

 <input checked="checked" type="checkbox"/> <b>P O L I C Y / P R O C E D U R E</b> <input type="checkbox"/> <b>S T A N D A R D I Z E D   P R O C E D U R E</b> <input type="checkbox"/> <b>P L A N</b> <input type="checkbox"/> <b>G U I D E L I N E</b>	ORIGINAL EFFECTIVE DATE <b>August 2012</b>	CURRENT EFFECTIVE DATE <b>August 2012</b>	MANUAL: <b>CPM</b>
	TRACKING # <b>11-96</b>		
	TITLE: <b>FINANCIAL CONFLICT OF INTEREST RELATED TO PUBLIC HEALTH SERVICE SPONSORED RESEARCH</b>		
PERFORMED BY: <b>Research Administration, Staff and Affiliates conducting or proposing PHS funded research</b>			

### **1.0 PURPOSE**

As a steward of the public trust, Rady Children’s Hospital San Diego (RCHSD) is committed to the principle that its research be carried out with integrity, open inquiry, and rigorous analysis, free from outside conflicts of interest that might compromise, or give the appearance of compromising, the sound professional judgment of its investigators. This policy sets forth that position and provides a mechanism for ensuring the integrity of RCHSD research when such conflicts arise. The RCHSD Department of Research Administration and Compliance are jointly responsible for oversight and administration of the FCOI program, which includes training on FCOI, disclosure review of all reported financial interests, effective monitoring and management of FCOI matters and reporting to appropriate federal agencies as needed.

This FCOI policy facilitates compliance with federal requirements defined in 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) and facilitates promotion and enforcement of investigator compliance with applicable regulations. Federal law and policy require that for research studies funded in whole or in part by the United States Public Health Service (PHS), the institution conducting the research must gather information related to each investigator’s financial interests in the research, and financial interests that may be affected by the research itself. The United States Public Health Service (PHS) includes the following eight agencies:

1. Agency for Healthcare Research and Quality (AHRQ),
2. Agency for Toxic Substances and Disease Registry (ATSDR),
3. Centers for Disease Control and Prevention (CDC),
4. Food and Drug Administration (FDA),
5. Health Resources and Services Administration (HRSA),
6. Indian Health Service (IHS),
7. National Institutes of Health (NIH), and
8. Substance Abuse and Mental Health Services Administration (SAMHSA)

This policy applies to all grants and cooperative agreements with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are for research. These federal requirements are applicable to all proposals for extramural awards submitted to PHS.

## **2.0 DEFINITIONS**

### **Financial Conflict of Interest**

A SFI that is related to the PHS-funded research activity in which the Investigator is engaged and that could directly and significantly affect the design, conduct and/or reporting of PHS-funded research activity.

### **Financial Conflict of Interest Review Committee (FCOIRC)**

A Committee comprised of the RCHSD Research Administration Officer, the RCHSD Chief Compliance & Privacy Officer and Chair of the RCHSD Institutional Review Board. The FCOIRC reviews Investigators' SFIs related to PHS funded research and determines whether any of the SFIs constitutes a financial conflict of interest. The FCOIRC may consult with hospital leadership with specific expertise (may include but not limited to RCHSD General Counsel, Chief Scientific Officer, Chief Medical Officer, Chief Operating Officer and/or Sr. Vice President Health Affairs) when reviewing a significant conflict of interest.

### **Institutional Responsibilities**

Teaching/education, research, outreach, clinical service, and Hospital or public service on behalf of RCHSD which are in the course and scope of the Investigator's RCHSD appointment/employment.

### **Investigator**

Any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the PHS-sponsored project. This includes the Principal Investigator, Co-Investigators, Collaborators, Consultants, and any other individual who has responsibility for designing, conducting, or reporting of research funded by PHS or proposed for such funding.

### **Principal Investigator**

An Investigator who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.

### **Key Personnel**

A PHS research Project Director, Principal Investigator and any other personnel considered essential to work performance and identified as Key Personnel in the contract proposal, grant, or contract.

### **Research**

As used in this Policy, research includes any activity for which research funding is available from a PHS-awarding agency, including but not limited to research grants, cooperative agreements, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards, conference grants, and Phase II Small Business Innovative Research (SBIR) and Phase II Small Business Technology Transfer Research (STTR) awards. Excluded from this

policy, consistent with the underlying federal regulations, are Phase I Small Business Innovative Research (SBIR) and Phase I Small Business Technology Transfer Research (STTR) awards.

### **Significant Financial Interest (SFI)**

As used in this Policy, pursuant to applicable federal regulations, SFI means a financial interest consisting of one or more of the following interests of the Investigator or the Investigator's spouse or registered domestic partner<sup>1</sup> or dependent children for the following categories:

1. For any publicly-traded entity, a SFI exists if any remuneration (other than remuneration described in Paragraph 5, below) 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. Included are salary (other than salary described in Paragraph 5, below), consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value.
2. For any non-publicly-traded entity, a SFI exists if any remuneration (other than remuneration described in Paragraph 5, below) 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, registered domestic partner, or dependent children) holds any equity interest.
3. Intellectual property rights and interests, upon receipt of income, exceeding \$5,000 during the twelve months preceding disclosure from such rights and interests. However, SFIs do not include royalties received from RCHSD.
4. Travel reimbursements made to, or on behalf of, the Investigator, regardless of amount, by a for-profit or non-profit entity related to the Investigator's Institutional Responsibilities. However, SFIs do not include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.
5. The term Significant Financial Interest (SFI) does not include the following types of financial interests:
  - Salary, royalties, or other payments made by RCHSD to an RCHSD Investigator who is currently employed or otherwise appointed by the Hospital;
  - Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government, agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.
  - Income from investment vehicles, such as mutual funds and retirement funds, in which the Investigator does not directly control investment decisions.

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<sup>1</sup> Including "registered domestic partner" is consistent with California law (Family Code § 297 et seq.)

### **3.0 DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS (SFIs)**

Investigators seeking PHS research funding or receiving PHS research support are required to disclose all SFIs related to their Institutional Responsibilities. These Investigators must submit a disclosure(s) of SFIs in accordance with this Policy.

The requirement that an Investigator disclose a SFI under the terms of this Policy does not in and of itself imply the existence of an actual or potential financial conflict of interest. The existence of a financial conflict of interest, based upon the relationship of the Investigators' SFIs to the Investigators' Institutional Responsibilities, is determined by the FCOIRC with input from the Investigator. If a financial conflict of interest is identified, the FCOIRC shall recommend additional steps to manage or eliminate the conflict, to the RCHSD Chief Compliance & Privacy Officer or designee.

Investigators as defined by this policy, shall disclose all SFIs related to their Institutional Responsibilities, no later than at the time of application for PHS funding. This initial disclosure responsibility is separate from and in addition to an Investigator's ongoing duty throughout the period of a PHS research award to disclose all SFIs, and those of a spouse or registered domestic partner, or dependent children related to the Investigator's Institutional Responsibilities:

- Within thirty days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new SFI (with the exception of travel disclosures, noted below); and
- At least annually throughout the award.

Before joining an on-going PHS-funded research project new Investigators must submit a disclosure of SFIs.

Principal Investigators must identify all Investigators on an award who (that is, all individuals who will have responsibility for designing, conducting, or reporting the research to be funded by PHS) are required to disclose SFIs.

Sponsored or reimbursed travel must be disclosed either:

- a) Prospectively listing all anticipated travel (including information about the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration of the trip, as well as any other information that may be required) for the 12 month period following the filing of the Investigator's annual disclosure form; and/or
- b) Within 30 days of the occurrence of travel that either was not listed on the prospective annual travel report pursuant to paragraph a) or that significantly varied in the threshold reporting details from what was listed in the prospective report.

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from RCHSD are expected to comply with the policies and procedures for disclosure and review of a SFIs at the institution at which they are employed, or, if their institution does not have a conflict of interest policy that complies with the Department of Health and Human Services (DHHS) regulations, they must comply with RCHSD's policies and procedures for disclosure and review of any SFIs related to PHS sponsored awards. Subawards issued by RCHSD will ask the subrecipient institution to certify that its policy is in compliance with DHHS conflict of interest regulations, and unless the subrecipient does not have a DHHS-

compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a Financial Conflict of Interest is identified, for sending RCHSD notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.

Collaborators, who share responsibility for the design, conduct, and reporting of research results, and who will participate in research under an independent consulting agreement issued by RCHSD should be identified as Investigators by the Principal Investigator and should complete the RCHSD disclosure forms. If, upon review, the FCOIRC determines that these financial interests could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, consultants will be expected to adhere to the plans put in place to eliminate, reduce or manage the identified conflicts of interest.

#### **4.0 REVIEW OF DISCLOSURES; MANAGEMENT PLAN**

With each PHS proposal, progress report, incremental funding or extension, occurring on or after August 24, 2012, Investigators' SFI disclosures will be reviewed by the FCOIRC to determine whether any SFIs reasonably appear to be related to the PHS-funded research activity at issue. Investigators shall have an opportunity to provide an opinion on whether their SFIs are related to their PHS-funded research activities.

In the event that an Investigator's SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded research; or involves an entity whose financial interest could be affected by the research, the Disclosure and appropriate documentation shall be forwarded to the Research Administration Officer for consideration by the FCOIRC. When it is determined that there is a financial conflict of interest, the FCOIRC shall make a final recommendation to the RCHSD Chief Compliance & Privacy Officer about whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest before the support can be accepted.

The recommended management plan will be calibrated to correspond to the seriousness of the conflict of interest, and the likelihood that the conflict of interest could influence persons to make inappropriate, unfair or unwise decisions in their research. The plan may include, but is not limited to, one or more of the following:

- Disclosing the financial interest to participants as part of the informed consent process.
- Eliminating the conflict by referring the study to non-conflicted investigators, by the investigator's divesting or sequestering the SFI or eliminating the leadership role, or by the IRB's referring the study to another site at which investigators are not conflicted;
- Requiring that investments posing a conflict of interest in a research study be "frozen" for a designated period of time lasting beyond the termination of the study, with the investigator not allowed to sell or transfer those interests until the end of that time period, thus providing for a forced attenuation of the research and its results from the investigator's conflicting SFI;
- Disclosing the conflicting SFI or leadership role to Sponsors and/or journals and other publications;
- Providing independent monitoring of the subject recruitment and/or informed consent processes;

- Requiring independent monitoring and oversight of subject-researcher interactions, data gathering, data analysis, and/or data reporting;
- Arranging for strengthened review of all adverse events, including review of subject records on a comprehensive, periodic or sampled basis to assure that reports of adverse events have been timely and properly made; and/or
- Adopting procedures for updating information relating to the conflict, if it appears that the conflict might significantly change during a study.

The management plan shall be implemented prior to RCHSD's expenditure of PHS funds awarded for the research project, and shall specify the actions required to manage the SFI, and shall include:

- The role and principal duties of the conflicted Investigator;
- Conditions of the management plan;
- How the plan will safeguard objectivity in the research activity;
- Confirmation of the investigator's agreement to the plan; and
- How the plan will be monitored.

The same review process takes place when an Investigator reports a new SFI.

## **5.0 REPORTING TO THE PUBLIC HEALTH SERVICE (PHS)**

Prior to the Hospital's expenditure of any funds provided under a PHS award, RCHSD must provide to the PHS funding agency an initial report regarding Investigator Financial Conflicts of Interest. If Financial Conflicts of Interest are eliminated before research funds are expended, the Hospital is not required to submit a report to the PHS funding agency.

During the award, the Hospital shall, within sixty days of receipt of disclosure of a new or newly-discovered SFI, review the disclosure, determine whether it is related to PHS-funded research, determine whether it constitutes a Financial Conflict of Interest, and if so, implement a management plan and report the Financial Conflict of Interest to the PHS funding agency.

For any Financial Conflict of Interest that the Hospital reports to a PHS awarding agency, RCHSD shall provide to the PHS awarding agency an annual Financial Conflict of Interest report that addresses the status of the conflict and any changes to the management plan, for the duration of the project. The annual report shall specify whether the financial conflict is still being managed or explain why it no longer exists. RCHSD must provide annual reports to the PHS awarding agency for the duration of the project period (including extensions with or without funds).

Within sixty days of determining that a Financial Conflict of Interest exists for a new Investigator who joins an on-going PHS-funded research activity, RCHSD must implement a management plan and submit a report to the PHS funding agency.

In any case in which the Department of Health and Human Services (DHHS) determines that a PHS-sponsored project of clinical research where the purpose of the project is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by the Hospital as required by this policy and Federal regulation, the Hospital shall require the

Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

## **6.0 MONITORING**

The management plan implemented by RCHSD shall specify how the Investigator's compliance with the plan will be monitored until completion of the PHS-funded research project.

## **7.0 RETROSPECTIVE REVIEWS AND MITIGATION REPORTS**

When during an ongoing PHS-funded research project, the Hospital identifies a SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the RCHSD Chief Compliance & Privacy Officer will, within sixty (60) days, review the SFI to determine whether it is related to PHS-funded research activity, determine whether a Financial Conflict of Interest exists, and if so, implement a management plan on at least an interim basis.

In addition, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, regardless of whether the Investigator disclosed an SFI that was later determined to be a Financial Conflict of Interest, or RCHSD did not review or manage the Financial Conflict of Interest, or the Investigator failed to comply with a previously implemented management plan, RCHSD must within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research. This retrospective review is to determine if the ongoing PHS-funded research was biased in its design, conduct or reporting.

RCHSD will document all such retrospective reviews; such documentation will include the project number; project title; name of Investigator with the Financial Conflict of Interest; name of the entity with which the Investigator has a Financial Conflict of Interest; the reasons for the retrospective review; detailed methodology used for the retrospective review; findings; and conclusions.

- Based on the results of the retrospective review, if appropriate, the previously submitted Financial Conflict of Interest report should be updated to specify the actions that RCHSD will take to manage the identified Financial Conflict of Interest going forward.
- If bias was found during the retrospective review, RCHSD will promptly notify the PHS funding agency and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the Hospital's plans to eliminate or mitigate the effect of the bias.

## **8.0 RECORDS RETENTION**

Records of financial disclosures and the Hospital's review of, or response to, SFI disclosures, whether or not a disclosure resulted in the Hospital's determination of a Financial Conflict of Interest, and all actions under this policy or retrospective review shall be maintained for at least three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report. Records relating to unfunded awards need not be retained.

## **9.0 TRAINING**

Each Investigator, including collaborators, consultants or subcontractors, must complete NIH-compliant training on this policy prior to engaging in research related to any PHS-funded project. This training shall also occur at least every four years thereafter, while receiving PHS research funding, and at other times as may be required by RCHSD in accordance with DHHS regulations. PHS-funded Investigators who are new to RCHSD or who are joining on-going PHS research activity must complete training within 60 days of employment/appointment.

## **10.0 PUBLIC ACCESS TO INFORMATION**

Prior to the expenditure of any funds under a PHS funded research project, RCHSD will disclose via the RCHSD Internet website information concerning any significant financial conflict of interest disclosed to the Hospital when the following three criteria are met:

- The SFI was disclosed and is still held by the senior/key personnel as defined in the applicable regulation;
- The Hospital determines that the SFI is related to the PHS funded research; and
- The Hospital determines that the SFI is a financial conflict of interest.

## **11.0 SANCTIONS**

An investigator may be audited to validate whether the investigator truthfully and accurately disclosed financial interests and leadership roles to the FCOIRC on the Investigator Conflict of Interest Disclosure Form (and in any updates thereto), and to verify whether the investigator is complying with any action plan specified by the IRB. An investigator who does not comply with the IRB's determinations on these issues will face potential sanctions. Sanctions include: formal admonition or censure; suspension or termination of the Investigator's eligibility for grant applications and/or IRB approval; non-renewal of appointment; and/or dismissal and other remedies available pursuant to applicable laws or regulations.

## **12.0 PROCESS RESPONSIBILITIES**

Title/Function	Responsibilities
Investigators, as defined by this Policy	<ul style="list-style-type: none"><li>▪ Disclose all Significant Financial Interests (SFIs) related to the Investigator's Institutional Responsibilities, no later than at the time of application for PHS funding,</li><li>▪ Throughout the PHS research award, disclose their SFIs, and those of their spouse or registered domestic partner and dependent children.</li><li>▪ Within thirty days of discovering or acquiring any new SFI; and</li><li>▪ At least annually throughout the award.<ul style="list-style-type: none"><li>▫ Before joining an on-going PHS-funded research project, new Investigators must submit a disclosure of SFIs.</li><li>▫ Principal Investigators must fully identify all Investigators on the award who are required to disclose SFIs under the terms of this Policy.</li><li>▫ Investigators must complete NIH-compliant</li></ul></li></ul>



	<p>training on RCHSD’s PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded project and at least every four years thereafter, while receiving PHS research funding and at other times as may be required by the Hospital under this Policy.</p> <ul style="list-style-type: none"> <li>▫ In cases where the Hospital has identified a financial conflict of interest held by the Investigator, and has implemented a management plan to eliminate, reduce or manage the conflict, adhere to the terms of the management plan.</li> <li>▫ Where Department of Health and Human Services (DHHS) determines that a PHS-sponsored project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by the Hospital as required by this policy and Federal regulation, the Hospital shall require the Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.</li> </ul>
Non-RCHSD collaborators, consultants or subcontractors who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from RCHSD	<ul style="list-style-type: none"> <li>▪ Comply with the policies and procedures for disclosure and review of SFIs at the institution at which they are employed, or, if their institution does not have a conflict of interest policy that is compliant with the DHHS regulations, they must comply with this Policy for disclosure and review of SFIs related to PHS-sponsored awards.</li> <li>▪ Comply with all requirements of their institution’s (or this) Policy that pertain to Investigators, including completing NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded contract and at least every four years thereafter, while receiving PHS research funding.</li> </ul>
Institutions that receive subawards issued by RCHSD for PHS-funded research	<ul style="list-style-type: none"> <li>▪ In cases where the agreement between the Hospital and the subrecipient specifies that the subrecipient’s conflict of interest policy shall apply: <ul style="list-style-type: none"> <li>▫ Certify that the subrecipient’s conflict of interest policy complies with the requirements of the DHHS regulations,</li> <li>▫ Review financial disclosures made by Investigators at the subrecipient institution and, if any Financial Conflicts of Interest are identified, send the Hospital</li> </ul> </li> </ul>

	<p>notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements, and</p> <ul style="list-style-type: none"> <li>▪ In cases where the agreement between the Hospital and the subrecipient specifies that the Hospital's conflict of interest policy shall apply, submit to the Hospital, within the time period specified in its subrecipient agreement with the Hospital, all disclosures by subrecipient Investigators of SFIs, for the Hospital's review.</li> </ul>
RCHSD Research Administration Officer	<ul style="list-style-type: none"> <li>▪ Solicit and review Investigators' SFI disclosures for each PHS proposal, progress report, incremental funding or extension, to determine whether there are any SFIs that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged.</li> <li>▪ If an SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded research activity, the Research Administration Officer shall forward the disclosure and appropriate documentation to FCOIRC for consideration.</li> <li>▪ Upon the FCOIRC's determination of a Financial Conflict of Interest (see below), develops a Management Plan specifying actions required to manage the Financial Conflict of Interest, how the plan will safeguard objectivity in the research activity, confirms the investigator's agreement to the plan, and specifies the way in which the Investigator's compliance with the management plan shall be monitored.</li> <li>▪ Respond within five (5) business days to any request for information submitted in accordance with this policy about SFIs held by Key Personnel when the Hospital has determined that the disclosed SFIs are related to the PHS-funded research, and constitute Financial Conflicts of Interest.</li> <li>▪ Prior to the Hospital's expenditure of any funds provided under a PHS award (and within sixty days of any subsequently identified financial conflict of interest), provide to the PHS funding agency an initial report regarding Investigator Financial Conflict of Interest (including financial conflicts of interest of subrecipient investigators in cases where the agreement with the subrecipient institution specifies that they will</li> </ul>

	<p>follow the Hospital's financial conflict of interest policy.</p> <ul style="list-style-type: none"> <li>▪ During the period of the award shall, within sixty days of receipt of disclosure new or newly-discovered SFI, review the disclosure, determine whether it constitutes a Financial Conflict of Interest, and if so, report the Financial Conflict of Interest to the PHS-funding agency. If a Financial Conflict of Interest ceases to exist during the course of the award, updated information about the status of that Financial Conflict of Interest should be reported to the PHS funding agency.</li> <li>▪ Provide an annual Financial Conflict of Interest report to the PHS awarding agency addressing the status of the conflict and any changes to the management plan, for the duration of the project period (including extensions with or without funds).</li> <li>▪ Must submit a report to the PHS-funding agency within sixty days of determining that a Financial Conflict of Interest exists for a new Investigator who joins an on-going PHS-funded research activity.</li> <li>▪ If RCHSD is a subrecipient of a PHS award from another institution, for reporting to that institution any FCOIs that RCHSD identifies for RCHSD investigators.</li> </ul>
RCHSD Financial Conflict of Interest Review Committee (FCOIRC)	<ul style="list-style-type: none"> <li>▪ Determine whether, based on documentation from Research Administration Officer, there is a financial conflict of interest, and make a final recommendation to the RCHSD Chief Compliance &amp; Privacy Officer about whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest.</li> </ul>
RCHSD Grants & Contracts Coordinator	<ul style="list-style-type: none"> <li>▪ If the PHS award is to be conducted thru a subaward, incorporate as part of written agreement with subrecipient's terms that establish whether the RCHSD PHS COI policy or the policy of the subrecipient (which must be compliant with DHHS regulations) will apply to the subrecipient's investigators.</li> </ul>
The RCHSD Chief Compliance & Privacy Officer	<ul style="list-style-type: none"> <li>▪ Determine, based on recommendations of the FCOIRC, the nature and extent of conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest.</li> </ul>

#### REFERENCES:

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).