John Muir Clinical Research Center
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FAQ's: JMH Conflict of Interest in Research (COIR) Policy

Federal regulations regarding financial conflict of interest disclosure have changed, and institutions receiving federal funds must comply with the new regulations. This policy has been revised to meet the requirements of this regulation.

1. **What is the purpose of the federal Financial Conflict of Interest (FCOI) regulation?**
   The purpose of the regulation is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

2. **What is the most significant difference between the previous regulation and the new revised regulation?**
   The revised regulation includes comprehensive changes focusing on these areas in particular:

   a. Definition of a Significant Financial Interest (SFI)
   b. Extent of Investigator's disclosure of information to Institutions regarding their SFI
   c. Institution's management of identified FCOI
   d. Information that needs to be reported to the Public Health Service funding component (e.g., NIH)
   e. Information that must be made accessible to the public (i.e., Institutional FCOI policy and FCOIs of senior/key personnel)
   f. Investigator training requirement

   There are new definitions of "Investigator" including a relationship to institutional responsibilities rather than related to a specific project. There is also a new requirement to report travel reimbursed by an outside non-federal entity.

3. **What is an FCOI related to research?**
   An FCOI exists when JMH, through its 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, determines that an Investigator's SFI is related to a research project and could directly and significantly affect the design, conduct, or reporting of the research.

4. **The revised regulations apply only to NIH-funded research. Why does JMH apply the policy to all research, federal and non-federal?**
   JMH believes that it is in the best interest of the organization to ask all Investigators involved in research in any capacity under our oversight to complete the disclosure. Our approach is to promote objectivity and maintain public trust with all research conducted at our facilities.

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5. **Who is covered by the policy?**
At JMH the regulation applies to each Investigator (as defined in the policy) who is planning to participate in, or is participating in, any research activities conducted in whole or in part at JMH owned or operated facilities, regardless of the source of funding (funded or not).

6. **Who is considered an "Investigator" for the COIR policy?**
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.

7. **How often do Investigators need to complete the COIR disclosure?**
COIR disclosure must be completed annually or more frequently if requested by the Conflict of Interest in Research Committee. A current COIR form must be on file prior to submitting research studies through a JMH or non-JMH IRB of record and prior to submitting a grant. If an Investigator discovers or acquires a new SFI, or when a change in financial interest occurs, it is the Investigator's responsibility to update the disclosure immediately, providing any information that was not disclosed previously.

   Investigators are required to disclose the occurrence of any reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities by an outside non-federal entity. **The COIR travel disclosure must be updated immediately when travel occurs**. A form has been developed to assist with reporting travel outside of the annual disclosure process. Investigators/ assistants should complete this form when scheduling travel. Forms should be submitted to JM Clinical Research Center (JMCRC) via fax or email. The Investigator Travel Disclosure Form is available from JM CRC or the JMH intranet.

8. **What information do I need in order to complete the disclosure forms?**
If you know you will be disclosing a SFI, you will need the following information available in order to complete this form:
   - Name of the entity
   - Type/purpose of the entity
   - Nature of your relationship with the entity
   - Specific dollar amounts of your financial interests in the entity (number of stock shares, total compensation, etc.)
   - Information about intellectual property rights or royalty fees

   If you know you will be disclosing travel reimbursement, you will need the following information available in order to complete this form:
   - Name of sponsoring organization
   - Dates of travel
   - Purpose of trip
   - Research project to which travel is related
   - Destination and duration

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9. **Who reviews the disclosures?**
   Investigator disclosures are received and reviewed initially by JMCRC Director, or assignee. As needed, the disclosure will also be reviewed by the COIRC.

10. **Are Investigators required to disclose interests in mutual funds or retirement accounts?**
    No, as long as the Investigator does not directly control the investment decisions made in these vehicles.

11. **How often do Investigators need to complete the FCOI Training?**
    Investigators must complete training prior to engaging in research and at least every four years, and immediately under designated circumstances outlined in the policy. Instructions for how to access online CITI FCOI training is available on the JMH intranet and at the end of this document.

12. **What information will be made available to the public by the new regulations?**
    The regulations require that the organization maintain its COIR Policy on a public internet site. JMH is posting the COIR policy on our JMH website under Health Education > Clinical Trials. Additionally, JMH must respond in writing within five days to any request for information concerning a SFI disclosed by our Investigators that is related to research conducted at JMH and determined by JMH to be a FCOI. The information provided will be limited to the Investigator's title and role in the research, name of the entity in which the SFI is held, nature of the SFI, dollar value (in ranges) of the SFI, or justification of why value cannot easily be determined.

13. **What happens if an Investigator fails to comply with the JMH COIR policy?**
    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, JMCRC Director, or designee, shall promptly report the corrective action taken to the appropriate funding agency, if required. The COIRC will address all breaches of this policy.

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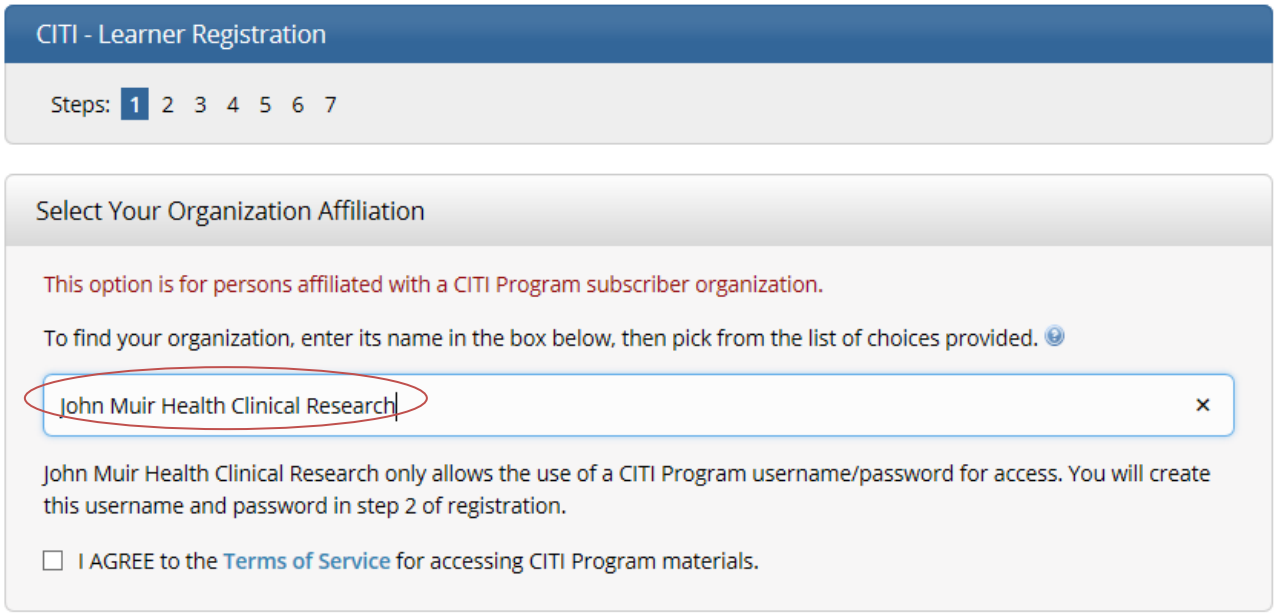
CITI Training for Researchers

Access via: https://www.citiprogram.org/

Click 'Register' in the top right corner of the main page to create a new CITI account

If you already have a CITI account, login and under the main menu, select 'click here to affiliate with another institution.' You will search for John Muir Health Clinical Research and follow steps below to add the conflict of interest course.

Search for our institution, listed as **John Muir Health Clinical Research**



You have the option of picking modules when you create your account. You are welcome to do all; however, **at this time only <u>Question 3: Conflict of Interest course</u> is required.**

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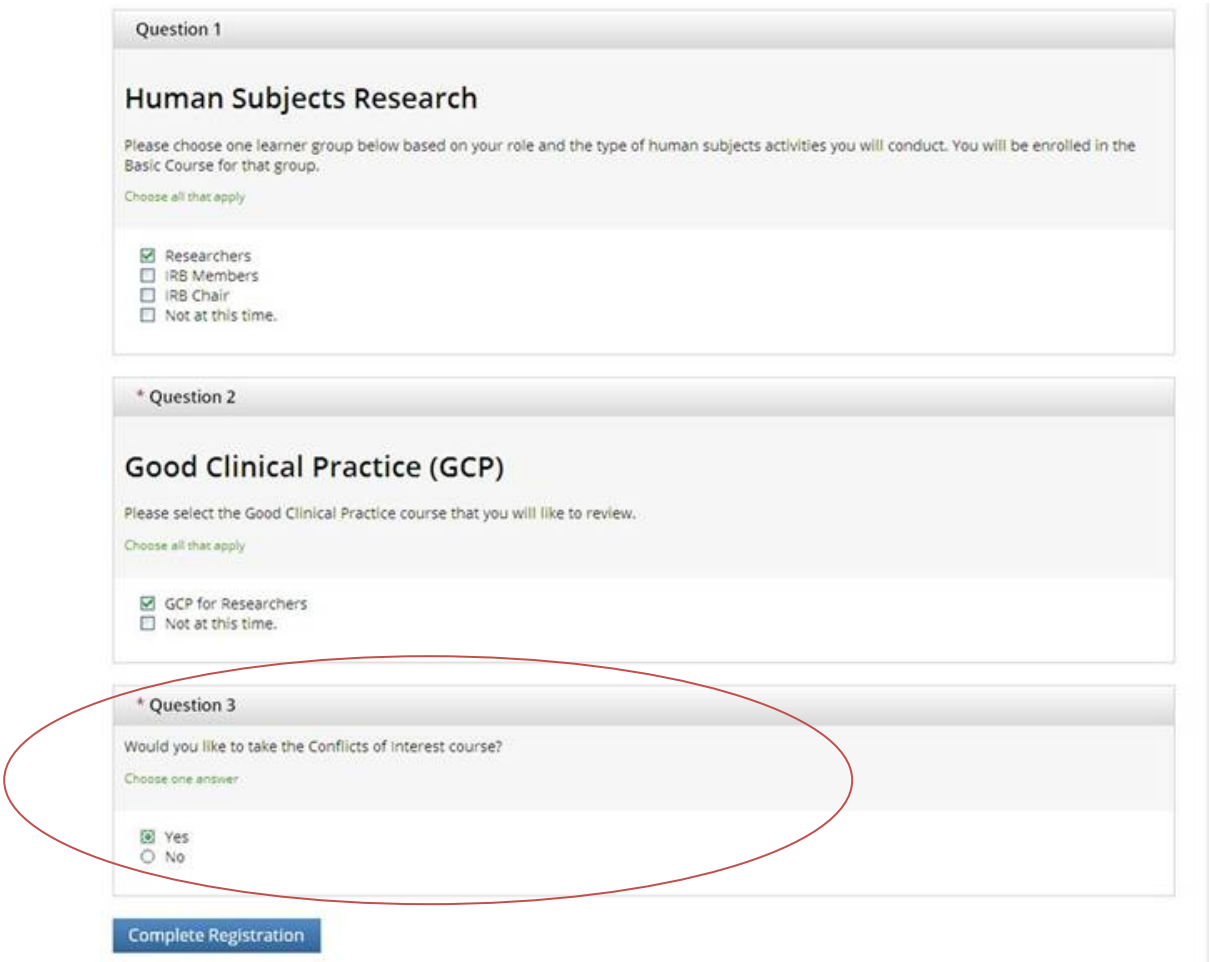

Once training is complete, you can view and print/email your report.