McLaren HEALTH CARE		Policy Title:	Conflict of Interest IRB Members
Effective Date:	February 17, 2012	**Policy Number:**	MHC_RP0126
Review Date:	August 17, 2020	**Section:**	Research Integrity
Revised Date:	March 22, 2024	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity 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 members of the MHC IRB and to ad hoc reviewers, who are not IRB members but 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 or any other type of review including reviews of potential non-compliance or unanticipated problems) 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 voting 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.

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

5.3. Disclosure of Conflict of Interest

5.3.1. **IRB Member Voluntary Disclosure** - All members of the IRB will 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 Manager of Research Integrity will be notified. Members are required to update the disclosure annually and whenever there are changes in their (or their immediate family members') financial interests.

5.3.2. **Query at Convened IRB Meetings** - The IRB chair will remind IRB members at each convened meeting that members are required to recuse themselves from the room during discussion "except to provide information if requested by the IRB." and vote on any item(s) in which they have an interest (financial or other).

5.3.2.1. IRB members with conflicting interests are excluded from being counted towards quorum.

5.3.2.2. IRB staff will record recusals by members with COI in the meeting minutes with an indication that COI was the reason for recusal.

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 the 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 the Corporate Manager of Research Integrity.

5.4. Conflict of Interest Process

5.4.1. IRB Member Voluntary Disclosure. It is the responsibility of the IRB member to disclose all certain or potential conflicts of interest prior to engaging in any IRB review or determination activities.

5.4.1.1. IRB must notify IRB analyst of disclosure to avoid being expected to complete research review, whether expedited or convened, to an IRB member or 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. IRB reviewers will examine the materials assigned to them upon receipt to identify any financial and/or non-financial conflicts of interest.

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

5.4.2.2. The IRB analyst will then reassign the proposal to another IRB member and document a conflict of interest as the reason for reassignment.

5.4.3. IRB members may contact the Corporate Manager of Research Integrity or IRB chair for information or assistance with conflict-of-interest questions.

5.4.4. 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. References:

6.1. 45 CFR 46

6.2. 21 CFR 56

6.3. Appendix I “Definitions”

7. Previous Revisions: 8/6/12, 9/18/13, 12/3/15, 11/24/21, 1/16/23

8. Supersedes Policy: MHC_RP0110 Conflict of Interest: IRB Committee Members

9. Approvals:

MHC Institutional Review Board initial review: 2/17/12

MHC Institutional Review Board acknowledgment: 2/7/12, 12/18/15, 4/14/16

Signature on File *3/22/2024*

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