1.0 **PURPOSE:**

The objective of this policy is to promote the highest ethical standards in situations where conflicts of interest may occur in the conduct of research.

Children's Hospital Los Angeles ("CHLA") encourages its faculty, staff and students to participate in meaningful professional relationships with industrial and other private partners. These partnerships are established for mutually beneficial reasons and many times produce knowledge and technology that will help to meet societal needs.

In certain circumstances, relationships with outside interests can create, or appear to create, conflicts of interest. While having a conflict of interest does not imply wrongdoing or inappropriate activity, conflicts do require review and management to ensure that the conflict does not improperly influence, or appear to improperly influence, how CHLA research is proposed, conducted or reported. For this reason, all potential conflicts covered by this policy must be disclosed promptly and completely so that they can be properly evaluated and managed. This policy explains the process for identifying and disclosing potential conflicts and the methods by which they are managed by CHLA.

Transparency is the cornerstone of effective conflict oversight and management. Many times, disclosure itself minimizes a perception of bias in the conduct of research. It is therefore critical that all potential conflicts be disclosed promptly and thoroughly in the manner provided in this policy.

This policy represents one aspect of CHLA's commitment to address and manage conflicts of interest. As set forth more fully in the Ethics: Conflict of Interest policy, CHLA also has policies that address conflicts of interest with respect to Employment and Business Practices, Conflict of Commitment and Personal Conflict of Interest.

2.0 **Scope**

This policy applies to all CHLA faculty members (including part-time and visiting faculty), staff and other employees, and students (including postdoctoral and clinical fellows) who propose, conduct or report research on behalf of CHLA, regardless of funding source. This policy applies to all sponsored projects, including government and non-government funded projects (such as industry or foundation sponsors), CHLA funded projects, clinical trials and also to unfunded research projects. Disclosure and evaluation criteria for conflict of interest and commitment in research do not vary by funding or regulatory oversight. Reporting of financial conflicts of interest to government agencies may differ depending on funding source, in accordance with this policy and federal regulations related to promoting objectivity in research sponsored by the federal government.

This policy supersedes the Children's Hospital Los Angeles Conflict of Interest in Research Policy and Procedure ADM 157.0, dated June 13, 2007.

3.0 **Definitions**

3.1 Research

"**Research**" is a systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral and social-sciences research or other scholarly activity.

3.2 Investigator

An "**Investigator**" is the principal investigator, co-principal investigator, contact principal investigator, or co-investigator. Other persons may be an Investigator, but only if they have independent responsibility for some aspect of the design, conduct, or reporting of Research.

3.3 Research Personnel

"**Research Personnel**" is any other CHLA faculty member (including part-time and visiting faculty), staff, other employees, and students (including postdoctoral fellows) who contributes to a research activity, whether or not the Research is funded, and regardless of status (e.g., faculty key personnel, research associates, technicians, nurse coordinators, administrators, graduate assistants).

3.4 Close Relation

"**Close Relation**" means the spouse, domestic partner, or dependent child of an Investigator or Research Personnel.

3.5 CHLA Responsibilities

"**CHLA Responsibilities**" means an Investigator's professional responsibilities on behalf of CHLA, including but not limited to activities such as research, teaching, professional practice, patient care and administration including service on CHLA committees including the Institutional Review Board or Data and Safety Monitoring Boards.

3.6 Conflict of Commitment

A "**Conflict of Commitment**" is a conflict between outside activities and a full-time employee's responsibility to devote his or her primary professional loyalty, time and energy to his or her teaching, research, service, administrative, and clinical duties, as applicable. Refer to Ethics: Conflict of Interest policy and the Faculty Handbook for more detail.

3.7 Significant Financial Interest

A "**Significant Financial Interest**" (or "SFI") is a financial interest consisting of one or more interests of the Investigator and/or Research Personnel (and those of the Investigator's and/or Research

Personnel's spouse and dependent children) that reasonably appear to be related to the Investigator and/or Research Personnel's CHLA Responsibilities. All SFIs must be disclosed to CHLA in accordance with this policy.

- With regard to a publicly-traded company or other entity, a SFI exists if the value of 1) any remuneration received from the entity in the twelve months preceding the disclosure; and 2) the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Such remuneration includes salary and any payment for services including consulting fees, honoraria, paid authorship; equity interest includes stock, stock options, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- With regard to a non-publicly traded company or other entity, a SFI 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/Research Personnel (or Investigator's / Research Personnel's spouse or dependent child) holds **any** equity interest (e.g., stock, stock options, or other ownership interest) in the entity; or

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

- Investigators and Research Personnel must also disclose the occurrence of any reimbursed or sponsored travel (that which is paid on behalf of the Investigator or Research Personnel and not reimbursed to the Investigator or Research Personnel such that the exact monetary value may not be readily available) related to CHLA Responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by (i) a federal, state, or local government agency; (ii) an institution of higher education as defined in 20 U.S.C. 1001(a) ("Institution of Higher Education"); or (iii) an academic teaching hospital, medical center, or research institute that is affiliated with an Institution of Higher Education.

3.8 Conflict of Interest

A "**Conflict of Interest**" is a situation in which financial or other personal considerations may compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising or reporting research. Conflicts of Interest include non-financial as well as Financial Conflicts of Interest, because non-financial interests can also come into conflict with a researcher's primary commitment to maintain scientific objectivity. Whether a relationship or situation constitutes a Conflict of Interest is a decision made by CHLA; however, Investigators and Research Personnel must disclose all potential Conflicts of Interest to CHLA as described herein. Investigators should not only consider situations that are unacceptable, but also gray areas that might create the appearance of a Conflict of Interest.

Conflicts of Interest include the following types of interests maintained by an Investigator, Research

Personnel or his or her Close Relations. These must be disclosed in accordance with this policy:

Significant Financial Interests

- As described above, which include both equity interests, funding/compensation, intellectual property rights and sponsored travel.

Management Roles

- Holding a **Management Role** (e.g., director, officer, or similar position of significant decision-making authority) in a research sponsor or in a company having an economic interest in the research (e.g., licensee).

Prohibited Conflict

- Described in Section 3.10 below.

Significant Conflicts

- Described in Section 3.11 below.

3.9 Financial Conflict of Interest

"**Financial Conflict of Interest**" or "**FCOI**" means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Public Health Service (PHS)-funded research. Whether a Significant Financial Interest constitutes a Financial Conflict of Interest is a decision that CHLA will make in accordance with this policy.

3.10 Prohibited Conflict

A "**Prohibited Conflict**" is a Conflict of Interest that is never acceptable because there is no feasible way to manage the conflict. These conflicts call into question the integrity of the research and create significant reputational risk for both the Investigator and CHLA. Prohibited Conflicts include, but are not limited to:

- Participating in a **paid "speakers bureau"** (i.e., contractual relationships to give talks in which the topic(s) and/or content are provided by the company) for any company that has sponsored the Investigator's research, or that of their Close Relations.

- Any personal **incentive payments, bonus payments, finder fees,** or any type of **payment or incentive based on outcome** that are made directly to the Investigator or Research Personnel relating to the proposal, conduct, supervision, or reporting of research (e.g.,

additional personal payments by research sponsors to Investigators or Research Personnel who enroll a certain number of participants in a project within a certain period of time), or with respect to the evaluation of a product or service intended for a commercial market (e.g., a clinical trial for a pharmaceutical company), regardless of the amount of compensation or payments received.

- Any sponsored agreement in which **publication rights are restricted**, except for reasonable delays in order to protect proprietary rights (i.e. patent rights), in combination with the Investigator, Research Personnel or Close Relation holding a Conflict of Interest.

- **Accepting personal gifts, gratuities or special favors** from an actual or prospective sponsor of an Investigator's research, other than occasional gifts of nominal or modest value (less than $50 in value or isolated invitations to meals).**1**

3.11 Significant Conflict

A "**Significant Conflict**" is one whose potential for actual or perceived bias is great enough that the Investigator or Research Personnel must present compelling circumstances as to why the research should proceed despite the presence of the conflict. A Significant Conflict includes situations when an Investigator and/or his or her Close Relation maintains any of the following interests:

- **Equity in a privately-held entity** (e.g., stocks, stock options, or other ownership interests) that is a research sponsor, unless the Investigator provides verification that the equity interest is less than 10% of the outstanding stock of the research sponsor.

- **Equity in a publicly traded entity in excess of $50,000**, where that entity is a research sponsor (except when the interest is maintained in an investment vehicle, such as mutual funds and retirement accounts, where the Investigator does not directly control the investment decisions made).

- **Management Roles** in a research sponsor (e.g., a director, officer, or other position that has significant decision-making authority).

- **Receipt of payment for services** related to promoting, marketing or selling products (e.g., paid public appearances, endorsements or speaking engagements aimed to encourage purchase or use of products) on behalf of a company for whom the Investigator has also conducted (or intends to conduct) CHLA research as an independent evaluator of the company's products (note that

1 Investigators and/or Research Personnel who are healthcare providers are subject to additional requirements under CHLA's *Vendor Gratuity* policy. (See also Footnote 1, *supra*).

participation in a paid speaker's bureau for a research sponsor is a Prohibited Conflict under Section 3.10).

In the case of human subject research, a conflict is also a Significant Conflict when any Investigator, Research Personnel and/or his or her Close Relation maintain any of the following interests:

- Receipt of **personal funding and compensation** that totals $25,000 or more when aggregated in any twelve month period, from a sponsor or a company that holds an economic interest (e.g., licensee) in the outcome of a human subject trial.

- **Equity in a privately-held company** (e.g., stocks, stock options, or other ownership interests) that is a research sponsor and that holds an economic interest (e.g., licensee) in the outcome of a human subject trial regardless of the value of such equity interest.

- **Publicly traded equity interests in excess of $50,000** from a sponsor or a company that holds an economic interest (e.g., licensee) in the outcome of a human subject trial (except when the interest is maintained in an investment vehicle, such as mutual funds and retirement accounts, where the Investigator or Research Personnel or Close Relation does not directly control the investment decisions made).

- **Management Roles** (e.g., a director, officer, or other position that has significant decision-making authority) in a sponsor or a company that holds an economic interest in the outcome of a human subject trial (e.g., licensee).

3.12 Student Conflict of Interest

A "**Student Conflict of Interest**" exists when a company in which an Investigator, Research Personnel or Close Relation has an ownership interest or management role retains a student to provide services (paid or unpaid) and:

(1) The Investigator, Research Personnel or Close Relation currently supervises the student in an academic capacity;
(2) The Investigator, Research Personnel or Close Relation has the ability to influence the academic progress of the student; or
(3) The Investigator, Research Personnel or Close Relation otherwise supervises the student as a research assistant or student employee.

3.13 Conflict of Interest in Research Committee

The **Conflict of Interest in Research Committee** ("COIRC") consists of members appointed by the Director of The Saban Research Institute or the Director's designee, and may be chosen from CHLA

faculty members, administrative and research operational staff, and other CHLA employees displaying familiarity with issues relevant to research including scientific methods, medical treatments, financial management, intellectual property, and/or public affairs. The COIRC is charged with reviewing Conflict of Interest disclosures and formulating recommendations to manage, reduce, or eliminate Conflicts of Interest. The Director of The Saban Research Institute or the Director's designee shall also select the Committee Chair.

4.0 **Policy**

4.1 Investigators and Research Personnel are responsible for identifying and disclosing all potential Conflicts of Interest covered by this policy to CHLA, including Significant Financial Interests, Management Roles and other non-financial potential conflicts, and Significant Conflicts. Investigators and/or Research Personnel should evaluate potential Conflicts of Interest not only at the outset of their research, but also when a change occurs in their relationship with an outside entity. This may occur at the time a new proposal is submitted, when a new relationship is established with an outside entity, or when a prior relationship with an outside entity changes.

4.2 Investigators and Research Personnel are responsible for updating their disclosures whenever there is a change to the information contained in the initial disclosure.

4.3 In addition, Investigators must submit an annual disclosure of financial interests related to their CHLA Responsibilities (regardless of whether the interest creates a potential Conflict of Interest in Research). Investigators who are seeking support from Public Health Service ("PHS") agencies must have a current annual disclosure at the time of proposal submission. Investigators with PHS sponsored funding must update their annual disclosures within thirty (30) days of the time they obtain or discover a financial interest with an entity that was not disclosed at the time of the most recent annual disclosure. All changes to financial interests with entities disclosed in the annual disclosure must be updated at the time of the next annual disclosure.

4.4 Investigators are not permitted to commence any research activity when they have disclosed a potential Conflict of Interest before they receive a written determination from the COIRC as to whether a Conflict of Interest exists and, if so, how to manage the conflict. Investigators also are not permitted to commence an external activity that would create a Conflict of Interest relative to an ongoing research activity before they receive a written determination from the COIRC as to whether a Conflict of Interest exists and, if so, how to manage the conflict.

4.5 Investigators and Research Personnel must provide timely and accurate information in response to the COIRC and its designees in order for the COIRC to make an initial determination regarding whether a disclosure constitutes a Conflict of Interest and/or to monitor compliance with the COIRC-imposed Management Plan (described below).

4.6 In the case of a Significant Conflict, the Investigator or Research Personnel must present compelling circumstances as to why the research should proceed despite the conflict. This determination will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, the degree to which the interest may be affected by the research, and the degree to which the interest may be affected by the research.

4.7 Investigators and Research Personnel must comply with all of the elements of a COIRC-imposed Management Plan.

4.8 All Investigators must complete training relating to Conflicts of Interest in research as prescribed by this policy.

4.9 Each Investigator also is responsible for confirming that Research Personnel under his or her supervision who are involved in proposing, conducting or reporting research on the Investigator's project identify and disclose any potential Conflict of Interest.

4.10 Prohibited Conflicts are never acceptable and, therefore, should not occur. Immediate action must be undertaken to eliminate any Prohibited Conflict.

5.0 **Procedure to Disclose Potential Conflicts**

5.1 Investigators and Research Personnel must disclose potential Conflicts of Interest:

- Prior to, but in no event later than at the time of, proposal submission.
- In connection with human subjects research, at the time of submission of the initial and continuing review application to the Committee on Clinical Investigations and/or in connection with animal research, at the time of submission of the initial and continuing review application to the Institutional Animal Care and Use Committee (IACUC).
- Within 30 days of discovering or acquiring a new or previously undisclosed outside relationship, or change an existing relationship, which creates a potential Conflict of Interest under this policy.
- At least annually during the term of each research project and/or period of award for any PHS-funded research project.
- In accordance with other sponsor-specific disclosure requirements.

CHLA will establish procedures by which Investigators and/or Research Personnel must disclose potential Conflicts of Interest. The disclosure forms will require the Investigator and/or Research

Personnel to describe the proposed research and the nature and extent of the potential Conflict of Interest.

5.2 Additional disclosures may be needed under other CHLA policies. Conflicts of Commitment must be disclosed, following the procedures in the Conflicts of Interest and Ethics policy. When an Investigator and/or Research Personnel disclose a Conflict of Commitment under the Conflict of Interest and Ethics policy, the Investigator and/or Research Personnel must provide a copy of any such disclosure to the COIRC, as well as a copy of all documentation reflecting any management decision. If the Investigator and/or Research Personnel's Chair, Department Chair, or supervisor, as appropriate, requires subsequent disclosures at specified intervals with respect to a Conflict of Commitment, copies of any such disclosures as well as any documentation reflecting management decisions must also be provided to the COIRC.

6.0 **Procedure to Evaluate Potential Conflicts and Manage Conflicts**

6.1 Given the complexity of financial and non-financial relationships within CHLA, disclosures will be evaluated on a case-by-case basis by the COIRC at CHLA to determine whether the disclosed relationship or interest constitutes a Conflict of Interest and, if so, to determine an appropriate action.

6.2 All disclosed potential Conflicts of Interest first receive an administrative pre-review to assess the circumstances of the potential conflict. When requested, Investigators and/or Research Personnel are required to provide additional information, to perform this initial assessment.

6.3 The disclosure and pre-review will be forwarded to the COIRC, which is charged with reviewing all disclosures, determining if disclosed interests or relationships constitute Conflicts of Interest, and formulating recommendations to manage, reduce, or eliminate Conflicts of Interest, as appropriate. The COIRC shall meet on a regular basis, as determined by the Director of The Saban Research Institute.2

6.4 The COIRC will make the final determination as to whether the potential Conflict of Interest is in fact a Conflict of Interest. The COIRC will then decide whether the research may proceed: (1) Permitted as is (i.e., CHLA determines no Conflict of Interest exists); (2) Permitted contingent upon implementation of a Management Plan (i.e., CHLA determines a Conflict of Interest exists, but can be managed); or (3) Unacceptable, and thus prohibited (i.e., CHLA determines a Conflict of Interest exists that cannot be managed, for instance, a Prohibited Conflict).

6.5 With particular regard to potential Conflicts of Interest, including Significant Financial Interests, which are disclosed in connection with PHS-funded research, the COIRC will review disclosures indicating a Significant Financial Interest and make the determination as to whether the SFI is related to PHS-funded research. If so, COIRC will then determine whether the SFI constitutes a FCOI. In making this determination, the COIRC may meet with the Investigator, Research Personnel and others, as appropriate, and may request and/or examine data, reports, laboratory notebooks and other records.

- An Investigator's or Research Personnel's SFI is related to PHS-funded Research when the COIRC reasonably determines that the SFI could be affected by the PHS-funded Research or is in an entity whose financial interest could be affected by the PHS-funded research.

- A FCOI exists when the COIRC reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.

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2 The Director of The Saban Research Institute, or his or her designee, shall educate the members of the COIRC about the importance of confidentiality in its deliberations and will take reasonable steps to ensure the confidentiality of the information provided. Meetings will be closed for confidentiality reasons. However, investigators or other individuals with relevant information may be invited to discuss a particular project. Committee members who breach the confidentiality requirements will be sanctioned as appropriate, including removal from the COIRC.

6.6 When a disclosure reveals a Significant Conflict, the COIRC will make an assessment of whether compelling circumstances exist that justify allowing the research to proceed despite the presence of the Significant Conflict.

6.7 A Management Plan is a written document defining the actions the COIRC has determined necessary to manage a relationship or interest it has determined is a Conflict of Interest.

6.7.1 All management plans shall contain, at a minimum, the following elements. Collectively, these elements constitute the "**General Rule**."

- All relevant **publications, proposals and presentations** must contain a statement disclosing support received from, or financial interests in, any source outside of CHLA;
- All **informed consent documents** in the context of human subjects research must disclose support received from, or financial interests in, any source outside of CHLA. Conflicted Investigators and/or Research Personnel are not permitted to consent human subjects;
- The Investigator and/or Research Personnel and their Close Relations will not represent CHLA in any **intellectual property negotiations**, or other contractual negotiations, between CHLA and the outside entity;
- Investigators must **notify students** of the presence of a Conflict of Interest if the student is to perform as a research assistant on the Research, along with a notification to the student and his or her advisor of the student's rights.

6.7.2 Management Plans may contain a variety of additional elements, including:

- Monitoring and oversight by the COIRC or by an individual delegated to monitor by the COIRC;
- Referral to a COIRC-appointed subcommittee for oversight.
- Reformulation of the research workplan;
- Restrictions on the analysis of data;
- Close monitoring of the research project by independent reviewers;
- Termination or reduction of involvement in the relevant research project;

- Termination of inappropriate student involvement in projects;

- Where the Investigator and/or Research Personnel receive payments for personal services related to research involving human subjects (e.g., consulting arrangements, non-managerial scientific or technical appointments, and payments for lectures and similar public appearances), the Committee on Clinical Investigations may require written disclosure of such payments during the informed consent process, regardless of dollar amount;

- Removal from the research project of an Investigator and/or Research Personnel with an Conflict of Interest;

- Creation of an escrow account and/or blind trust to hold equity interests or intellectual property interests that constitute a Conflict of Interest;

- Divestiture of relevant financial interests;

- Severance of outside relationships that pose a Conflict of Interest.

The COIRC may also consider steps taken by the Investigator and/or Research Personnel to minimize potential bias and include protective factors in the design of the study, such as using multiple investigators, blinding, or establishing objective endpoints. Possible management recommendations may apply to the monitoring of research, conduct of research, or the Investigator or Research Personnel's outside interests.

6.7.3 Management Plans for PHS-funded Research. When required in relation to PHS-funded research, CHLA will develop and implement a Management Plan:

- Before CHLA's expenditure of funds, for new PHS-funded projects;
- Within sixty (60) days whenever CHLA identifies a SFI that was not disclosed timely by an Investigator or Research Personnel or not previously reviewed by CHLA during the course of an ongoing PHS-funded project;
- Within sixty (60) days whenever an Investigator or Research Personnel who is new to an ongoing PHS-funded project discloses a SFI, or whenever an existing Investigator or Research Personnel discloses a new SFI.

6.8 In cases where the COIRC's review of a disclosure raises a potential **Conflict of Commitment**, the COIRC will notify the Investigator and/or Research Personnel's supervisor, Division Chief, Chair or CEO pursuant to the *Conflict of Interest and Ethics* policy, as appropriate. The Investigator and/or

Research Personnel's supervisor, Division Chief, or Department Chair should provide a copy of all documentation reflecting his or her decision with respect to the Conflict of Commitment to the Investigator and/or Research Personnel.

6.9 Once the COIRC makes its final determination, the COIRC will notify the following individuals and/or entities in writing, as appropriate:

- The individual(s) who has disclosed the potential Conflict of Interest. If this individual(s) is someone other than the Investigator, the Investigator will be notified as well;
- The relevant Department Chair;
- If the Conflict of Interest involves human subjects, the Committee on Clinical Investigations;
- If the Conflict of Interest has been identified in connection with a sponsored research project, the appropriate person at The Saban Research Institute;
- Other individuals at CHLA who have a "need to know"(e.g., principal investigator).

6.10 It is the responsibility of the Investigator and/or Research Personnel to comply with each element of a required Management Plan. The Investigator and/or Research Personnel must also provide all required **follow-up disclosures** updating the COIRC on the status of the Conflict of Interest and Investigator and/or Research Personnel's compliance with the measures put in place to manage it.

6.11 This policy does not preclude the Department Chair or a CEO from requiring faculty or staff to provide additional Conflict of Interest information or to do so on a more regular basis (e.g., annually).

7.0 Violations and Sanctions

7.1 Failure to report a potential Conflict of Interest or to submit an annual or updated disclosure, or refusal to cooperate in the management of a Conflict of Interest, may be cause for disciplinary action. Possible violations of this policy include, but are not limited to, failure to file the disclosure form or furnishing false, misleading, or incomplete information on the disclosure form, or failure to follow a Management Plan. Sanctions for violations of this policy for faculty will observe all provisions of the policies published in the Conflict of Interest Procedures approved by the CHLA Governance Committee on January 19, 2009 and the Board of Trustees on January 22, 2009. Sanctions for violations of this policy for students will require that students observe all provisions of their institutions policies.

Sanctions for violations of this policy for staff or other non-faculty may include termination. Research Administration and/or the Compliance Office will notify both the department and the non-faculty employee of the prescribed action. Departments are required to implement the remedial or

disciplinary action prescribed by Research Administration and/or the Compliance Office. A non-faculty employee may file a written appeal with the Research Administration and/or the Compliance Office within ten business days of his or her receipt of notice of the disciplinary action. The COIRC must respond to the employee's appeal within 30 business days.

7.2 Violations that appear to have resulted from a misrepresentation of research results will be handled according to the CHLA's *Scientific Misconduct Policy*, and other misconduct will be handled under the procedures specified in the Faculty Handbook, and for non-faculty employees as described in Section 7.1 above. Violations of federal or state statutes and guidelines must be handled according to federal and state laws and requirements.

7.3 For PHS-funded Research:

7.3.1 If CHLA determines that a FCOI was not identified or managed in a timely manner, then within one hundred twenty (120) days of such determination, CHLA will complete a retrospective review of the Investigator's or Research Personnel's activities and the PHS-funded Research project to determine whether any PHS-funded research conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research in accordance with 42 CFR 50.605(a)(3) ("Retrospective Review").

7.3.2 If the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator or Research Personnel with a FCOI that was not properly disclosed or managed, then CHLA will require the Investigator(s) to: (i) disclose the FCOI in each public presentation of the results of the research, and (ii) request an addendum to previously published presentations.

8.0 **Government Reporting and Appeals**

8.1 A faculty member seeking review of the decision by the Conflict of Interest in Research Committee may do so by filing a grievance under the provisions of the Faculty Handbook on any of the grounds on which a tenure decision may be grieved. The decision of the Conflict of Interest in Research Committee will remain in full force and effect throughout the review process.

8.2 When a Financial Conflict of Interest has been identified in connection with PHS funded awards, the Director of The Saban Research Institute, or his or her designee, will report to the federal awarding agency the existence of the FCOI and assure that the conflict has been managed, reduced, or eliminated prior to the expenditure of any funds under the award as described herein (the "FCOI Report").

8.2.1 When required, CHLA shall submit a FCOI Report:

- Before CHLA's expenditure of funds, for new PHS-funded projects;
- Within sixty (60) days whenever the COIRC determines an Investigator or Research Personnel who is new to an ongoing PHS-funded project has a FCOI, or whenever the COIRC determines an existing Investigator or Research Personnel has a new, or newly identified, FCOI;
- At least annually until the completion of the project, to provide the status of a FCOI and any changes to any relevant Management Plan; and
- Following a Retrospective Review as described in Section 7.3.1.

8.2.2 If the COIRC determines that bias has occurred within the research design, conduct, or reporting of PHS-funded research following a Retrospective Review, CHLA will submit a Mitigation Report as required by 42 CFR 50.605.

8.2.2.1 If the COIRC determines that an Investigator has failed to comply with this policy or a Management Plan as required by the COIRC, resulting in potential bias in the design, conduct or reporting of PHS-funded research, CHLA will notify the PHS awarding component and promptly take corrective action, as required by 42 CFR 50.605 and 50.606.

8.2.2.2 All FCOI Reports will include sufficient information to enable the PHS awarding component to understand the Financial Conflict of Interest and to assess the Management Plan implemented by CHLA's COIRC. At a minimum, FCOI Reports will include the required elements at 42 CFR 50.605(b)(3).

8.3 With respect to research funded by the NSF, if for any reason the Conflict of Interest cannot be managed satisfactorily, then the Director of The Saban Research Institute, or his or her designee, will promptly inform the NSF of this fact.

9.0 Training, Records and Subrecipients

9.1 CHLA shall give each Investigator and Research Personnel a copy of this policy: (i) at the time of employment, (ii) as requested by Investigator or Research Personnel, and (iii) when CHLA revises this policy in a manner affecting the Investigator or Research Personnel's obligations hereunder.

9.2 Each Investigator and Research Personnel is required to complete financial conflict of interest training: (i) prior to engaging in PHS-funded research; (ii) at least every four (4) years thereafter; and (iii) immediately if: (a) CHLA revises this policy in a way that affects Investigators' or Research Personnel's obligations, (b) upon hiring, or (c) the COIRC determines that an Investigator or Research Personnel is not in compliance with this policy or a Management Plan.

9.3 Records relating to disclosures of potential Conflicts of Interest and the determinations of the Conflict of Interest in Research Committee will be kept by the Compliance Office for three years after the termination or completion of the project, whichever is later, and/or for PHS Research, as may required by 45 CFR 74.53(b) and 92.42(b).

9.4 CHLA may carry out PHS-funded Research through a subrecipient entity (e.g., subcontractors or consortium members). CHLA shall take reasonable steps to ensure that any subrecipient investigator complies with federal financial conflict of interest regulations by establishing such compliance via a written agreement.

10.0 Public Accessibility

10.1 CHLA shall make this policy, as may be updated from time to time, publicly accessible on CHLA's website.

10.2 For PHS-funded research, CHLA shall make publicly accessible certain information concerning Financial Conflicts of Interest held by senior/key personnel, defined as the principal investigator and any other person identified as senior/key personnel by CHLA in the grant application, progress report, or any other report submitted to the PHS funding agency. Such information shall be provided within five (5) business days of CHLA's receipt of a written request. Requests should be directed to the Compliance Office.

10.3 Such responses will only be made in response to a written request related to a Significant Financial Interest of a senior/key personnel about which the COIRC has determined:

a. The SFI was disclosed and is still held by the senior/key personnel,

b. COIRC has determined that the SFI is related to the PHS-funded research, and

c. COIRC has determined that the SFI constitutes a Financial Conflict of Interest.

10.4 Information concerning the Significant Financial Interests of senior/key personnel that is provided upon written request will be available for responses to written requests for at least three (3) years from the date that the information was most recently updated.

10.5 CHLA will prepare and approve a timely response that will be communicated to the requestor through a CHLA-appointed designee. Such response will include all required elements set forth at 42 CFR 50.605(a)(5)(ii).

11.0 **Resources**

"Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought" 42 CFR Part 50 and "Responsible Prospective Contractor" 45 CFR Part 94.

Objectivity in Research - NIH Guidance
http://grants2.nih.gov/grants/policy/coi/index.htm and
http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

Conflict of Interest Policies – NSF Grant Policy Manual
http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510

OHRP Guidance on Financial Relationships and Interests in Research Involving Human Subjects
http://www.hhs.gov/ohrp/humansubjects/finreltn/finalguid.pdf

AAMC Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research
http://www.aamc.org/research/coi/firstreport.pdf

AAU Report on Individual and Institutional Financial Conflict of Interest
http://www.aau.edu

Food and Drugs: FDA Guidance on Financial Disclosure by Clinical Investigators
http://www.fda.gov/oc/guidance/financialdis.html

CHLA Conflict of Interest and Ethics Policy
CHLA Purchasing Policy – Conflict of Interest
CHLA Faculty Handbook

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