McLaren HEALTH CARE		**Policy Title:**	Conflict of Interest: IRB Members
Effective Date:	February 17, 2012	**Policy Number:**	MHC_RP0126
Review Date:	April 14, 2016	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	February 12, 2016	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is to describe when IRB members are considered to have conflicts of interest, the procedures that must be followed for disclosure, and IRB review of research when such conflicts exist.

2. Scope

2.1. This policy applies to all IRB members at MHC IRB and to ad hoc reviewers, who are not IRB members but sometimes are asked to review a research project because of their expertise.

3. Definitions

3.1. Refer to Appendix I *"Definitions"*

4. Policy

4.1. It is McLaren's policy to preserve public trust in the integrity and quality of research by reducing actual and perceived conflict of interest in the conduct and review of research.

4.2. Federal regulations do not permit an IRB member to participate in the review of research in which he/she has a conflicting interest, except to provide information requested by the IRB. This requirement helps to ensure that financial or other interests do not compromise the rights and welfare of human research subjects.

4.3. IRB members will disclose all financial and non-financial interests with respect to the protocols of which they are proposed to be involved in the review.

4.4. No IRB member may participate in the review (initial, continuing, or modification) of any research project in which the member has a COI, except to provide information as requested.

4.5. Each IRB member is responsible to disclose any COI related to a study submitted for review and recuse him/herself from the deliberations and vote by leaving the room.

5. Procedure

5.1. These procedures apply to both financial and non-financial conflicts of interest and are guided by Code of Federal Regulations (Title 42 of the Code of Federal Regulations (CFR) Part 50 Subpart F) that promotes objectivity in research to ensure conflict of interests do not adversely affect the protection of participants or the credibility of McLaren Healthcare Corporation Human Research Protection Program (HRPP).

5.2. IRB members may find themselves in any of the following conflicts of interest when reviewing research:

5.2.1. Where the member is involved in the design, conduct, and reporting of the research.

5.2.2. Where an immediate family member of the member is involved in the design, conduct, and reporting of the research.

5.2.3. Where the member holds significant financial interests (as defined in MHC_RP0202 Review and Management of Conflict of Interest in Research) related to the research being reviewed.

5.2.4. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

5.3. Disclosure of Conflict of Interest

5.3.1. All members of the IRB complete an **"IRB Member Human Research Conflict of Interest Disclosure Form"** when first appointed and annually thereafter. If a member responds affirmatively to the existence of a potential conflict, the Corporate Director of the HRPP is notified.

5.3.2. The IRB Chair will remind IRB members at each convened meeting that members are required to recuse themselves from the room during discussion and vote on any item(s) in which they have an interest (financial or other). IRB members with a conflicting interest are excluded from being counted towards quorum. All recusals by members with COI are recorded in the meeting minutes.

5.3.3. Should a quorum fail to be present at any time throughout the course of the meeting, the meeting will be suspended by the IRB Chair and such suspension will be reflected in the minutes.

5.3.4. IRB reviewer checklists have reminders about COI which allows members to disclose any potential COI.

5.3.5. If the COI status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair and/or Corporate Director of the HRPP.

5.4. Conflict of Interest Process

5.4.1. IRB Analysts utilize Board members' CVs and IRB Member COI Disclosure Form when making reviewer assignments to avoid assigning research review to an IRB member with an identified financial or non-financial conflict of interest. IRB Analysts will select IRB members without apparent conflicting interests as primary or secondary reviewers; however, IRB members are ultimately responsible for final identification of conflicts.

5.4.2. If an IRB member has been assigned to review a research proposal with which he/she has a conflict of interest, the IRB member should alert the IRB staff.

5.4.2.1. The IRB staff will assign the research proposal to another IRB member and/or document in the IRB minutes that the IRB member left the room during the discussion and voting on the proposal.

5.4.3. IRB reviewers will examine the materials assigned to them upon receipt to identify any financial and/or non-financial conflicts of interest.

5.4.4. If a conflict exists, the reviewer should immediately contact the appropriate IRB Analyst so that the review can be reassigned to another IRB member. IRB Analysts will document a conflict of interest as the reason for reassignment.

5.4.5. IRB members may contact the Corporate Director of the HRPP or IRB Chair for information or assistance with conflict of interest questions.

5.4.6. Consultants (ad hoc reviewers) will receive a copy of this policy with materials for the project they are reviewing and will be asked to disclose any financial or non-financial interests to the MHC IRB office.

6. Responsibilities

6.1. The Institutional Official and Corporate Director of the HRPP are responsible for articulating and enforcing the conflict of interest policy.

6.2. The IRB Chair is responsible for identifying COI disclosures at each IRB meeting.

6.3. IRB staff is responsible to ensure that IRB members and alternates are not assigned to conduct reviews of studies for which the member has a conflict and to ensure appropriate recusal during convened meeting.

6.4. IRB staff is responsible for documenting all COI disclosures and recusals in the IRB meeting minutes.

6.5. IRB members and IRB staff are required to be knowledgeable about conflict of interest issues and institutional policies pertaining to COI.

6.6. It is the responsibility of each IRB member to disclose any COI in a study submitted for review and recuse him/herself from the deliberations and/or vote by leaving the room.

7. Reference:

7.1. 45 CFR 46

7.2. 21 CFR 56

7.3. Appendix I “Definitions”

8. Previous Revisions: August 6, 2012, September 18, 2013, December 3, 2015

9. Supersedes Policy: *MHC_RP0110 Conflict of Interest: IRB Committee Members*

10. Approvals:

MHC Institutional Review Board initial review:	February 17, 2012
MHC Institutional Review Board acknowledgment:	January 7, 2012 December 18, 2015 April 14, 2016

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Date