



Subject: AD CRC - Conflict of Interest in Research (COIR)				
Applies to: upon approval by the applicable governing body(ies)	<input type="checkbox"/>	John Muir Medical Center – Concord	<input type="checkbox"/>	John Muir Medical Center – Walnut Creek
	<input type="checkbox"/>	John Muir Physician Network	<input type="checkbox"/>	John Muir Health Behavioral Health Center
	<input checked="" type="checkbox"/>	John Muir Health and all entities		

I. Purpose:

John Muir Health (JMH) and its employees are committed to conducting themselves in accordance with the highest standards of integrity and ethics in compliance with all applicable regulations related to Conflict of Interest in research. **This policy implements federal requirements pertaining to “Objectivity in Research” made public by the U.S. Public Health Service (PHS) which includes the National Institutes of Health (NIH). This policy is applicable to all sponsored clinical trials regardless of source of funding including any studies in which the Investigators receive finances outside of the Clinical Trial Agreement/ budget.**

This policy is applicable to any “Investigator” (see definitions below) who participates in or plans to participate in clinical research in any JMH owned or operated facility.

Definitions:

Disclosure of Significant Financial Interests: Means an Investigator’s disclosure of significant financial interests to an Institution. The Financial Conflict of Interest in Research Disclosure Form must be completed prior to engaging in research at JMH.

Family Member: Spouse, dependent child, stepchild, parents, siblings, or domestic partner.

Financial Interest: Anything of monetary value whether or not the value is easily determined.

Financial Conflict of Interest (FCOI): Means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

Financial Conflict of Interest in Research Disclosure Form (COIR Form): Shall refer to the form for reporting potential conflicts of interest that is required to be submitted at least annually by Investigators.

FCOI Report: Means an Institution’s report of a financial conflict of interest to a PHS Awarding Component.

Institutional Review Committee (IRC): The Medical Staff Committee charged with assuring initial and continuing protection of human subjects of medical research by reviewing, evaluating, and approving or disapproving all research both prior to initiation and through periodic review in accordance with Federal Regulations.

Investigator: The Principal Investigator/project director, **sub-investigators, research nurses, clinical research associates**, and any other persons **regardless of title or position** who are responsible for the design, conduct, or reporting of research, funded – or proposed for funding – by an external sponsor. **For research funded by PHS, the term Investigator includes, but is not limited to, all key personnel identified in the grant application, progress report, or other report submitted to the PHS by JMH.**

Investigator's Institutional Responsibilities: Means an Investigator's research responsibilities on behalf of JMH as defined by the Institution and this policy of financial conflicts of interest, which may include activities such as medical directorships, all research activities, research consultation, teaching, professional practice, institutional committee memberships, and service on committees such as Institutional Review Committees.

John Muir Clinical Research Center (JMCRC): The central office within JMH charged with review of all clinical research studies to ensure all clinical research involving JMH are reviewed and that JMH's financial, reputational, and regulatory responsibilities are addressed.

Conflicts of Interest in Research Committee (COIRC): A research advisory group composed of representatives from legal, compliance, research administration, Risk Management, and the JMH Research Integrity Officer.

Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests of the Investigator or his/her Family Member:

- A. For any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value.
- B. For any non-publicly traded entity, a significant financial interest exists if the Investigator or his/her Family Member holds any equity interest (e.g., stock, stock option, or other ownership interest in the sponsor regardless of value), or if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000.
- C. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interest, regardless of the value.

- D. **Investigators must also disclose the occurrence and value of any reimbursements for or sponsored travel expense including the purpose of the trip, identity of the sponsor/organizer, destination, and the duration.**

Significant Financial Interest does not include the following:

- A. **Salary, royalties, consulting fees, or other remuneration paid by JMH to the Investigator;**
- B. **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;**
- C. **Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities; and**
- D. **Income from service on advisory committees or review panels for public or non-profit entities.**

II. Policy:

- A. **JMH follows all federal, state, and local regulations to detect, disclose, and resolve conflicts of interest. It is the policy of JMH to promote 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 financial conflict of interest.**
- B. **Applicable regulations and this policy require that Investigator or his/her Family Member disclose all SFIs:**
 - 1. **That would reasonably appear to affect or be affected by the research; and**
 - 2. **In entities whose financial interests would reasonably appear to affect or be affected by the research.**
- C. **Failure to comply with timely, accurate, and complete reporting or with appropriately addressing conflicts will result in:**
 - 1. **Loss or suspension of an individual's participation in research projects;**
 - 2. **May result in the cancelation of research projects; or**
 - 3. **Other actions as allowed by Human Resources or Medical Staff Policies and Procedures.**

III. Procedure:

A. Investigator Responsibilities

- 1. **Regardless of the source of funding, Investigators conducting research at JMH shall disclose all SFIs in accordance with this policy to the JMCRC on the COIR form provided by JMCRC and available on the JMH Intranet. Investigators will**

receive an email with a link to the online COIR form. Investigators shall certify on the COIR form that they have read the JMH COIR policy and shall conduct their research in a manner that promotes objectivity in research. The COIR form must be updated to reflect all current activities at the following times:

- a. Prior to submitting any application for a new research study to a JMH IRC or non-JMH IRB of record for review;
 - b. Updated immediately when a change in financial interest occurs;
 - c. Updated once a year at minimum during the life of any research study to allow the JMCRC and Investigator to report any subsequently identified conflicts of interest within 60 days if required by federal regulations; and
 - d. Before submitting a grant.
2. Investigators must disclose the occurrence of any reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/ organizer, destination, and duration). Disclosure will be made on the JMH Investigator Travel Disclosure Form provided by the JMCRC or available on the JMH Intranet.
 3. Investigators are required to complete conflict of interest training (through the CITI on-line program found at www.citiprogram.org) at the following times:
 - a. Prior to engaging in research;
 - b. Every four years thereafter; and
 - c. Immediately when: 1) This policy is revised in a manner that affects the requirements for Investigators; 2) an Investigator is new to JMH; or 3) upon recommendation of COIR when an Investigator is not in compliance with the policy.
 4. If a conflict exists, all Investigators will address those conflicts pursuant to section B.2. below prior to beginning or resuming research activities. Upon recommendation by the COIRC, a conflict management plan may be implemented. The JMH IRC may also require disclosure of FCOI in the IRB-approved consent form for research projects involving human subjects.

B. Institutional Responsibilities

1. Disclosure Process

- a. The JMCRC shall obtain the COIR form from each Investigator annually and updated prior to study enrollment for both industry and federally funded research projects.
- b. The Director of JMCRC, or designee, is responsible for ensuring that all Investigators complete disclosures and COIR training according to the process set forth in this policy. The Director of JMCRC, or designee, shall also review the COIR forms for completeness and all reported SFIs. When a

disclosure is made that may be perceived as a conflict, the Director of JMCRC, or designee, submits the disclosure to the COIRC for review of any potential conflict.

2. Resolution of Conflicts

- a. In situations in which an Investigator or his/her Family Member has a SFI that would reasonably appear to present a FCOI, the Director of JMCRC, or designee, shall refer the disclosure to the COIRC to make recommendations to manage, reduce, or eliminate the conflict. For research projects involving human subjects, the JMH IRC will be provided with the disclosure information and the recommendations from the COIRC.**
- b. COIRC recommendations may include, but are not limited to, the following options that the disclosed financial interest is:**
 - 1) Not acceptable (in which case the financial interest must be divested or other action taken);**
 - 2) Acceptable with some form of management plan (such as disclosure or restrictions on the activities of the Investigator, or such other form as determined appropriate); or**
 - 3) Acceptable without any need for management.**
- c. Examples of conditions or restrictions that might be considered include but are not limited to:**
 - 1) Public disclosure of the FCOI (e.g. when presenting or publishing the research);**
 - 2) Request an addendum to any previously published presentations to disclose the FCOI;**
 - 3) For research projects involving human subjects research, disclosure of FCOI directly to the participants;**
 - 4) Monitoring of the research by independent reviewers;**
 - 5) Modification of the research plan;**
 - 6) Disqualification from participating in all or a portion of the sponsored research;**
 - 7) Reduction or elimination of the SFI (e.g. sale of an equity interest);**
 - 8) Severance of the relationships between an Investigator and a research sponsor which may create financial conflicts; and**
 - 9) Any other action deemed necessary by the COIRC to manage, reduce, or eliminate the conflict of interest and potential bias.**

3. Reporting and Monitoring

- a. The JMCRC sends a COIR form to all Investigators for completion annually. The JMCRC shall report any FCOI as may be required by federal regulations. If the conflict involves PHS funding, the National Institutes of Health (NIH) will be notified by the COIRC.**

- b. Any conflict of interest disclosed after the initial report shall be subject to review pursuant to this policy. The COIRC shall complete its review and report the existence of the conflict of interest and the measures taken to reduce, manage, or eliminate it within sixty (60) days of disclosure to federal agencies if appropriate. The Director of JMCRC, or designee, will inform those sponsors that require notification of the conflict and actions taken.
- c. The Director of JMCRC, or designee, is responsible for overseeing the implementation of the disclosure, the review process, and for monitoring compliance with any conflict management plan.

4. Maintenance of Records

The JMCRC shall maintain records of all financial disclosures, applicable conflict management plans covered by this policy, and actions taken to resolve any conflicts of interests for at least three years beyond the conclusion of the study or as otherwise provided under 45 CFR 74.53(b).

5. Public Accessibility

Prior to expenditure of any research funds, JMH shall assure public accountability by maintaining the current JMH COIR policy on JMH's public website.

6. Failure to Comply

- a. Failure to comply with this policy may result in an Investigator no longer being able to conduct further research at JMH and being removed from all currently approved research studies. When an Investigator's failure to comply with this policy biases the design, conduct, or reporting of the research, the Director of JMCRC, or designee, shall promptly report the corrective action taken to the appropriate funding agency, if required.
- b. The Director of JMCRC, or designee, shall report any failures to comply with this policy or related regulations or laws to the JMH Compliance Office, Risk Management, Chief Medical Officer, and JMH general counsel or designee as appropriate.
- c. The COIRC will address all breaches of this policy including:
 - 1) Failure to comply with the disclosure requirement, whether by virtue of a refusal, late responses, or by responding with incomplete or inaccurate information;
 - 2) Failure to remedy conflicts; and
 - 3) Failure to comply with conditions in a prescribed conflict management plan.

IV. Patient/Family Education: N/A

V. Documentation: **Disclosure statement completed by each Investigator and submitted in accordance with this policy and procedure.**

VI. Relevant Hyperlinks: N/A

Reference/Regulations:							
21 CFR § 54.1-6– Financial disclosure by clinical investigators							
42 CFR § 50.601-607 (2011)(Responsibility of applicants for promoting objectivity in research for which PHS funding is sought– (conflicts of interest)							
42 CFR Part 50, Subpart F,							
45 CFR Part 94.1-6 – Public Health Service regulations for Conflict of Interest for grantee organizations							
45 CFR 74.62- Uniform administrative requirements for awards and subawards- enforcement							
State of California Form 700-U, 2 Cal. Code of Regs. § 18351 – Statement of economic interestNSF 09-01 Proposal and Award Policies and Procedure Guide							
Sponsor(s) Name & Title:			Origination Date:				
Tish Murphy- Director, JM Clinical Research Center			6/2008				
Supersedes: (with last approval date)							
Record of Review Dates							
Review Only Dates:			Revision Dates:				
6/11							
List Committee, Medical Staff, etc. Reviews: (with approval date)							
04/24/14 Research Advisory Group; 04/01/2014 Institutional Review Committee,04/09/14 Chief Compliance Officer, 04/09/14 Legal Services							
Record of Approval Dates							
PPRC:	7/16/14	Admin:	8/15/14	MEC-WC:	N/A	MEC-CC:	N/A
Operations Council:	9/12/14	Board:	10/08, 9/11, 9/14				