



EXECUTIVE POLICY

Financial Conflict of Interest – Objectivity in Research

<i>Manual:</i>	<i>Section:</i>	<i>Category:</i>	<i>Policy No:</i>	<i>Eff. Date:</i>	<i>Page No:</i>
Sponsored Awards Administration	General	Authorities	20.02	12/11/12 Revised	1 of 6

Purpose: In accordance with federal regulations at 42 CFR 50 Subpart F and 45 CFR 94, the purpose of this policy is to promote objectivity in research conducted at Children’s Hospital & Research Center at Oakland (“CHRCO”), including its department Children’s Hospital Oakland Research Institute (“CHORI”), by establishing standards and requirements that will provide a reasonable expectation that the design, conduct, and reporting of any research funded by the Public Health Services (“PHS”) and conducted at CHRCO will not be biased by Investigator Financial Conflicts of Interest (the “Policy”). This Policy is to be used in conjunction with Conflict of Interest – Objectivity in Research Procedure #20.03 (“Procedure”) and related forms.

Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR), Phase I applications are exempt from the requirements herein.

This policy is to be utilized in accordance with CHRCO Conflict of Interest Policy 3.8. It supplements that policy with regard to federal regulations pertaining to objectivity in research.

Definitions: “**Entity**” means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (or Investigator’s spouse or a dependent child) receives remuneration or in which any such person has an ownership or equity interest.

“**CHRCO Responsibilities**” means an Investigator’s professional responsibilities on behalf of CHRCO, including research activities, research consultation, teaching, professional practice, patient care and administration including service on CHRCO committees including the Institutional Review Board or Data and Safety Monitoring Boards.

“**FCOIC**” means the CHRCO Financial Conflict of Interest Committee which is vested with authority from CHRCO to review Investigator disclosures of Significant Financial Interests and that is charged with determining if a Significant Financial Interest is a Financial Conflict of Interest, and managing such Financial Conflicts of Interest when appropriate, as further described below.

“**Financial Conflict of Interest**” or “**FCOI**” means a SFI that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

“**Investigator**” means the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of PHS-funded research.

“**Significant Financial Interest**” or “**SFI**” means a financial interest consisting of one or more interests of the Investigator (and those of the Investigator’s spouse or dependent children) that reasonably appear to be related to the Investigator’s CHRCO Responsibilities, which are enumerated in General Requirements Paragraph 2 below.

General Requirements:

1. Each Investigator is required to disclose to CHRCO any Significant Financial Interest held by the Investigator and/or the Investigator’s spouse or any dependent child.
2. A Significant Financial Interest consists of one or more of the following interests that may be related to the Investigator’s CHRCO Responsibilities, including:
 - With regard to a publicly-traded Entity, a SFI exists if the value of 1) any



EXECUTIVE POLICY

Financial Conflict of Interest – Objectivity in Research

Manual:	Section:	Category:	Policy No:	Eff. Date:	Page No:
Sponsored Awards Administration	General	Authorities	20.02	12/11/12 Revised	2 of 6

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 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 (or Investigator'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, where such income exceeds \$5,000 in aggregate over the twelve months preceding the disclosure.
- Investigators must also disclose the occurrence of any reimbursed or sponsored travel (that which is paid on behalf of the Investigator and not reimbursed to the Investigator such that the exact monetary value may not be readily available) related to CHRCO Responsibilities, where such reimbursed or sponsored travel exceeds \$5,000 in aggregate from such sponsoring or reimbursing entity over the twelve months preceding the disclosure. 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. A Significant Financial Interest does not include:

- Salary, royalties, or other remuneration received from CHRCO if the Investigator is currently employed or otherwise appointed to CHRCO;
- Intellectual property rights assigned to CHRCO and agreements to share in royalties under the Intellectual Property Policy of CHRCO;
- Income from investment vehicles, such as mutual funds and retirement accounts, so long as Investigator does not directly control the investment decisions made in these vehicles;
- Any income from seminars, lectures, or teaching engagements sponsored by (i) a federal, state, or local government agency; (ii) an Institution of Higher Education; or (iii) an academic teaching hospital, medical center, or research institute that is affiliated with an Institution of Higher Education; or
- Income from services on advisory committees or review panels for (i) federal, state, or local government agency; (ii) an institution of Higher Education; or (iii) an academic teaching hospital, medical center, or research institute that is affiliated with an Institution of Higher Education.

4. CHRCO is responsible for developing, communicating, maintaining, and enforcing this



EXECUTIVE POLICY

Financial Conflict of Interest – Objectivity in Research

Manual:	Section:	Category:	Policy No:	Eff. Date:	Page No:
Sponsored Awards Administration	General	Authorities	20.02	12/11/12 Revised	3 of 6

Policy, including: (1) establishing a process by which CHRCO or its designee shall solicit, receive and review disclosure of financial interest forms, and take action in accordance with this Policy to determine if a FCOI exists and, when so, to resolve or manage the FCOI; (2) make all required FCOI reports to PHS regarding same; (3) establishing adequate enforcement mechanisms, sanctions for noncompliance with this Policy and/or relevant federal regulations; (4) providing required training to Investigators; (5) maintaining and retaining appropriate records as required; (5) establishing a process to ensure that Subrecipient Investigators are compliant with relevant federal regulations; and (6) providing public accessibility of certain information related to FCOIs, all as required by federal regulation.

Policy:

A. Disclosure, Review and Monitoring of Financial Interests

1. An Investigator must complete Disclosure of Financial Interest Related to Sponsored Projects (“DFI”) forms (see Procedure 20.03 and SAAM forms 20.101 through 20.104), which shall list all of the Investigator’s Significant Financial Interests and those of Investigator’s spouse or any dependent child.
2. An Investigator must submit completed DFI forms (i) no later than at the time of application for PHS-funded research; (ii) during the period of an award, within thirty (30) days of identifying a new SFI (e.g., completion of sponsored or reimbursed travel not earlier disclosed, which meets the threshold specified herein; or through purchase, marriage or inheritance); and (iii) not less than annually during the period of the award. CHRCO will maintain the confidentiality of all records and DFI forms to the extent practicable, except where disclosure to the public or a government agency is required.
3. The FCOIC shall review all DFI forms indicating a SFI and shall make the determination as to whether the SFI is related to PHS-funded research and, if so, whether the SFI constitutes a FCOI. In making this determination, the FCOIC may meet with the Investigator and others, as appropriate, and may request and/or examine data, reports, laboratory notebooks and other records.
 - *An Investigator’s SFI is related to PHS-funded research when the FCOIC 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 FCOIC reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.*
4. At the conclusion of its review, the FCOIC will prepare a report with findings and a final determination regarding whether the SFI is related to PHS-funded research and, if so, whether the SFI constitutes a FCOI. If the FCOIC determines that no FCOI exists, it will so state in its report. If the FCOIC determines that a FCOI exists, then the FCOIC may (i) decide to impose restrictions or conditions upon the Investigator in order to manage the FCOI (a “Management Plan”); or (ii) prohibit the Investigator from further involvement in the research under the PHS-funded grant unless the FCOI is eliminated. See Procedure #20.03 B. Reporting Requirements 3. h.
5. CHRCO shall monitor all Management Plans on an ongoing basis until the completion



EXECUTIVE POLICY

Financial Conflict of Interest – Objectivity in Research

Manual:	Section:	Category:	Policy No:	Eff. Date:	Page No:
Sponsored Awards Administration	General	Authorities	20.02	12/11/12 Revised	4 of 6

of all PHS-funded research.

6. The FCOIC shall undertake its review of SFI disclosures; and determine whether the SFI relates to PHS-funded research; if so, shall determine whether a FCOI exists, and if so, develop and implement a Management Plan:
 - Before CHRCO's expenditure of funds, for new PHS-funded projects;
 - Within sixty (60) days whenever CHRCO identifies a SFI that was not disclosed timely by an Investigator or not previously reviewed by CHRCO during the course of an ongoing PHS-funded project;
 - Within sixty (60) days whenever an Investigator who is new to an ongoing PHS-funded project discloses a SFI, or whenever an existing Investigator discloses a new SFI.
7. The Investigator shall provide complete and accurate information on a timely basis and shall comply with all requests, requirements and decisions of the FCOIC.

B. Reporting Requirements

1. CHRCO shall make all required reports to the PHS awarding agency.
2. Whenever the FCOIC determines that a FCOI exists that can be managed and implements a Management Plan, the FCOIC shall prepare a FCOI Report, in sufficient time for the Vice President, Research Operations to submit same to the PHS awarding component. A FCOI Report shall not be submitted if the FCOIC identifies a FCOI and eliminates it prior to the expenditure of PHS funds. See Procedure #20.03 Section B. Reporting Requirements.
3. When required, CHRCO shall submit a FCOI Report:
 - Before CHRCO's expenditure of funds, for new PHS-funded projects;
 - Within sixty (60) days whenever the FCOIC determines an Investigator who is new to an ongoing PHS-funded project has a FCOI, or whenever the FCOIC determines an existing Investigator 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 the Management Plan; and
 - Following a Retrospective Review as described in Section C. Enforcement Mechanisms, Remedies and Noncompliance, 3. and Procedure #20.03 C. 3. through 7.
4. If the FCOIC determines that bias has occurred within the research design, conduct, or reporting of PHS-funded research following a Retrospective Review, CHRCO will submit a Mitigation Report as required by 42 CFR 50.605. See Procedure #20.03 C. Enforcement Mechanisms, Remedies and Noncompliance, 6.
5. If the FCOIC determines that an Investigator has failed to comply with this Policy or a Management Plan as required by the FCOIC, resulting in potential bias in the design, conduct or reporting of PHS-funded research, CHRCO will notify the PHS awarding component and promptly take corrective action, as required by 42 CFR 50.605 and



EXECUTIVE POLICY

Financial Conflict of Interest – Objectivity in Research

Manual:	Section:	Category:	Policy No:	Eff. Date:	Page No:
Sponsored Awards Administration	General	Authorities	20.02	12/11/12 Revised	5 of 6

50.606.

C. Enforcement Mechanisms, Remedies and Noncompliance

1. CHRCO shall establish adequate enforcement mechanisms and recommend sanctions where appropriate. The FCOIC shall review all breaches of this Policy whether by virtue of the Investigator's refusal to respond or by his/her responding with incomplete or knowingly inaccurate information; failures to remedy conflicts; and/or failure to comply with a prescribed Management Plan.
2. Violations of this Policy and relevant federal regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with Policy 19.2 and other relevant CHRCO policies.
3. If CHRCO determines that a FCOI was not identified or managed in a timely manner (Procedure #20.03 Enforcement Mechanisms, Remedies and Noncompliance C. 3. through 7.), then within one hundred twenty (120) days of such determination, CHRCO shall complete a retrospective review of the Investigator'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 ("Retrospective Review"). See Procedure #20.03 Enforcement Mechanisms, Remedies and Noncompliance C. 4. through 7 for documentation and reporting requirements for Retrospective Reviews.
4. 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 with a FCOI that was not properly disclosed or managed, then CHRCO 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.

D. Training Requirements

1. The Sponsored Research Office shall give each Investigator a copy of this Policy: (i) at the time of employment, (ii) as requested by Investigator, and (iii) when CHRCO revises this Policy.
2. Each Investigator 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) CHRCO revises this Policy in a way that affects Investigators' obligations, (b) upon hiring, or (c) the FCOIC determines that an Investigator is not in compliance with this Policy or a Management Plan.

E. Records

1. CHRCO shall maintain all records relating to Investigator disclosures and CHRCO's review of such disclosures, and all actions taken by CHRCO and its FCOIC for at least three (3) years from the date of submission of the final expenditure report to PHS or as required by 45 CFR 74.53(b) and 92.42(b).

F. Subrecipient Requirements

1. CHRCO may carry out PHS-funded research through a subrecipient entity (e.g., subcontractors or consortium members). CHRCO shall take reasonable steps to ensure



EXECUTIVE POLICY

Financial Conflict of Interest – Objectivity in Research

<i>Manual:</i>	<i>Section:</i>	<i>Category:</i>	<i>Policy No:</i>	<i>Eff. Date:</i>	<i>Page No:</i>
Sponsored Awards Administration	General	Authorities	20.02	12/11/12 Revised	6 of 6

that any subrecipient Investigator complies with federal financial conflict of interest regulations by establishing such compliance via a written agreement. See Procedure #20.03 F. Subrecipient Requirements.

G. Public Accessibility

1. CHRCO shall make this Policy, as may be updated from time to time, publicly accessible on CHRCO's website.
2. CHRCO shall make publicly accessible certain information concerning FCOIs held by senior/key personnel, defined as the principal Investigator and any other person identified as senior/key personnel by CHRCO in the grant application, progress report, or any other report submitted to the PHS agency. Such information shall be provided within five (5) business days of a written request. See Procedure #20.03 G. Public Accessibility.