBI. An FCOI may be an SFI defined above, or an FI.

3.4 PHS: Public Health System.

3.5 PHS Awarding Component: The organizational unit(s) of the PHS that has awarded funds to support a project.

3.6 Individuals Affiliated with LJBI: Employees, non-employees as defined by LJBI, officers, board members, investigators, and consultants (limited to consultants working on a PHS funded project).

3.7 Investigator: Principal Investigators and any other person, who is responsible for, or has material input into, the design, conduct, or reporting of funded research.

3.8 Non-Compliance: Situations in which this FCOI policy is not followed including but not limited to: failure of an investigator or subrecipient to disclose an SFI
timely, failure of an investigator to follow a management plan, failure of the Institution to review or manage an FCOI in a timely manner.

4.0 APPLICABILITY

This policy is applicable to all individuals affiliated with LJBI: employees, non-employees as defined by LJBI, officers, board members, investigators, and consultants (limited to consultants working on a PHS funded project).

All subrecipients of PHS funding where LJBI is prime awardee Institution, or pass-through Institution, will be required to follow this policy and/or submit certification that its policy complies with regulations and reports COIs as required by 42 CFR 50.604(c).

5.0 POLICY STATEMENT

5.1 Disclosure of Financial Interests

Individuals affiliated with LJBI must report all financial interests (and those of his/her spouse and dependent children) with an outside entity which does, or contemplates doing business with LJBI whose activities are related in any way to the individual’s research or clinical activities, patent or licensing activities, purchasing activities or any other job responsibilities related to the individual’s role at LJBI; or who operates within LJBI’s field and may be considered competing with or complementing LJBI’s mission. These disclosures must made at the time of hire or contract, updated annually, updated within 30 days of discovering or acquiring a new significant financial interest, and updated no later than the time of application of PHS funded research.

5.2 Reimbursed/Sponsored Travel

Reimbursed or sponsored travel related to institutional responsibilities must be disclosed as a financial interest, except if funded by the Institute, by any government agency within the U.S., or by an institution of higher learning within the U.S., including academic teaching hospitals.

5.3 Review of Disclosures – Designation of Responsibilities

The President/CEO is the designated Institutional Official responsible for the solicitation and review of disclosures as required under 42 CFR 50.604(d). Under the supervision of the Institutional Official, the administrative office will review any disclosure and determine if it represents a potential conflict of interest. Potential conflicts will be referred to the Conflicts Committee for evaluation. All potential conflicts of officers, executives, and board members will be referred to the chairman of the board.
5.4 Conflicts Committee

The Conflicts Committee (CC) is appointed by the President/CEO. The committee meets as needed to review and evaluate disclosures of potential conflicts of interest to determine appropriate management plans. For the purposes of this policy, the Conflicts Committee is designated as John A. Frangos, Michael Nicolaou and Michelle Florance.

5.5 Management Plans

The CC will determine an appropriate management plan for significant financial conflicts of interest. Management plans may include, but are not limited to, the following: internal or external disclosure of significant financial interests, divestiture of significant financial interests, severance of relationships that create actual or potential conflicts, disclosure to the IRB or IACUC, restriction from participating in designated research activities or other job responsibilities or notification requirements (e.g. notifying the Director of Technology Transfer for intellectual property issues or notifying the Institutional Official for PHS reporting).

5.6 PHS Funded Research

As described in section 5.1 above, investigators are required to submit updated disclosures of financial interests no later than the time of application for PHS funded research.

Prior to the expenditure of any funds awarded from PHS, LJBI must review all investigator disclosures (sections 5.3 through 5.5) and report any PHS research related FCOI’s to the PHS awarding component as required pursuant to 42 CFR 50.605(b), including sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution’s management plan. If after the initial report, a conflicting interest is identified, LJBI must review and submit a report to the PHS awarding component within 60 days of that identification.

To ensure public accessibility regarding expenditure of any funds under a PHS funded research project, the Institution will provide a written response to any requestor within 5 business days of a request that meets the criteria of 41 CFR 50.605(a)(5).

The Institutional Official is responsible for reporting as required to the PHS awarding component and to requests for significant financial interests related to PHS funded research projects.
5.7 Training

Investigators are required to complete COI training prior to engaging in research related to any PHS funded grant and at least every 4 years. Investigators are also required to complete COI training immediately whenever LJBI’s FCOI policy is revised regarding investigator requirements, and whenever the individual is found to be in non-compliance with this policy or management plan. LJBI will provide training through regularly scheduled orientation training sessions, and/or PowerPoint based training modules.

5.8 Non-Compliance

If the Institution is made aware of non-compliance with this policy, the President/CEO or designee, must conduct a retrospective review of the investigator’s and/or institution’s activities within 60 days to determine whether it is related to PHS funded research, whether an FCOI exists, and if so, implement an interim management plan. Within 120 days of the Institution’s determination of non-compliance, the Institution must complete the retrospective review including determination whether bias in the design, conduct or reporting of research occurred. If bias is found with PHS funded research, the designated official must notify the PHS Awarding Component promptly and submit a mitigation report that meets the requirements of 42 CFR 50.605(a)(3). In all cases, such retrospective review must be documented.

If an investigator is in non-compliance he/she is required to complete COI training as part of a mitigation plan.

5.9 Records Maintenance

Records of individual disclosures and training, the Institution’s review of, and response to the disclosures, and actions taken by the Institution including any management plans or retrospective review, will be retained by the administrative office for at least 3 years past the end of the relationship of the individual with LJBI, or 3 years from the date the final expenditures report is submitted to NIH for individuals on PHS research projects, whichever is longer. Records will be made accessible as needed to other LJBI administrative units, such as the Conflicts Committee.