McLaren HEALTH CARE		Policy Title:	IRB Membership
Effective Date:	July 20, 2012	**Policy Number:**	MHC_RP0103
Review Date:	August 3, 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 ensure McLaren Health Care (MHC) maintains membership with a broad spectrum of scientific, scholarly, and ethical expertise to appropriately review medical and social behavioral human subjects research presented by MHC's subsidiary hospital physicians, employees, residents, or agents acting on behalf of MHC.

1.2. This policy provides guidance regarding board members' roles and responsibilities, training, compensation, and liability.

2. Scope

2.1. This policy applies to all members who serve on the MHC IRB.

3. Definitions

3.1. Refer to Appendix I "Definitions"

4. Policy

4.1. Each IRB member's primary duty is to review research to ensure the protection of the rights and welfare of the individual human beings who are serving as the subjects of that research.

4.2. To fulfill their duties, IRB members are expected to be versed in regulations governing human subject protection, biomedical and behavioral research ethics, and the policies of the MHC Research Integrity Department.

5. Procedure

5.1. Composition of the IRB

5.1.1. The IRB will have at least *five members* with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the MHC and its subsidiary hospitals.

5.1.2. Each IRB has at least one member who is not otherwise affiliated with the organization and who is not part of the immediate family of a person who is affiliated with the organization.

5.1.3. The IRB shall not consist entirely of men or entirely of women. Every nondiscriminatory effort will be made to ensure gender balance on the IRB,

including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB based on gender.

5.1.4. The IRB will be sufficiently qualified by the experience, expertise of its members, and the diversity of the members including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

5.1.5. The IRB shall not consist entirely of members of one profession.

5.1.6. The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

5.1.7. The IRB includes at least one member who represents the general perspective of participants.

5.1.8. One member may satisfy more than one membership category.

5.1.9. The IRB Chair and Vice-Chair are voting members of the IRB.

5.1.10. In addition to possessing the professional competence necessary to review specific research activities, The IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice.

5.1.11. If the IRB regularly reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons), consideration will be given to the inclusion of one or more individuals on the IRB, who are knowledgeable about, and experienced in, working with these subjects.

Primary and Alternate Members

5.1.12. The IRB roster identifies the primary member(s) for whom each alternate member may substitute.

5.1.12.1. Alternates are allowed to attend and contribute during meetings.

5.1.12.2. The alternate member will not be counted as a voting member unless the primary member is absent.

5.1.12.3. The IRB minutes will document when an alternate member replaces a primary member.

Reporting to OHRP

5.1.13. Changes in IRB membership will be reported to the OHRP as needed.

5.2. Appointment of IRB Members to the IRB

5.2.1. The MHC Institutional Official (IO) or designee, in consultation with the Corporate Manager of Research Integrity, appoints a Chair and Vice Chair of the IRB to serve on the MHC IRB.

5.2.2. The MHC Institutional Official (IO) along or designee with the IRB chair and Corporate Manager of Research Integrity has the authority to appoint members to the IRB.

5.2.3. Members will be solicited from MHC subsidiary hospitals to ensure representation from each subsidiary hospital participating in human subject research.

5.2.4. IRB members are selected based on diversity, including consideration of race, gender, cultural backgrounds, specific community concerns in addition to representation by multiple, diverse professions, knowledge and experience with vulnerable subjects, and inclusion of both scientific and non-scientific members.

5.2.5. A letter of appointment is sent to each member from the IO or designee welcoming them into the program.

5.2.6. Any change in appointment, including reappointment or removal, requires written notification.

5.2.7. Members may resign by written notification to the chair, Corporate Manager of Research Integrity, or the Institutional Official (IO) or designee.

5.2.8. The structure and composition of the IRB must be appropriate to the amount and nature of the research that is reviewed. Every effort is made to have member representation that has an understanding of the areas of specialty that encompasses most of the research performed at the MHC.

5.2.9. Individuals from MHC Office of Budgets and Contract or Office of Development may not serve as members of the IRB or carry out day-to-day operations of the review process.

5.2.10. Once appointed, a member of the IRB will remain on the committee until s/he withdraws his/her appointment, or the Research Integrity office decides that his/her appointment to the committee is no longer needed.

5.2.11. On an annual basis, the IRB Chair and the Corporate Manager of Research Integrity review the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements.

5.2.12. The appointment and function of alternate members is the same as that of primary IRB members and the alternate's expertise and perspective are comparable to those of the primary member.

5.2.12.1. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting or must recuse due to a conflict of interest.

5.2.12.2. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received.

5.2.13. On a regular basis, the Corporate Manager of Research Integrity reviews the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements.

5.3. Compensation of IRB Members:

5.3.1. All designated physicians, contracting employees, and community members that serve on the MHC IRB will receive a total of $2000 per year if they attend at least 80% of their scheduled IRB meetings.

5.3.1.1. IRB primary members referenced above who attend less than 80% of IRB meetings will not be compensated.

5.3.1.2. When a member joins the IRB at other times during the year and qualifies for the compensation, the funds will be pro-rated appropriately.

5.3.2. Physicians, contracting employees, and community alternate members who are asked to attend in lieu of the designated member will receive $200 for each meeting they are invited to attend.

5.4. IRB Members Conflict of Interest:

5.4.1. 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 supply information as requested.

5.4.2. Refer to Research Integrity policy MHC_RP0126_Conflict of Interest: IRB Members.

5.5. Liability Coverage for IRB Members

5.5.1. The institution's insurance coverage applies to employees and any other person authorized to act on behalf of the institution or acts or omissions within the scope of their employment or authorized activity.

5.6. Review of IRB Member Performance

5.6.1. The performance of IRB chair will be reviewed on an annual basis by the Corporate Manager of Research Integrity in consultation with the institutional official or designee.

5.6.1.1. Feedback from this evaluation will be provided to the chair.

5.6.1.2. If the chair is not acting following the IRB's mission, following these policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the chair, he/she may be removed.

5.6.2. The performance of IRB members will be reviewed by the Corporate Manager of Research Integrity annually. IRB members will receive formal feedback on the results of this review.

5.6.3. Members who are not acting in accordance with the IRB's mission or policies and procedures or who have an undue number of absences may be removed.

5.7. Review of HRPP/IRB Staff Performance

5.7.1. HRPP and IRB staff are evaluated and provided feedback in accordance with corporate human resources procedures.

5.8. Reporting and Investigation of Allegations of Undue Influence

5.8.1. If the IRB chair, member, or staff person feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the IO, depending on the circumstances.

5.8.2. The official receiving the report will conduct a thorough investigation and corrective action will be taken to prevent added occurrences.

6. Responsibilities

6.1. Duties of IRB Members:

6.1.1. The role of the IRB member is to ensure human research activities comply with federal regulations, state and local laws, and organizational policies and procedures by:

6.1.1.1. Review IRB meeting materials at least one week before each meeting, in order to participate fully in the review of each proposed project.

6.1.1.1.1. The agenda, submission materials, protocols, proposed informed consent forms and other appropriate documents are made available to members prior to the convened meetings at which the research is scheduled to be discussed.

6.1.1.2. Review assigned protocols using IRB electronic application system.

6.1.1.3. Provide a summary during convened meetings for all studies to which a member is assigned as the presenter.

6.1.1.4. At convened meetings, participate in the discussion of agenda items requiring full board review.

6.1.1.5. Keep current on regulations and policies.

6.1.1.6. Participate in IRB educational activities. This includes, but is not limited to, education during IRB meetings and attending some conferences.

6.1.2. IRB members will treat the research proposals, protocols, and supporting data confidentially.

6.1.3. 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.

6.2. Duties of the IRB Chair

6.2.1. The IRB chair should be a highly respected individual, from within the organization, fully capable of managing the IRB, and the matters brought before it, with fairness and impartiality.

6.2.2. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the chair.

6.2.2.1. The IRB must be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and non-professional sources.

6.2.3. The IRB chair is responsible for conducting the meetings and is a signatory for correspondence generated by the IRB.

6.2.4. The IRB chair may designate other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions (e.g., the vice chair and VP of Clinical Excellence and Research.

6.2.5. The IRB chair advises the institutional official or designee about IRB member performance and competence.

6.2.6. The IRB chair is authorized to take immediate action to suspend a study or studies if information presented affects subject safety or for any other reason where such action would be deemed appropriate.

6.2.6.1. Such action requires subsequent notice to and review by the convened IRB.

6.3. Duties of the IRB Vice Chair

6.3.1. The vice chair serves as the chair of the IRB in the absence of the chair and has the same qualifications, authority, and duties as the chair.

6.4. Attendance Requirements:

6.4.1. Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform the IRB chair, vice chair, or a staff member from the Research Integrity office.

6.4.1.1. To maintain the quorum, an alternate member may be asked to attend.

6.4.2. If an IRB member is going to be absent for an extended period of time, such as for a sabbatical, he or she must notify the IRB at least 30 days in advance so an appropriate replacement can be obtained.

6.4.2.1. The replacement can be temporary, for the period of absence, or permanent, in the event the member is not returning to the IRB.

6.4.2.2. If the member has a designated alternate, the alternate can serve during the member's absence, provided the IRB has been notified in advance.

6.4.3. If an IRB member is absent for a number of meetings without any explanation, the member will be removed from the board.

6.4.3.1. The members will be notified in writing.

7. References:

7.1. 21 CFR 56.107

7.2. 45 CFR 46.107

7.3. Research Integrity policy MHC_RP012_Conflict of Interest: IRB Members

7.4. Appendix I "Definitions"

8. Previous Revisions: 10/29/12, 3/18/13, 11/26/21, 1/12/2023

9. Supersedes Policy: MHC_RP0106_IRB Membership .

10. Approvals:

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

MHC Institutional Review Board acknowledgment: 7/20/12, 12/21/12, 11/6/15

Signature on File *3/22/2024*

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Justin Klamerus, MD, MMM Date
Executive Vice President/ Chief Clinical Officer
Institutional Official of Research