

<b>Title:</b> AD CRC - Conflict of Interest in Research (COIR)				
<b>Policy Level</b>	<input checked="" type="checkbox"/>	System Level – Sets expectations for all JMH employees		
	<input type="checkbox"/>	Entity Level – Sets expectations for employees in <u>multiple departments</u> within one or more entities		
	<input type="checkbox"/>	Department Level – Sets expectations for employees in <u>only one</u> department at one or more sites		
<b>Department</b>	<input type="checkbox"/>			
<b>Entity(ies)</b>	<input type="checkbox"/>	Concord Medical Center (CMC)	<input type="checkbox"/>	Walnut Creek Medical Center (WCMC)
	<input type="checkbox"/>	Physician Network (PN)	<input type="checkbox"/>	Behavioral Health Center (BHC)
<b>Document Type</b>	<input type="checkbox"/>	Policy	<input type="checkbox"/>	Procedure
	<input checked="" type="checkbox"/>	Policy and Procedure		

I. Purpose:

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.

Definitions:

**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.**

**Disclosure of Significant Financial Interests: An Investigator’s disclosure of significant financial interests to an Institution. The Financial Conflict of Interest 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 Conflict of Interest (FCOI): A significant financial Interest that could directly and significantly affect the design, conduct, or reporting of research.**

**Financial Conflict of Interest (FCOI) Report: An Institution’s report of a financial conflict of interest to a U.S. Public Health Service (PHS) awarding component.**

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.

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

Institutional Review Committee (IRC)/ Institutional Review Board (IRB): **An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, evaluating and approving or disapproving all research both prior to initiation and through periodic review in accordance with Food and Drug Administration (FDA) IRB regulations set forth at 21 Code of Federal Regulations (CFR) Part 56.**

Investigator: The Principal Investigator/project director, sub-investigators, research nurses, **study coordinators**, and any other persons regardless of title or position who are responsible for the design, conduct, or reporting of research. 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: **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 IRC/IRBs.**

John Muir Clinical Research Center (JM CRC): The designated office that oversees research activity occurring at JMH, facilitates research with affiliates, coordinates the necessary approvals (budgetary, IRC, scientific/operational, and institutional), provides necessary training to the researchers, and ensures that all clinical research projects are conducted in a manner compliant with JMH policies and procedures.

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.
- E. Significant Financial Interest does not include the following:
  - 1. Salary, royalties, consulting fees, or other remuneration paid by JMH to the Investigator;
  - 2. 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;
  - 3. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities; and
  - 4. Income from service on advisory committees or review panels for public or non-profit entities.

II. Policy:

- A. **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 COIR. This policy implements federal requirements pertaining to “Objectivity in Research” made public by the 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 above) who participates in or plans to participate in clinical research in any JMH owned or operated facility.**

- 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 JM CRC on the COIR form provided by JM CRC 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 IRC 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 JM CRC and Investigators 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 JM CRC or available on the JMH Intranet.
3. Investigators are required to complete conflict of interest training (through the **Collaborative Institute Training Initiative (CITI)** on-line program found at [www.citiprogram.org](http://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 COIRC 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. JMH IRC may also require disclosure of FCOI in the IRC-approved consent form for research projects involving human subjects.

#### B. Institutional Responsibilities

1. Disclosure Process

- a. JM CRC 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 JM CRC, 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 JM CRC, or designee, shall also review the COIR forms for completeness and all reported SFIs. **Conflicts of Interest reported to the Compliance Office will also be reviewed and reconciled with those reported to JM CRC.** When a disclosure is made that may be perceived as a conflict, the Director of JM CRC, or designee, submits the disclosure to the COIRC for review of any potential conflict.
- c. **JM CRC Director, or designee, will provide aggregate reporting of COI disclosures to the Management Compliance Committee periodically.**

## 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 JM CRC, 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, 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. JM CRC sends a COIR form to all Investigators for completion annually. JM CRC shall report any FCOI as may be required by federal regulations. If the conflict involves PHS funding, the 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 60 days of disclosure to federal agencies if appropriate. The Director of JM CRC, or designee, will inform those sponsors that require notification of the conflict and actions taken.
- c. The Director of JM CRC, 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

JM CRC 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 § 75 (2016).

### 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 JM CRC, or designee, shall promptly report the corrective action taken to the appropriate funding agency, if required.
- b. The Director of JM CRC, 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.

<b>Reference/Regulations:</b>	
21 CFR § 54.1-6– Financial disclosure by clinical investigators (2019)	
<b>21 CFR § 56 (2019) Institutional Review Boards</b>	
42 CFR § 50.601-607 (Responsibility of applicants for promoting objectivity in research)	
45 CFR Part 94.1-6 – Public Health Service regulations for Conflict of Interest for grantee organizations & remedies	
<b>45 CFR § 75 (2019) – Uniform administrative requirements, cost principles and audits</b>	
45 CFR 75.62- Uniform administrative requirements for awards and subawards- enforcement	
State of California Form 700-U, 2 Cal. Code of Regs. § 18351 – Statement of economic interest (2017)	
NSF 18-1 Proposal and Award Policies and Procedure Guide (Jan 2018)	
<b>AD - Standards of Ethics and Business Conduct Policy</b>	
<b>AD - Internal Reporting of Compliance Concerns and the Compliance Hotline Policy</b>	
<b>Supersedes:</b>	
<b>Sponsor(s) Name &amp; Title: Sally Hallas - Manager, JM Clinical Research Center</b>	
<b>Owner(s) Name &amp; Title (manager level or above): Sally Hallas - Manager, JM Clinical Research Center</b>	
<b>Record of Review Dates</b>	
<b>List Committee, Medical Staff, etc. Reviews: (with approval date)</b>	
<b>Research Advisory Committee 5/13/20; Institutional Review Committee 5/5/20</b>	
<b>Origination Date:</b>	6/08

Record of Approval Dates – System or Entity Level Documents			
<b>PPRC:</b>			
<b>JMPN:</b> N/A			
<b>MEC – BHC:</b> N/A		<b>MEC – WC:</b> N/A	
<b>MEC – CC:</b> N/A			
<b>Operations Council:</b>		<b>Senior Exec. / VP, or designee(s):</b>	
<b>Board</b> <i>(if applicable)</i>	10/08, 9/11, 10/14		
<b>Effective Dates:</b>			