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<b>Section: Research</b>	<b>Title: CONFLICT OF INTEREST IN PUBLIC HEALTH SERVICES (PHS) FUNDED RESEARCH</b>

**Financial conflict of interest (FCOI)** - means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

**Financial interest** - means anything of monetary value, whether or not the value is readily ascertainable.

**Investigator** - means the Project Director or Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research, which may include, for example, collaborators or consultants.

**Institutional Responsibilities** - means an Investigator's professional responsibilities on behalf of the Institution and may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**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.

**PHS-funded research** – means research that receives funding from any of the agencies designated as components of the U.S. Public Health Service (PHS) which may include: (1) the Agency for Healthcare Research and Quality (AHRQ), (2) the Agency for Toxic Substances and Disease Registry (ATSDR), (3) the Centers for Disease Control and Prevention (CDC), (4) the Food and Drug Administration (FDA), (5) the Health Resources and Services Administration (HRSA), (6) the Indian Health Service (IHS), (7) the National Institutes of Health (NIH), and (8) the Substance Abuse and Mental Health Services Administration (SAMHSA).

**Principal Investigator** means an investigator who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.

**Remuneration** – includes salary and any payment for services not otherwise identified as salary (*e.g.*, consulting fees, honoraria, paid authorship).

**Research** - means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (*e.g.*, a published article, book or book chapter) and product development (*e.g.*, a diagnostic test or drug).

**Senior/key personnel** - means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart. For the purpose of this policy, Senior/key personnel are included in the group termed Investigator and must meet the same requirements as Investigators.

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**Significant Financial Interest (SFI) - means:**

- (1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
  - (i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.;
  - (ii) With regard to any non-publicly traded entity, a *significant financial interest* 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 (or the Investigator's spouse or dependent children) holds any equity interest; or
  - (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
  
- (2) PHS funded investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The disclosure shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Further information may be necessary to determine whether the travel constitutes an FCOI.
  
- (3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

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### III. POLICY:

The ultimate goal of this policy is to protect the integrity and credibility of activities related to PHS funded research and to maintain public trust and confidence in CHOC Children's and its employees. All research activity undertaken at CHOC Children's shall be conducted in compliance with applicable federal regulations, which include the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR part 50 subpart F (grants) and 42 CFR part 94 (contracts). Research projects sponsored by the United States National Science Foundation (NSF) are also subject to NSF's Investigator Financial Disclosure Policy.

Persons failing to comply with this policy shall be subject to sanctions as provided herein.

### IV. PROCEDURE:

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

- 1) All PHS funded individuals meeting this policy's definition of an Investigator are required to report SFI. This policy's definition of an Investigator includes but is not limited to: Principal Investigators, Co-Investigators, Study Coordinators and other senior/key research personnel.
- 2) 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. It is the Principal Investigator's responsibility to ensure Investigators identified as having SFI submit the necessary disclosure forms.
- 3) It is the responsibility of any Investigator who is anticipating participation in PHS funded research or is already participating in PHS funded research to report any Significant Financial Interest.

#### B. When to Report a Significant Financial Interest:

- 1) Significant Financial Interests shall be reported under the following circumstances:
  - a) No later than at the time of application for PHS funded research
  - b) At least annually during the period of award
  - c) Within thirty (30) days of discovering or acquiring a new SFI
  - d) When an Investigator is added to a PHS funded project.
- 2) It is the Principal Investigator's responsibility to ensure that any newly acquired Investigators on a research project are identified and submit required SFI reports to ORC. This includes any Investigators added to a PHS funded research project through modifications to an IRB application.

#### C. How to Report a Significant Financial Interest

- 1) Investigators participating in PHS funded research shall report any research related Significant Financial Interests through submission of a completed disclosure form. The type of form to complete - whether the **Annual** Research Conflict of Interest Questionnaire, **Ad Hoc** Disclosure of Interests

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or Agency **Proposal** Disclosure, and the ways in which these disclosures are submitted are as follows:

- a) All PHS funded Investigators are required to complete and submit the **Annual** Research Conflict of Interest Questionnaire to the Office of Research Compliance (ORC) through the required electronic system.
- b) Upon discovery or acquisition, a new SFI must be reported within (30) days, to ORC, via the **Ad Hoc** Disclosure form. The Ad Hoc Disclosure form must also be completed by any new PHS funded Investigator before beginning work on a new project or beginning service on a research review board.
- c) 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 on the Agency **Proposal** Disclosure Form, attached to the Sponsored Projects Routing Form.

**D. Transmittal and Review of SFI Reports**

- 1) Disclosure forms that do not indicate any SFI will be retained in the appropriate SPA and/or ORC records as deemed necessary.
- 2) Disclosure forms that indicate SFI 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 SFI meets the definition of FCOI.
- 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, SFI disclosures revealed on the "CHOC Children's Conflict of Interest Disclosure Form" (as per policy #509), that are applicable to research, will be forwarded by the Corporate Compliance Office to ORC. ORC will compare these SFI disclosures with any previous SFI 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 SFI reports.

**E. Standards for Approval**

- 1) Proposed PHD 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

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interest are outweighed by the public interest in having the research go forward without the Management Plan.

### F. Management Plan and Notification

- 1) If the review committee concludes that a reported SFI 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 Chief Compliance Office, 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 Significant 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 Significant 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**

- 1) 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**

- 1) Upon determination of non-compliance with this policy, the Office of Research Compliance will conduct a retrospective review. CHOC will be required to 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 has taken, or will take, to eliminate or mitigate the effect of the bias.

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### K. Record Keeping

- 1) All materials related to this policy, submitted to ORC will be treated as confidential.
- 2) Records of and related to Significant Financial Interest 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 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 will ensure that this policy is made available via a publicly accessible website in accordance with regulation.
- 2) CHOC 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 PHS funded 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.

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**O. Auditing and Oversight**

- 1) 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.

**IV. CROSS REFERENCES:**

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