

**Terasaki Institute for Biomedical Innovation
Conflict of Interest Policy**

I. PURPOSE

The purpose of this policy is to provide guidance in identifying and handling potential and actual conflicts of interest involving the Terasaki Institute for Biomedical Innovation (the "Institute"). In most instances, conflicts of interest can be avoided simply by continuing to exercise good judgment and, indeed, the Institution relies on the sound judgment of its employees to prevent many such conflict situations. The general rule is that: **Institute employees are obligated to avoid and disclose ethical, legal, financial, or other conflicts of interest involving the Institute, and remove themselves from a position of decision-making authority with respect to any conflict situation involving the Institute.**

The Institute is committed to the highest levels of integrity. Employees of the Institute are expected to conduct their relationships with each other, the Institute, and outside organizations with objectivity and honesty. In furthering such relationships, the Institute is committed to working with its employees, faculty, affiliated research staff, as well as its executive and management staff, to ensure that potential conflicts of interest are identified, reviewed and appropriately managed. The Institute believes that potential conflicts of interest involving Industry and other outside organizations do not preclude partnerships that appropriately promote and support the Institute's mission. In turn, the Institute believes that beneficial relationships with such organizations do not preclude full transparency and effective management of potential conflict of interests involving the Institute or its employees. In the interest of such transparency, this policy shall always be available to the public on the Institute's publicly accessible website.¹

II. IDENTIFICATION OF CONFLICT SITUATIONS

Generally, a conflict of interest may occur if an interest or activity influences or appears to influence the ability of an individual to exercise objectivity or impairs the individual's ability to perform his or her employment responsibilities in the best interests of the Institute.

An individual is considered to have a potential conflict of interest when:

A. He or she or any member of his or her family² may receive a financial or other significant benefit as a result of the individual's position at the Institute;

B. The individual has the opportunity to influence the Institute's granting, business, administrative, or other material decisions in a manner that leads to personal gain or advantage;
or

¹ The public availability of this policy shall be in compliance with 45 CFR Part 50 Subpart F and 45 CFR Part 94 which require the Institute to maintain an up-to-date, written enforced policy on FCOIs (as defined by this policy), and make such policy available on the Institute's publicly accessible web site.

² The "family" of an individual includes his or her spouse, domestic partner, parents, siblings, children, and any other relative who resides in the *same household*.

C. The individual has an existing or potential financial or other significant interest which impairs or might appear to impair the individual's independence in the discharge of their responsibilities to the Institute.

III. DEFINITIONS

For purposes of this policy, the following terms are defined as follows:

A. Academic Activities means, for purposes of this policy, activities of the type indicated by (but not limited to) the following:

1. Serving as an officer, committee chair, program chair, or board member of a medical, scientific, or professional association;
2. Serving as a peer reviewer, editor, or on the editorial board of a peer-reviewed professional journal or other similar publication or activity;
3. Lecturing at a university, medical college, or other Institution of Higher Education (as defined below), or medical or scientific society meeting;
4. Serving as a speaker, program chair, or moderator at a program or event that meets the following three (3) criteria: (a) The program meets the accreditation or certification requirements and standards of a professional medical or scientific association; (b) The commercial sponsor, if any, does not select the speakers nor does it provide the program/event manager with a distinct, identifiable set of individuals to be considered as speakers; and (c) the commercial sponsor, if any, does not directly pay the speakers, program chairs, or moderators; or
5. Participation in health or biomedical-related governmentally convened bodies; to include but not limited to NIH study sections and FDA advisory committees.

This definition is intended to identify those types of outside, professional activities that presumptively would not constitute a conflict of interest for the Institute. It is, however, possible for conflicts of commitment to arise in relation to these and other outside activities. The Institute may, from time to time, establish policies or other requirements regarding the management of conflicts of commitment. The Institute may also, from time-to-time, require of some Covered Individuals an accounting of their Non-Institute Academic Activities.

B. Covered Individuals means those individuals who are obligated in part or in whole to comply with the provisions of this policy. Some policy provisions may apply only to some employees of the Institute, while other provisions may apply to all individuals otherwise covered by this policy.

C. Disclosure of Significant Financial Interests means a Covered Individual's disclosure of SFIs (as defined below) to the Institute, in a manner and at a time as provided for by this policy.

D. Extramural Professional Activity means any activity that relates to the Covered Individual's Institutional Responsibilities (as defined below) that are performed for or on behalf of Industry organizations, or otherwise outside of the Institute's oversight and administrative control, for which the Covered Individual receives direct or indirect remuneration of any kind. For purposes of this policy and except as otherwise expressly provided in this policy, Extramural Professional Activities performed for or on behalf of Industry organizations, without limitation, providing information, direction, guidance, advice, deliberation, consultation, or other services for which the Covered Individual receives direct or indirect remuneration of any kind. Examples of Extramural Professional Activities include, but are not limited to, providing medical and/or scientific consulting services to a medical device manufacturer, providing scientific training to employees of a pharmaceutical company, providing training to customers or potential customers of a medical device manufacturer at the request of the medical device manufacturer, and serving on the board of a health information technology company. (This definition is intended to be broad in scope and to be broadly interpreted.)

E. Financial Conflict of Interest ("FCOI") means an SFI that could directly and significantly affect the management decision-making process related to the Institute's services, the provision of professional training, or the design, conduct, or reporting of Research (as defined below).

F. FCOI Report means the Institute's report of a Financial Conflict of Interest to a PHS Awarding Component (as defined below) or other Federal agency.

G. Financial Interest ("FI") means anything of monetary value, whether or not the value is readily ascertainable, including, but not limited to, stock or options in a company that has no current commercial market by which to gauge the value.

H. Industry means pharmaceutical companies, medical device manufacturers, distributors of medical devices and implantables, biotech companies, health- or biomedical-related IT companies, and any other type of company involved in the creation, manufacturing, marketing, or distribution of products and services used in patient care, biomedical research, or the training of healthcare professionals.

I. Institution of Higher Education means an educational institution in any state that: admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the requirements of 20 USCS § 1091(d)(3); is legally authorized within such state to provide a program of education beyond secondary education; provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the relevant department of the federal government; is a public or other nonprofit institution; and is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted pre-accreditation status by such agency or association that has been recognized by the relevant department of the federal government for the granting of pre-accreditation status, and the relevant department of the federal government has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

J. Institutional Responsibilities means a Covered Individual's professional responsibilities on behalf of the Institute as those responsibilities may be defined by employment or personal services agreements, job descriptions, consulting contracts, or the Institute's policies. These may include, for example: activities such as administration and management functions, research, research consultation, teaching, professional or clinical services, and service on the Institute's committees.

K. Investigator means the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for (as opposed to simply assisting with) the design, conduct, or reporting of Research, which may include, for example, collaborators or consultants.

L. Leadership Role means serving as a Board member or company officer, or their equivalent, in an Industry organization.

M. Management Plan means a plan of action that has been or will be taken to manage a FCOI that a Research project.

N. PD/PI means a Project Director or Principal Investigator of a Research project; the PD/PI is included in the definitions of Senior/Key Personnel and Investigator (as defined below) under this policy.

O. PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health ("NIH").

P. PHS Awarding Component means the organizational unit of the PHS that funds any Research that is subject to this policy.

Q. Research means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term "Research" is intended to encompass basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this policy, the term includes, but is not limited to, any activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract whether authorized under the Public Health Service Act (42 U.S.C. 201, et seq.) or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. For the purposes of this policy, "Research" also includes educational activities funded by the National Science Foundation (NSF).

R. Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by the Institute in the grant application, progress report, or any other report submitted to the PHS by the Institute; or in any other sponsored Research application and/or agreement.

S. Significant Financial Interest (“SFI”) means:

1. An ownership interest in a publicly-traded Industry organization provided the ownership interest is valued at \$5,000 or more and the ownership interest was purchased at the specific direction of the Covered Individual, or his/her spouse, registered domestic partner, or dependent children;
2. An ownership interest in a privately-held Industry organization regardless of the current value of the ownership interest provided the ownership interest is personally held by the Covered Individual or his/her spouse, registered domestic partner, or dependent children;
3. A Leadership Role in an Industry organization held by a Covered Individual or his/her spouse, registered domestic partner, or dependent children;
4. Extramural Professional Activities performed for or on behalf of an Industry organization by a Covered Individual or his/her spouse, registered domestic partner, or dependent children provided the total payments, of all forms (e.g., income from intellectual property rights and interests, consulting fees, honoraria, travel, meals, etc.), totaled \$5000 or more for the twelve-month period preceding the last required disclosure as outlined in this policy; or
5. Travel sponsored or reimbursed by an Industry organization, provided the estimated value of the sponsored or reimbursed travel was \$5000 or more, to include travel involving a Covered Individual’s spouse, registered domestic partner, or dependent children. When required, a disclosure of reimbursed or sponsored travel will include the following information: (a) the purpose of the trip; (b) the identity of the sponsor/organizer; (c) the destination; (d) the duration of the trip; and (e) the name(s) of the Covered Individual’s spouse, registered domestic partner and/or dependent children if they received reimbursed or sponsored travel.

The term SFI does not include the following types of Financial Interests:

- a. Salary, royalties, or other remuneration paid by the Institute to the Covered Individual if the Covered Individual is currently employed or otherwise appointed by the Institute, including payments of a share in royalties by the Institute related to the Covered Individual’s assignment of intellectual property rights to the Institute;
- b. Income from investment vehicles such as mutual funds and retirement accounts, as long as the Covered Individual does not directly control the investment decisions made in these vehicles;
- c. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education; or

- d. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

IV. CONFLICT OF INTEREST REVIEW COMMITTEE

A. Purpose. The Conflict of Interest Review COI Committee (the “COI Committee”), chaired by the Chief Innovation Officer or his or her designee, is charged with reviewing conflict of interest disclosures and formulating recommendations to manage, reduce, or eliminate conflicts of interest by performing the following responsibilities:

1. Reviewing or causing to be reviewed, all disclosures of FIs and other interests required under the provisions of this policy;
2. Determining, or causing to be determined, whether each SFI disclosed is related to Research, and if so, whether the SFI is an FCOI. An SFI is “related to” Research if the COI Committee reasonably determines that the SFI could be affected by the Research or is in an entity whose financial interest could be affected by the Research or that the research could be affected by the SFI. An FCOI exists if the COI Committee reasonably determines that the related SFI meets the definition of FCOI set forth in this policy;
3. Developing, or causing to be developed, a Management Plan that specifies the actions that have been or will be taken to manage the FCOI, and ensuring that responsible Institute executive and management employees have implemented the Management Plan;
4. Reporting to the Institute’s President and CEO the COI Committee’s determinations under Sections IV.A.2 and IV.A.3 above, as well as any other matter regarding the Industry organizations and Extramural Professional Activities of Covered Individuals that the President/CEO directs or that the COI Committee determines warrants reporting;
5. Providing the Institute’s President and CEO with policy recommendations that the COI Committee judges may enhance or refine processes and practices in the management of industry relations and conflicts of interest; and
6. Fulfilling any other duties or responsibilities assigned to it by the Institute’s President and CEO.

B. Membership. The COI Committee will consist of the Chief Innovation Officer, and at least two (2) members of the Institute’s full-time employees, as designated by the Chief Innovation Officer.

C. Compliance with PHS Funding Requirements. The COI Committee is the Institute’s designated Institutional Official (“IO”) for purposes of complying with the requirements of 42 CFR Part 50 Subpart F (Promoting Objectivity in Research) and 45 CFR Part 94 (Responsible Prospective Contractors). The COI Committee is therefore also responsible for all reporting required under these requirements.

V. IMPLEMENTATION OF POLICY

A. Disclosures of Financial Interest and/or Extramural Professional Activities

1. Covered Individuals: The disclosure provisions of this Section V.A. apply to the Institute’s executives, core and affiliate faculty, scientific team members, and Investigators.
2. Covered Individuals, as defined in Section V.A.1. above, will be required to complete a no-less-than annual disclosure of all FIs in and Extramural Professional Activities performed on behalf of, Industry organizations. For some Covered Individuals, the annual disclosure process may take the form of a review and updating of previously pre-approved Extramural Activities, as well as publicly available information on the Covered Individual’s FIs with Industry organizations. Industry organization-related FIs of a Covered Individual’s spouse, domestic partner, or dependent child are attributable to the Covered Individual himself/herself and must be disclosed as such.
3. The COI Committee will be responsible for approving the design, timing, and content of the annual disclosure process, designated the “Annual Conflict of Interest Review” process.
4. Investigators may have additional disclosure requirements as provided below in Section VI, “Special Provisions for Investigators Engaged in Research Projects.”

B. Pre-Approval Requirement for Industry Involvement

1. Covered Individuals, as defined in Section V.A.1. above, must receive prior approval, as provided below, for the following FIs and Extramural Professional Activities:
 - a. The acquisition of any ownership interest in a privately-held Industry organization (other than those acquired through managed investment and/or retirement accounts);
 - b. The assumption of any Leadership Role in an Industry organization, or in a hospital or health system, regardless of compensation; and
 - c. Any Extramural Professional Activities provided to or on behalf of an Industry organization, or hospital or health system.

2. Pre-approval is not required for engaging in Academic Activities as defined by this policy.

C. Recusal Requirements for Covered Individuals with Industry Relations

1. Any Covered Individual, as defined in Section V.A.1. above, with an FI in an Industry organization, must recuse himself or herself from any purchasing or other business decision affecting the Industry organization with whom the Covered Individual has an FI.
 - a. The Covered Individual must disclose the FI to the other members of the COI Committee, work group, or process which will make the purchasing or other business decision prior to any decision being made;
 - b. The Covered Individual with the FI in the affected Industry organization may participate in discussions regarding a product or service to be purchased provided that the FI has already been disclosed; and
 - c. The Covered Individual with the FI may not be present when a purchasing or other business decision is made.
2. The COI Committee has authority to grant exceptions to this recusal requirement.

D. Gifts, Gratuities, and Offers of Entertainment from Industry Organizations

1. Covered Individuals: The provisions of this Section V.D. apply to all Institute employees.
2. The Institute wishes to establish and maintain, to the extent reasonably possible, an environment free of Industry-provided gifts, offers of entertainment, and other gratuities. This goal of gift-free environment pertains to:
 - a. Personal gifts, regardless of value;
 - b. Free meals, whether provided on or off campus, regardless of value;
 - c. Offers of entertainment (e.g., tickets to sporting events, concerts, etc.), regardless of value;
 - d. Compensation, or any other forms of gratuity, offered for listening to a sales talk by an Industry representative;
 - e. Compensation or any other forms of gratuity, including reimbursement for travel-related costs, for attending a professional conference or Industry-

sponsored event, where the Covered Individual is not speaking or otherwise actively participating or representing the Institute at the event;

- f. Any other items or services offered as a gratuity by Industry representatives.
3. The Institute's establishment of a gift-free environment does not apply to holiday gifts from Industry representatives provided (a) the gift is consumable (e.g., food, candy, non-alcoholic beverages, etc.); (b) the gift is \$200 or less in value; (c) the gift is intended for the benefit of an entire department, office, or unit; and (d) the manager of the department, office, or unit has expressly authorized the acceptance of the gift.
4. The Institute's establishment of a gift-free environment also does not apply to personal gift giving between a Covered Individual and an Industry representative with whom the Covered Individual has a family relationship or with whom the Covered Individual has a personal relationship that pre-dates any professional relationship.
5. The Institute intends to create this gift-free environment through the voluntary cooperation and "self-policing" of Covered Individuals.

VI. SPECIAL PROVISIONS FOR INVESTIGATORS ENGAGED IN RESEARCH PROJECTS

A. Scope of Special Provisions

The provisions in this Section VI apply to Investigators (as defined by this policy) engaged in any Research project, regardless of the source of the project's funding. Such projects include, but are not limited to, Research funded by PHS, as well as Research funded by any philanthropic organization in compliance with PHS FCOI regulations, including 45 CFR Part 50 Subpart F (Promoting Objectivity in Research) and 45 CFR Part 94 (Responsible Prospective Contractors).

B. Special Disclosure Requirements

1. Each Investigator is responsible for ensuring that the COI Committee has the latest information on the Investigator's Industry-related FIs (and those of his/her spouse, registered domestic partner, and/or dependent children) as well as the Investigator's Extramural Professional Activities, on the following four (4) occasions:
 - a. Prior to the time the Investigator submits an application or proposal for Research funding;
 - b. Prior to the Investigator's expenditure or use of any newly awarded Research funding;

- c. During the annual “Annual Conflict of Interest Review” under the auspices of the COI Committee; and
 - d. Within 30 days of the Investigator discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; unless the SFI was pre-approved as provided in Section V.B.1. above.
2. In addition, Investigators will be required to provide the following information on any Industry-related sponsored or reimbursed travel within 30 days of the conclusion of travel:
 - a. The purpose of the trip;
 - b. The identity of the sponsor/organizer;
 - c. The destination;
 - d. The duration of the trip; and
 - e. The name(s) of the Investigator’s spouse, registered domestic partner and/or dependent children if they received reimbursed or sponsored travel.

C. Determination of FCOI for Investigators

Prior to the Institute’s expenditure of any funds awarded to a Research project (or prior to the application submission, if required by the federal funding agency) and upon any disclosure by an Investigator as required by this policy, the COI Committee shall:

1. Review an Investigator’s Industry-related FIs and Extramural Professional Activities;
2. Determine whether any disclosed FI or Extramural Professional Activity qualifies as an SFI;
3. Determine whether any SFI, determined to exist, relates to the applicable Research project; and
4. Determine whether any related SFI constitutes an FCOI that requires a Management Plan, a report to the PHS Awarding Component or other applicable Federal agency, and/or a public disclosure upon request.

D. Management of FCOI of Investigators

If a FCOI is determined to exist, the COI Committee will take such actions as necessary to manage the FCOI. Management of an identified FCOI must include development and implementation of a Management Plan that specifies the actions that have been or will be taken to manage such FCOI, and might include, if necessary, a retrospective review and a mitigation report, as further described below. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

1. Review Public disclosure of the FCOI (e.g., when presenting or publishing the Research results);
2. For Research involving human subjects, disclosure of the FCOI directly to participants in the informed consent document or other communication to the potential study participant;
3. 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;
4. Modification of the Research plan;
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
7. Severance of relationships that create financial conflicts.

E. Review and Management of Disclosures of New FCOIs

Whenever, in the course of an ongoing Research project, an Investigator who is new to participating in the Research project discloses an Industry-related FI or Extramural Professional Activity, or an existing Investigator discloses sufficient information about a new Industry-related FI or Extramural Professional Activity, the COI Committee shall, within 60 days:

1. Review the Industry-related or Extramural Professional Activity and determine whether it constitutes an SFI;
2. Determine whether the SFI is related to the applicable Research project;
3. Determine whether an FCOI exists; and, if so,
4. Implement, on at least an interim basis, a Management Plan that specifies the actions that have been or will be taken to manage such FCOI. Depending on the

nature of the SFI, the COI Committee may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS or other federally-funded Research between the date of disclosure and the completion of the COI Committee's review.

F. Review and Management of Disclosures of Existing FCOIs Not Previously Disclosed

Whenever the COI Committee identifies an Industry-related FI or Extramural Professional Activity that was **not** disclosed timely by an Investigator or, for whatever reason, was **not** previously reviewed by the Institute during an Research project, the COI Committee shall, within 60 days after receiving sufficient information about the existing FCOI in question:

1. Review the Industry-related FI or Extramural Professional Activity and determine whether it constitutes an SFI;
2. Determine whether it is related to the applicable Research project;
3. Determine whether an FCOI exists; and, if so,
4. Implement, on at least an interim basis, a Management Plan that specifies the actions that have been or will be taken to manage such FCOI going forward.

G. Retrospective Reviews

1. Whenever an FCOI is not in compliance with the disclosure and management provisions of this policy, the COI Committee, within 120 days of a determination of noncompliance, shall cause to be completed, by appropriate parties appointed by the COI Committee, a retrospective review of the Investigator's activities and the applicable Research project to determine whether any Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research. The COI Committee may make determinations of noncompliance based on, but not limited to, the following:
 - a. Failure by the Investigator to disclose an Industry-related FI as well as Extramural Professional Activity that is determined by the COI Committee to constitute an SFI and FCOI;
 - b. Failure by the COI Committee to review or manage a disclosed SFI and FCOI; or
 - c. Failure by the Investigator to comply with a Management Plan.

2. Under such circumstances, the COI Committee must document the retrospective review, and such documentation will include, but not necessarily be limited to, all of the following key elements:
 - a. Review Project number;
 - b. Project title;
 - c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - d. Name of the Investigator with the FCOI;
 - e. Name of the entity with which the Investigator has an FCOI;
 - f. Reason(s) for the retrospective review;
 - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - h. Findings of the review; and
 - i. Conclusions of the review.

H. Actions Following Retrospective Review; Mitigation Reports

1. If bias is found in a Research project based on the results of the retrospective review described above, the COI Committee shall, if appropriate, specify the actions that will be taken to manage the FCOI going forward in a mitigation report. The mitigation report must include, at a minimum, the key elements documented in the retrospective review (listed above), a description of the impact of the bias on the Research, and the COI Committee's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the Research; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; and analysis of whether the Research project is salvageable).
2. If bias is found in a PHS-funded Research project, the COI Committee will notify, or cause to be notified, the PHS Awarding Component promptly and submit, or cause to be submitted, the mitigation report to the PHS Awarding Component. If bias is found in other federally-funded Research projects, the notification and report requirements of the pertinent funding agency, if any, are followed.
3. Thereafter, the COI Committee will submit, or cause to be submitted, FCOI reports annually, as specified elsewhere in this policy. For PHS and other federally-funded Research projects, the COI Committee will submit such

reports annually to the PHS Awarding Component or other pertinent funding agency.

4. Depending on the nature of the FCOI, the COI Committee may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS or other federally-funded Research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of the COI Committee's retrospective review.

I. Monitoring Compliance with Management Plan

Whenever the COI Committee directs that a Management Plan be implemented under this policy, the COI Committee will monitor Investigator compliance with the Management Plan on an ongoing basis until the completion of the Research project.

J. Enforcement

The Institute has established adequate enforcement mechanisms, including providing for employee sanctions or other administrative actions, to ensure Investigator compliance with this policy, as appropriate. The COI Committee will monitor whether such enforcement mechanisms are in place and available to the Institute management when dealing with non-compliance of this policy. The COI Committee will report to the President and CEO any deficiencies it finds in monitoring these enforcement mechanisms.

K. Public Disclosure of FCOI of Investigator

Prior to the Institute's expenditure of any funds awarded to a Research project, the Institute will ensure public accessibility, via written response to any requestor within 5 business days of receipt of a request, of information concerning any SFI that the COI Committee determines to be a FCOI with regard to Research that is still held by Senior/Key Personnel of such Research.

1. In order to receive information on a Senior/Key Personnel's FCOI, a requestor must submit his/her request in writing to the following:

**Manager, COI Committee
Conflict of Interest Review Committee
Terasaki Institute for Biological Innovation
1018 Westwood Blvd.
Los Angeles, CA 90024**

2. The request for information must specify the Research project for which the information is requested. The Institute will not honor requests for information that are not sent to the above listed party and address and/or that do not specify the Research project. Email requests for information or postings to the Institute's internet website will not be honored.

3. For requests that meet the above requirements, the COI Committee shall make available, via a written response, the following information regarding the Senior/Key Personnel's FCOI:
 - a. Senior/Key Personnel's name;
 - b. Senior/Key Personnel's title and role with respect to the Research;
 - c. Name of the entity in which the SFI is held;
 - d. Nature of the SFI; and
 - e. Approximate dollar value of the SFI, stated in the following dollar ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
4. The COI Committee will note in each written response that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of the COI Committee's identification of any new FCOI. Information concerning the SFI of an individual Investigator subject to this Section VI.K. will remain available for responses to written requests for at least 3 years from the date that the information was most recently updated.

L. Records Maintenance and Records Access

The Institute's COI Committee will maintain records relating to all Investigator disclosures of financial interests and the Institute's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institute's determination of an FCOI) and all actions under this policy or retrospective review, if applicable, for the longest of the following:

1. At least 3 years:
 - a. From the date the final expenditures report is submitted to the PHS or other federal agency;
 - b. From, where applicable, the starting dates specified in 45 CFR 74.53(b) and/or 45 CFR 92.42(b); or
 - c. From the date of final payment; and
2. Until resolution of any federal agency action involving those records.

M. Training

The COI Committee will inform each Investigator of the Institute's policy on FCOIs as set forth herein, the Investigator's responsibilities regarding disclosure of SFIs, and of the federal regulations underlying this policy. The Institute will require each Investigator to complete training regarding these elements prior to engaging in research related to any grant or contract and at least every 4 years, and immediately when any of the following circumstances apply:

1. If the Institute revises this policy in any manner that affects the requirements of Investigators;
2. If an Investigator is new to the Institute; or
3. If the Institute finds that an Investigator is not in compliance with this policy or a Management Plan developed under this policy.

N. Additional Provisions for PHS and Other Federally-Funded Research

1. Reporting FCOI to PHS Awarding Component and Other Federal Agencies

- a. Prior to the Institute's expenditure of any funds under a PHS or other federally-funded Research project (or prior to the application submission, if required by the federal funding agency), the COI Committee shall provide, or cause to be provided, to the PHS Awarding Component or other federal agency, as appropriate, an FCOI report regarding any Investigator's SFI found by the COI Committee to be a reportable FCOI and ensure that Institute management has implemented a Management Plan in accordance with the provisions of this policy.
 - i. In cases in which the COI Committee identifies an FCOI which is eliminated prior to the expenditure of PHS-awarded funds, the COI Committee shall not submit an FCOI report to the PHS Awarding Component.
 - ii. For any SFI that the COI Committee identifies as a reportable FCOI subsequent to any initial FCOI report during an ongoing PHS-funded Research project (e.g., upon the participation of an Investigator who is new to the Research project), the COI Committee shall provide to the PHS Awarding Component, within 60 days of the disclosure, an FCOI report regarding the newly disclosed reportable FCOI and ensure that the Institute's management has implemented a Management Plan in accordance with the provisions of this policy. For other federally-funded research, a Management Plan shall also be implemented, and the notification and reporting requirements of the pertinent funding agency, if any, shall be followed.

- iii. Pursuant to Section VI.G. above, where such FCOI report involves an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the COI Committee, the COI Committee will also cause to be completed a retrospective review to determine whether any PHS or other federally-funded Research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such Research.
- iv. Additionally, pursuant to Section VI.H. above, if bias is found in a PHS-funded Research project, the COI Committee will notify, or cause to be notified, the PHS Awarding Component promptly and submit, or cause to be submitted, a mitigation report to the PHS Awarding Component. If bias is found in other federally-funded Research projects, the notification and reporting requirements of the pertinent funding agency, if any, shall be followed.
- v. Any FCOI report required under this Section VI.N.1. shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI, and to assess the appropriateness of the Institute's Management Plan. Elements of the FCOI report submitted to the PHS Awarding Component shall include, but are not necessarily limited to, the following:
 - Project/Contract number;
 - PD/PI or Contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has an FCOI;
 - Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - Value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
 - A description of how the financial interest relates to the PHS-funded Research and the basis for the COI Committee's determination that the financial interest conflicts with such Research; and

- A description of the key elements of the Institute’s Management Plan, 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 to ensure Investigator compliance; and (vi) other information, as needed;
- b. For any FCOI previously reported by the Institute with regard to an ongoing PHS-funded Research project, the Institute will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the Management Plan for the duration of the PHS-funded Research project. The annual FCOI report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. The Institute will provide annual FCOI reports to the PHS Awarding Component for the duration of the Research project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.
2. Certifications Related to PHS-Research Funding Applications and Contract Proposals

In each of its applications for Research funding and contract proposals to which 42 CFR Part 50 Subpart F or 45 CFR Part 94 applies, the Institute will certify that it:

- a. Has in effect an up-to-date, written policy, and enforced administrative process to identify and manage FCOIs with respect to all Research projects for which funding is sought or received from the PHS;
- b. Will promote and enforce Investigator compliance with the requirements of 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable, including those pertaining to disclosure of SFIs;
- c. Will manage FCOIs and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with 42 CFR Part 50 Subpart F or 45 CFR Part 94;
- d. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institute’s review of, and response to, such disclosure, whether or not the disclosure resulted in the Institute’s determination of an FCOI; and
- e. Will fully comply with the requirements of 42 CFR Part 50 Subpart F or 45 CFR Part 94.

3. Sub-Recipient Contract Requirements

If the Institute carries out PHS-funded Research through a sub-recipient (e.g., subcontractors or consortium members), the Institute, as the awardee institution, will take reasonable steps to ensure that any sub-recipient Investigator complies with 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable, by:

- a. Incorporating as part of a written agreement with the sub-recipient terms that establish whether this policy or the sub-recipient's own FCOI policy will apply to the sub-recipient's Investigators.
 - i. If the sub-recipient's Investigators must comply with the sub-recipient's FCOI policy, the sub-recipient shall certify as part of the agreement referenced above that its policy complies with 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable. If the sub-recipient cannot provide such certification, the agreement shall state that sub-recipient Investigators are subject to the Institute's policy for disclosing SFIs that are directly related to the sub-recipient's work for the Institute;
 - ii. Additionally, if the sub-recipient's Investigators must comply with the sub-recipient's FCOI policy, the agreement referenced above shall specify time period(s) for the sub-recipient to report all identified FCOIs to the COI Committee. Such time period(s) shall be sufficient to enable the COI Committee to provide timely FCOI reports, as necessary, to the PHS as required by 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable.
 - iii. Alternatively, if the sub-recipient's Investigators must comply with the Institute's policy, the agreement referenced above shall specify the manner and timing in which the sub-recipient's investigators are to disclose SFIs to the COI Committee. Such time period(s) shall be sufficient to enable the COI Committee to comply timely with its review, management, and reporting obligations under 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable.
- b. Providing FCOI reports to the PHS Awarding Component regarding all FCOIs of all sub-recipient Investigators consistent with 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI. However, in instances where the sub-recipient is required by the sub-recipient agreement to comply with the Institute's policy, this reporting requirement will be carried out by and through the COI Committee.

4. Cooperation with PHS Awarding Component and HHS Regarding Remedies

- a. If the COI Committee determines that the failure of an Investigator to comply with this policy or an FCOI Management Plan biased the design, conduct, or reporting of the PHS-funded Research, the COI Committee will promptly notify, or cause to be notified, the PHS Awarding Component of the corrective action taken or to be taken by the Institute. If the PHS Awarding Component refers the matter back to the Institute for further action with directions on how to maintain appropriate objectivity in the PHS-funded Research project, the Institute will cooperate with such directions.
- b. The Institute acknowledges that the PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the COI Committee's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the COI Committee's determination of a reportable FCOI.
 - i. The Institute will, as requested by the PHS Awarding Component and/or HHS, submit or permit on site review of all records pertinent to compliance with 42 CFR Part 50 Subpart F and 45 CFR Part 94, with the understanding that, to the extent permitted by law, the PHS Awarding Component and/or HHS will maintain the confidentiality of all records of financial interests.
 - ii. The Institute acknowledges that the PHS Awarding Component may decide, based on its review, that a particular FCOI will bias the objectivity of the PHS-funded Research to such an extent that further corrective action is needed or that the Institute has not managed the FCOI in accordance with 42 CFR Part 50 Subpart F or 45 CFR Part 94, and that the PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding, or the issuance of a Stop Work Order by the Contracting Officer, or other enforcement action, such as under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.
- c. In any case in which the HHS determines that a PHS-funded Research project 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 a reportable FCOI that was not managed or reported by the Institute as required by 42 CFR Part 50 Subpart F or 45 CFR Part 94, the Institute will require the Investigator involved to disclose the FCOI in each public presentation of the results of the Research and to request an addendum to previously published presentations.