



Manual: Administrative and Patient Care

Section: Research

Number: K2014

Policy     Procedure

Title: Financial Conflict of Interest

<p><b>Originator:</b> Office of Research Compliance</p> <p><b>Current Content Expert:</b> Megan Bailey, Manager, Office of Research Compliance</p> <p><b>Department Head:</b> Brent Dethlefs, Director of Research Institute</p>	<p><b>Committee Approval(s)</b> Standards Committee</p> <p><b>Date(s)</b> 06/19/13</p>
<p><b>Executive Management Team Member:</b> Maria E. Minon, MD, Vice President of Medical Affairs and Chief Medical Officer</p> <p><input type="checkbox"/> New <input checked="" type="checkbox"/> Revised <input type="checkbox"/> Reviewed (no changes)</p> <p>Track: <input type="checkbox"/>A <input type="checkbox"/>B <input checked="" type="checkbox"/>C <input type="checkbox"/>D</p> <p><b>Replaces:</b> 02/10</p>	<p><b>Medical Executive Committee Approval Date:</b></p> <p><b>Board of Directors Approval Date:</b></p> <p><b>Effective Date:</b> 06/19/13</p>

**I. PURPOSE:**

- A. The ultimate goal of this policy is to protect the integrity and credibility of activities related to research conducted at CHOC Children’s and to maintain public trust and confidence in CHOC Children’s and its employees. The policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator financial conflicts of interest.
- B. This policy is intended to establish compliance with federal regulations governing federally funded research, specifically the rules adopted effective September 26, 2011 by the U.S. Public Health Service and October 1, 1995 by the U.S. National Science Foundation (NSF) requiring that grantee institutions adopt, maintain and enforce written policies pertaining to researchers’ financial conflicts of interest.

**II. DEFINITIONS:**

- A. **Annual:** Within the calendar year for the purpose of this policy.
- B. **Compensation:** Salary, consulting fees, honoraria, or other payments.
- C. **Conflict of Interest (COI) in Research:** Situations in which financial interests may compromise, or have the appearance of compromising an investigator’s professional judgment in the design, conduct or reporting of research.
- D. **Entity:** Any domestic or foreign, public or private, for profit or not-for-profit legal entity or organization other than CHOC Children’s, any agency of the State of California, or the federal government.
- E. **Equity:** Any interest in the profits of or other ownership interest in any commercial or non-profit enterprise, including common stock and other equity securities, any right to acquire any of the foregoing such as an option, warrant or other security convertible into an equity security.
- F. **Financial conflict of interest (FCOI):** A Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

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- G. Financial interest:** Anything of monetary value, including but not limited to Compensation, Equity, Gifts, and Intellectual Property, of an Investigator or Related Party, whether or not the value is readily ascertainable. For the purposes of this policy financial interests are those that reasonably appear to be related to your research responsibilities and the aggregated value received in the preceding 12 months exceeds \$10,000.
- H. Investigator:** Any person, regardless of title or position, who shares responsibility the design, conduct or reporting of research results. Examples include, but are not limited to, principal investigator, project director, staff scientist, technicians, clinical research coordinator, student, trainee, collaborator or consultant. The primary factors to be used in determining who is an Investigator are the significance of the tasks assigned to the individual with regard to design, conduct and reporting of the research results and the degree of independence that individual may have in performing such Research related tasks.
- I. Institutional Responsibilities:** An Investigator’s professional responsibilities on behalf of CHOC Children’s which may include, but are not limited to, research, research consultation, teaching, professional practice, management duties, service on CHOC Children’s committees and boards.
- J. Intellectual Property:** The rights comprising a patent, trademark, copyright, trade secret, know-how or other similar intangible property right, including but not limited to inventorship, ownership, or authorship.
- K. Management Plan** means a written plan for the management, reduction or elimination of a potential Conflict of Interest relating to research, arising from a Significant Financial Interest.
- L. NSF:** National Science Foundation
- M. ORC:** Office of Research Compliance
- N. PHS:** Public Health Service of the U.S. Department of Health and Human Services and any PHS awarding components to which authority may be delegated, including without limitation the National Institutes of Health.
- O. PHS-Funded Investigator:** An Investigator applying for or participating in any PHS-funded research. For the avoidance of any doubt, PHS-funded Investigators includes an Investigator applying for or participating in both PHS-Funded Research and non-PHS Funded Research.
- P. PHS-Funded Research** Research that receives funding from any of the agencies designated as components of the U.S. Public Health Service (PHS) through a grant or cooperative agreement, however authorized, such as a research grant, career development award, center grant, individual fellowship, infrastructure award, institutional training grant, program project, or research resource award. PHS-funded research does not include any Phase I SBIR Program application or award. For the purposes of this policy PHS-Funded Research also includes research funded by an agency that has adopted the PHS regulations, including but not limited to, American Cancer Society (ACS), American Heart Association (AHA) and Juvenile Diabetes Research Foundation (JDRF).
- Q. Principal Investigator:** Any person designated by CHOC Children’s with the title of “Principal Investigator” or an Investigator who otherwise has primary

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responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a research or sponsored project.

- R. Reimbursed Travel:** Travel activity for which travel expenses are paid directly by the Investigator, who is then reimbursed by an Entity for such travel expenses.
- S. Remuneration:** Compensation that includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
- T. Related Party:** A person’s spouse, domestic partner, child, or anyone who qualifies as the person’s dependent under the U.S. Internal Revenue Code.
- U. Research:** 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 encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
- V. Senior/key personnel:** The Principal Investigator and any other person identified as senior/key personnel by CHOC Children’s in the grant application, progress report, or any other report submitted to the study sponsor. For the purpose of this policy, Senior/key personnel are included in the group termed Investigator and must meet the same requirements as Investigators.
- W. Significant Financial Interest (SFI):** A financial interest consisting of one or more of the following interests of the Investigator and Related Party that reasonably appears to be related to the Investigator's Institutional Responsibilities and meets the specified criteria below, after accounting for any specified exclusions.

<b>Type</b>	<b>Criteria</b>	<b>Exclusion</b>
1. Financial Interest in <i>Publicly Traded Entity</i>	If aggregate <u>total</u> of <i>one or more</i> of the following exceeds \$5,000: (i) any Compensation received during the 12 months preceding the date of SFI Disclosure; or (iii) value of any Equity interest as of the date of disclosure  <b>SFI = (Compensation in past 12 months + Equity at disclosure) &gt;5K</b>	Income from seminars, lectures, teaching engagements sponsored by or service on advisory committees or review panels for one of the following: <ul style="list-style-type: none"> <li>• CHOC Children’s</li> <li>• a Federal, state or local government agency</li> <li>• an institution of higher education</li> <li>• an academic teaching hospital</li> <li>• a medical center</li> <li>• a research institute affiliated</li> </ul> Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g. mutual funds, retirement accounts)
2. Financial Interest in <i>Non-Publicly Traded</i>	(i) the value of any Compensation received during the 12 months preceding the date of SFI Disclosure, when aggregated,	Income from seminars, lectures, teaching engagements sponsored by or service on advisory committees or review panels for one of the following: <ul style="list-style-type: none"> <li>• CHOC Children’s</li> </ul>

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<i>Entity</i>	<p>exceeds \$5,000.</p> <p>(ii) Equity interest as of the date of disclosure.</p> <p><b>SFI = Compensation in past 12 months &gt; 5K; or SFI = Equity at disclosure</b></p>	<ul style="list-style-type: none"> <li>• a Federal, state or local government agency</li> <li>• an institution of higher education</li> <li>• an academic teaching hospital</li> <li>• a medical center</li> <li>• a research institute affiliated with an institution of higher education</li> </ul> <p>Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g. mutual funds, retirement accounts)</p>
3. Intellectual Property in any Entity	Intellectual rights or income received from such rights	<ul style="list-style-type: none"> <li>• Intellectual property assigned to CHOC Children's</li> <li>• Royalty payments paid by CHOC Children's to the Investigator</li> <li>• Agreements entered into by CHOC Children's, which either via CHOC Children's policy or specific provisions of the agreement, provides for the Investigator to share in royalties</li> </ul>
4. Travel provided by any Entity	<p>Reimbursed Travel or Sponsored Travel</p> <p>All travel disclosures by PHS-funded Investigators shall include information regarding:</p> <ul style="list-style-type: none"> <li>• Purpose of the travel</li> <li>• Identity of the sponsor/organizer</li> <li>• Destination</li> <li>• Duration</li> <li>• The inclusion of any Related Party</li> <li>• Estimate of the approximate value of travel</li> </ul>	<p>Travel for which expenses are paid for or reimbursed by:</p> <ul style="list-style-type: none"> <li>• CHOC Children's</li> <li>• a Federal, state or local government agency</li> <li>• an institute of higher education</li> <li>• an academic teaching hospital</li> <li>• a medical center</li> <li>• a research institute affiliated with an institution of higher education</li> </ul>

**X. SPA: Sponsored Projects Administration**

**Y. Sponsored Travel:** Travel activity for which expenses are paid directly by an Entity on behalf of an Investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available. This does not include travel expenses paid directly by a study budget set up by the Research Institute.

**III. POLICY:**

**A.** No research activities occurring at CHOC Children's shall be adversely affected by the financial interests of individuals carrying out those activities. All research

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activity undertaken at CHOC Children’s shall be conducted in compliance with all CHOC Children’s policies and all applicable federal regulations pertaining to conflict of interest.

- B.** Persons failing to comply with this policy shall be subject to sanctions described in this document.

**IV. PROCEDURE:**

**A. Who is Required to Report a Significant Financial Interest (SFI) or a Financial Interest:**

1. SFI (>\$5,000 related to Institutional responsibilities): Investigators who are anticipating participation in PHS-Funded Research or are already participating in PHS-Funded Research are required to disclose all their Significant Financial Interests and those of Related Party.
  - a. It is the responsibility of the Principal Investigator of a PHS-Funded Research project to identify all Investigators who have SFI requiring reporting under this policy.
  - b. It is the Principal Investigator’s responsibility to ensure Investigators identified as having SFI submit the necessary disclosure forms.
2. Financial Interest (>\$10,000 related to Research responsibilities): Non-PHS funded Investigators are required to disclose any of their Financial Interest and those of Related Party that is related to the Investigator’s Research that is greater than \$10,000.

**B. When to Report a Significant Financial Interest (SFI) or a Financial Interest:**

1. The Investigator is required to make disclosures in accordance with the following:
  - a. At the time a new Research project is registered with the Research Institute and if PHS-funded Research no later than the submission of the application for PHS funds. .
  - b. At least annually to the ORC.
  - c. Within thirty (30) days of discovering or acquiring a new SFI (if PHS funded) or Financial Interest (if non-PHS funded).
  - d. When an Investigator is added to Research project.
  - e. Upon direction from the ORC or Institutional Official for Research
2. It is the Principal Investigator’s responsibility to ensure that any Investigators who join an ongoing research project are identified and submit the required disclosures to ORC within thirty (30) days of joining the project. This includes any Investigator added to a research project through modifications to an IRB application.

**C. How to Report a Significant Financial Interest (SFI) or a Financial Interest:**

Investigators shall make disclosures required by this policy by submission of a completed disclosure form. The type of form to complete whether the **Annual Research Conflict of Interest Form** , **Ad Hoc** Disclosure of Interests or **Agency Proposal Disclosure** (i.e. new project), and the ways in which these disclosures are submitted are as follows:

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1. All Investigators are required to complete and submit the Annual Research Conflict of Interest Form to the Office of Research Compliance (ORC) through the required electronic system.
2. Upon discovery or acquisition of a new Financial Interest for which disclosure is required by this policy, the Investigator must report within (30) days, to ORC, via the Ad Hoc Disclosure Form in the required electronic system.
3. When a proposal for a PHS funded research project is submitted to SPA, the Principal Investigator is required to indicate whether any of the Investigators have any Significant Financial Interest via the Proposal Disclosure Form in the required electronic system.

**D. Transmittal and Review of Disclosures**

1. Disclosure forms with negative disclosures will be retained in the appropriate SPA and/or ORC records as deemed necessary.
2. Disclosure forms with positive disclosures will be sent to a review committee consisting of at least one member representing each of the following: the CHOC Children’s Corporate Compliance Office, the CHOC Children’s Research Institute’s Office of Research Compliance and the Sponsored Projects Administration Office. The review committee will review positive disclosures to determine if the Financial Interest meets the definition of FCOI and may engage the assistance of other subject matter experts, as appropriate.
3. In the case of a new project, the committee review must be completed before any expenses are incurred under an award and before any research can begin.
4. On an annual basis, disclosures revealed on the “CHOC Children’s Conflict of Interest Disclosure Form” (as per Compliance Policy 509: Conflict of Interest), that are applicable to research, will be forwarded by the Corporate Compliance Office to ORC. ORC will compare these disclosures with any previous disclosures made to ORC. Any new reports will be followed up by ORC.
5. The review committee will contact the Investigator for any additional information and/or documentation needed for the review.
6. Investigators shall fully cooperate with ORC regarding any follow-up to their disclosures.

**E. Standards for Approval**

Proposed PHS funded research activities will only be approved if determined that they can be conducted in compliance with HHS regulations 42 CFR part 50 subpart F (grants) and 42 CFR part 94 (contracts), and if an adequate Management Plan can be implemented when necessary. When the research is sponsored solely by NSF and does not involve human subjects, the requirement for a Management Plan may be waived if determined that the risks of a potential conflict of interest are outweighed by the public interest in having the research go forward without the Management Plan.

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#### **F. Management Plan and Notification**

1. If the review committee concludes that a reported SFI or Financial Interest is an FCOI, they will propose a Management Plan including the terms, conditions and any required restrictions to the design, conduct or reporting of research. The Management Plan will be sent in writing to the Investigator with copies provided to the Compliance Officer, the Office of Research Compliance, Sponsored Projects Administration and to other persons or departments deemed appropriate by the review committee.
2. The Management Plan may require that one or more of the following actions be taken in order to **manage, reduce, or eliminate** a potential conflict of financial interest:
  - a. Disclosure of Financial Interests, including to the public, human subjects, researchers and other participants, publishers, and conference organizers;
  - b. Monitoring of research by independent researchers and/or reviewers, disinterested individual or committees;
  - c. Placing copies of research data with a neutral party
  - d. Disqualification from participation in all or a portion of the research;
  - e. Requiring that the Financial Interest be divested, restructured, or placed in a blind trust;
  - f. Modification or severance of relationships that create potential Conflicts of Interest;
  - g. Changing terms of agreement relating to the research;
  - h. Requiring that Investigator participation in the recruitment or consent of subjects in human subjects research be prohibited or restricted;
  - i. Requiring additional disclosures or actions with respect to matters before the IRB;
  - j. Requiring non-participation in any business transactions between the Hospital and parties to agreements involving sponsored research.

#### **G. Subrecipient Compliance**

1. CHOC Children's Subrecipients funded from HHS or NSF awards shall be required to notify CHOC Children's Sponsored Projects Administration (SPA) of the existence of any SFI identified by the Subrecipient. Subrecipients must certify and assure that a Management Plan is in place for any identified conflicting interest so that any reported conflicting interest has been managed, reduced or eliminated.
2. If a Subrecipient identifies any SFI subsequent to the initiation of the award, the following actions must be performed within thirty (30) days of identification of the interest:
  - a. The Subrecipient must notify SPA of the SFI;
  - b. The Subrecipient must certify that a Management Plan is in place that manages, reduces or eliminates the identified SFI.

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3. SPA will notify the CHOC Children’s Office of Research Compliance (ORC) of any SFI identified by a Subrecipient and of any certifications or assurances provided by the Subcontractor.
4. ORC will notify the Principal Investigator and if appropriate, the IRB, of any conflicting interests identified by a Subrecipient. The Principal Investigator and ORC will determine if continued participation by the Subrecipient is appropriate, and may seek consultation of the funding agency as appropriate.

**H. Annual Management Plan Reporting**

Investigators subject to a management plan under this policy shall report annually or more frequently if required by the plan or review committee. Reports shall be provided directly to ORC.

**I. Sanctions and Remedies for Violation of Policy**

1. Whenever a person has violated this policy, including failure to submit a required report of financial interests or failure to comply with the requirement of a management plan, ORC shall report violators to the Research Institute Executive Director and the Institutional Official for Research. The Executive Director and the Institutional Official shall be responsible for enforcing this policy, and shall take reasonable steps to respond appropriately to violations, including, but not limited to:
  - a. suspending expenditures on a research account,
  - b. administratively suspending IRB approval,
  - c. Instituting disciplinary measures to include suspension or termination.
2. If criminal conduct has been detected, CHOC Children’s shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making necessary modifications to this policy.

**J. Retrospective Review (Mitigation plan) for Non-Compliance**

Upon determination of non-compliance with this policy, the Office of Research Compliance will conduct a retrospective review. If the research is PHS funded, CHOC Children’s will notify and submit a Mitigation Report to the PHS Awarding Component in cases where bias is found. The report will address the impact of any found bias on the research project and the actions that CHOC Children’s has taken, or will take, to eliminate or mitigate the effect of the bias.

**K. Record Keeping**

1. All materials related to this policy, submitted to ORC will be treated as confidential.
2. Records of and related to disclosures pursuant to this policy shall be retained by ORC no less than three (3) years after the date of completion of the research. For research projects, the date of completion is the date of submission of the final expenditures report.

**L. Federal Reporting**

1. Prior to the expenditure of any PHS funds under an award, the ORC shall disclose to the Awarding Component the existence of any reported Significant Financial Interest which requires reporting according to 42



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CFR Part 50. ORC will assure the PHS Awarding Component that the interest has been managed, reduced or eliminated.

2. When any Significant Financial Interest is identified after CHOC Children's initial report under an award, **within sixty (60)** days of that identification, the interest will be managed, reduced or eliminated and if applicable an updated disclosure will be made to the PHS awarding component.

**M. Public Accessibility**

1. CHOC Children's will ensure that this policy is made available via a publicly accessible website in accordance with PHS regulation.
2. CHOC Children's will make required information concerning identified FCOIs available to a requestor within five (5) calendar days of a written request.

**N. Education and Training**

The Office of Research Compliance is responsible for the administration, tracking, documentation and enforcement of the training requirement pursuant to this policy.

1. All Investigators involved in Research at CHOC Children's must complete CHOC Children's conflict of interest training prior to engaging in research and at least every four (4) years thereafter. CHOC Children's conflict of interest training will be provided every three (3) years to ensure that training is completed by the fourth year. If training is not completed by the fourth year, the Investigator will be subject to sanctions as described in this policy.
2. All personnel involved in research will be required to complete additional training if the policy changes in a manner that affects reporting requirements.
3. If the Institution finds an individual to be noncompliant with Institution's FCOI policy or management plan he or she will be required to complete additional training.

**O. Auditing and Oversight**

ORC shall take such actions that it deems reasonable to audit and/or monitor compliance with Management Plans, including obtaining regular reports from individuals and committees charged with oversight responsibilities in connection with Management Plans.

**V. CROSS REFERENCES:**

Compliance Policy 509: Conflict of Interest

**VI. EVIDENCE BASED REFERENCES:**

- A. NSF Investigator Financial Disclosure Policy
- B. 42 C.F.R. Part 50, Subpart F: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought
- C. 45 C.F.R. Part 94: Responsible Prospective Contractors