

<h1>CHLA</h1>	<h2>HOSPITAL POLICY AND PROCEDURE MANUAL</h2>		
	TITLE: Conflict of Interest in Research: Policy & Procedure		
	ORIGINAL DATE: 06/13/2007	EFFECTIVE DATE: 06/29/2020	APPROVED BY: Chief Clinical Officer, Quality Improvement Committee, Board of Directors
REVISED DATE:			
POLICY NUMBER: COMP – 021.0	CHAPTER: ENTERPRISE – COMPLIANCE AND PRIVACY		PAGE 1 of 16

PURPOSE:

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

Children’s Hospital Los Angeles (“CHLA”) encourages its researchers 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. Having a conflict of interest does not, in itself, equate to wrongdoing or inappropriate activity; however, conflicts do require review and management to ensure that it does not improperly influence, or appear to improperly influence how CHLA research is designed, 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 represents one aspect of CHLA’s commitment to address and manage conflicts of interest. As set forth in COMP – 020.0 Conflicts 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. For the Physician Conflict of Interest Policy, see COMP – 028.0. For the Institutional Conflict of Interest in Research policy, see COMP – 022.0.

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) or any other persons 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 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.

This policy supersedes the Children’s Hospital Los Angeles Conflict of Interest in Research Policy and Procedure COMP – 021.0, dated June 13, 2007.

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1.0 DEFINITIONS

1.1 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.

1.2 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.

1.3 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).

1.4 Close Relation

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

1.5 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.

1.6 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.

1.7 Significant Financial Interest

A “**Significant Financial Interest**” (or “SFI”) is a financial interest consisting of one or more

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interests of the Investigator and/or Research Personnel (and those of the Investigator’s and/or Research Personnel’s Close Relation) 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, an 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
- Personal receipt of **intellectual property rights** (e.g., patents, copyrights or royalties) directly from a research sponsor or a company having an economic interest in the research (e.g., licensee).
- **Sponsored travel or reimbursement of expenses** associated with travel and provision of services that totals \$5,000 or more when aggregated per sponsor over a 12-month period is also considered an SFI to the extent the sponsorship/reimbursement is not reasonable. Unreasonable sponsored/reimbursed travel may include, for example, travel paid for or reimbursed for the investigator’s family.
- **Payments and travel reimbursement** from seminars, lectures, teaching arrangements, or service on advisory committees or review panels are excluded¹ if they are from (i) a United States federal, state, or local government agency; (ii) a United States university or research institute affiliated with a university; or (iii) a United States academic medical center or teaching hospital.

¹ The exclusion does not apply to financial interests received from a foreign university or institution of higher education, academic medical center or teaching hospital, or the government of another country (which includes local, provincial, or equivalent governments of another country).

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1.8 Conflict of Interest

A “**Conflict of Interest**” occurs when 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 requiring management 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 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 1.10 below.

Significant Conflicts

- Described in Section 1.11 below.

1.9 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.

1.10 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

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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 \$25 in value or isolated invitations to meals).²

1.11 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.

² Investigators and/or Research Personnel who are healthcare providers are subject to additional requirements under CHLA COMP - 017.0 Gifts and Interactions with Industry

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- **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 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).

1.12 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:

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- (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.

1.13 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.

POLICY:

1.14 Investigators and Research Personnel are responsible for identifying and disclosing all potential Conflicts of Interest covered by this policy at least annually. Potential Conflicts of Interest include, but are not limited to, Significant Financial Interests, Management Roles and other non-financial potential 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.

1.15 Investigators and Research Personnel must provide timely and accurate information in response to the COIRC and its designees. The COIRC will make an initial determination regarding whether a disclosure constitutes a Conflict of Interest and/or to monitor compliance with the COIRC-imposed Management Plan. Upon request by the COIRC or its designees, the Investigator or Research Personnel must present compelling circumstances as to why the research should proceed despite the conflict.

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1.15.1 The COIRC 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.

1.15.2 “Compelling circumstances” should address the following, at a minimum and where applicable:

- Unique qualifications of CHLA and/or its researchers (e.g., facilities and equipment, eligible patient population, unique expertise);
- The degree of risk to human subjects posed by the research study;
- Any steps taken by Investigators or others that serve to manage the risk of bias the conflict poses for research at CHLA;
- Additional items as requested by the COIRC or the Office of Compliance & Privacy.

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

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

1.18 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.

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

2.0 DISCLOSURE OF POTENTIAL CONFLICTS:

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

- Prior to, but in no event later than at the time of, funding proposal submission
- In connection with human subjects research, at the time of submission of the initial and continuing review application to the Institutional Review Board (IRB) 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).

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- 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.
- In accordance with other sponsor- or publisher-specific disclosure requirements.

2.2 Additional disclosures may be needed under other CHLA policies:

When an Investigator and/or Research Personnel disclose a Conflict of Commitment, 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.

3.0 **PROCEDURE TO EVALUATE POTENTIAL CONFLICTS AND MANAGE CONFLICTS:**

3.1 Given the complexity of financial and non-financial relationships, 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 for research and, if so, to determine appropriate management.

3.2 The disclosure, along with other materials required to evaluate the potential conflict, will be forwarded to the COIRC, as appropriate. The COIRC shall meet on a regular basis, as determined by the Director of The Saban Research Institute.

3.3 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).

3.4 With regard to Significant Financial Interests which are disclosed in connection with PHS-funded research, the COIRC will make the determination as to whether the SFI is related to PHS-funded research. If so, COIRC will then determine whether the SFI constitutes an FCOI. In making this determination, the COIRC may meet with the Investigator, Research Personnel and others, as

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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.

3.5 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.

3.6 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.

3.6.1 Examples of potential management plan elements include, but are not limited to:

- 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.
- Disclosure to co-investigators, collaborators, or study sponsors;
- Disclosure to the Office of Procurement when purchasing products or services;
- Restrictions on an investigator’s ability to recruit or obtain informed consent from prospective 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.
- Monitoring and oversight by the COIRC or by an individual delegated to monitor by the COIRC, or close monitoring of the research project by independent reviewers;
- Referral to a COIRC-appointed subcommittee for oversight.
- Reformulation of the research workplan;
- Restrictions on the analysis of data;
- Termination or reduction of involvement in the relevant research project(s);

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- Termination of inappropriate student involvement in projects;
- 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.
- Restrictions on the ability to conduct the study at CHLA

3.6.2 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 an SFI that was not disclosed timely by an Investigator or Research Personnel or not previously reviewed by CHLA during 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 an SFI, or whenever an existing Investigator or Research Personnel discloses a new SFI.

3.7 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, 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.

3.8 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 IRB;
- 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).

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3.9 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.

3.10 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 than prescribed by this policy.

4.0 **AUDIT:**

4.1 The Office of Compliance and Privacy may conduct routine or for-cause audits to evaluate compliance with CHLA policies. Concerns regarding compliance with this policy may be directed to the General Compliance Line at (323)361-2302 or at compliance@chla.usc.edu. You may also report anonymously through CHLA’s Compliance Hotline by calling 1-877-992-6675, faxing information to (323) 361-5269, or by submitting a report online at www.mycompliancereport.com (company ID: LAC).

5.0 **VIOLATIONS AND SANCTIONS:**

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

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	TITLE: Conflict of Interest in Research: Policy & Procedure		
	ORIGINAL DATE: 06/13/2007	EFFECTIVE DATE: 06/29/2020	APPROVED BY: Chief Clinical Officer, Quality Improvement Committee, Board of Directors
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appeal within 30 business days.

5.2 Violations that appear to involve a misrepresentation of research results will be handled according to the CHLA’s Research Misconduct Policy COMP – 025.0, and other misconduct will be handled under the procedures specified in the Faculty Handbook, and for non-faculty employees as described in Section 6.1 above. Violations of federal or state statutes and guidelines must be handled according to federal and state laws and requirements.

5.3 For PHS-funded Research:

5.3.1 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”).

5.3.2 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 an 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.

6.0 **GOVERNMENT REPORTING AND APPEALS:**

6.1 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.

6.2 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”).

6.2.1 When required, CHLA shall submit a FCOI Report:

- Before CHLA’s expenditure of funds, for new PHS-funded projects;

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- 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 at 42 CFR 50.605.

6.2.2 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.

6.2.3 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.

6.2.4 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).

6.3 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.

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7.0 TRAINING, RECORDS, AND SUBRECIPIENTS

7.1 CHLA shall make a copy of this policy available to the Investigator and Research Personnel.

7.2 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.

7.3 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).

7.4 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.

8.0 PUBLIC ACCESSIBILITY:

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

8.2 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.

8.3 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.

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8.4 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.

8.5 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).

9.0 RESOURCES:

- [42 CFR Part 50 and 45 CFR Part 94.](#)
- Objectivity in Research - NIH Guidance
 - <http://grants2.nih.gov/grants/policy/coi/index.htm>
 - http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- [45 CFR 74.53\(b\) and 92.42\(b\)](#)
- [Conflict of Interest Policies – NSF Grant Policy Manual](#)
- [OHRP Guidance on Financial Relationships and Interests in Research Involving Human Subjects](#)
- [AAMC Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research](#)
- [AAU Report on Individual and Institutional Financial Conflict of Interest](#)
- [Food and Drugs: FDA Guidance on Financial Disclosure by Clinical Investigators](#)
- [FIN – 010.0 Procurement](#)
- [COMP – 017.0 Gifts and Interactions with Industry](#)
- [EGEN – 013.0 Intellectual Property Policy](#)
- [COMP – 020.0 Conflicts of Interest Policy](#)
- [COMP – 025.0 Research Misconduct Policy](#)
- [NOT-OD-18-160, Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests](#)

POLICY OWNER:

Chief Compliance Officer

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