McLaren HEALTH CARE		Policy Title:	Authority and Responsibility of the IRB
Effective Date:	January 16, 2012	**Policy Number:**	MHC_RP0101
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 provide a clear understanding of the authority and responsibility of the IRB.

2. Scope

2.1. All non-exempt human subjects' research carried out at the MHC and its subsidiary hospitals or under its auspices must be reviewed and approved by the McLaren Health Care Institutional Review Board (MHC IRB) prior to the start of the research.

3. Definitions

3.1. Refer to Appendix I "Definitions"

4. Policy

4.1. Under the federal regulations, the IRBs authority includes:

4.1.1. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of the MHC.

4.1.2. To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.

4.1.2.1. Such actions may result from the review of an unanticipated problem(s) involving risks to human subjects or others.

4.1.2.2. Serious or continuing noncompliance with the federal regulations, state and local law, and institutional policies, serious or continuing noncompliance with the requirements or determinations of the IRB.

4.1.3. To observe, or have a third party observe, the consent process; and

4.1.4. To observe, or have a third party observe, the conduct of the research.

4.1.5. To obtain all research records and documents associated with an approved study and to audit the conduct of any research study it approves.

4.2. The IRBs are guided by the principles of the Belmont Report and the Common Rule when reviewing all human subjects' protocols.

4.3. Research that has been reviewed and approved by the MHC IRB may be subject to review and disapproval by officials of the institution. However, those officials may NOT approve of research if it has not been approved by the MHC IRB. Organization officials may strengthen requirements and/or conditions or add other modifications to secure organization approval or approval by another organization committee.

4.3.1. Previously approved research proposals and/or consent forms must be re-approved by the MHC IRB before initiating changes or modifications.

5. Procedure

5.1. The Board of Trustees for each McLaren Health Care (MHC) subsidiary hospital has authorized MHC IRB to review non-exempt research involving human subjects conducted by faculty, staff, and students at MHC and its subsidiary hospitals. This is reflected in the Letter of Resolution for each hospital.

5.2. The MHC IRB was established to ensure the protection of human subjects in human subject research conducted under the auspices of MHC and its subsidiary hospitals.

5.3. Results of Reviews, Actions and Decisions

5.3.1. The results of reviews and actions taken by the convened IRB that grant or may appear to grant investigators with initial or continuing approval of research involving human subjects, must be signed off by the IRB Chair, IRB Vice Chair, or designee except when the convened IRB approves research as submitted. All results and actions taken by the IRB will be reflected in the IRB minutes.

5.4. Routine Internal Correspondence

5.4.1. Any action, letters, memos or emails between the IRB, and members of the faculty or staff of MHC and its subsidiary hospitals that provide information concerning the review of research protocols by the IRB or staff which do not imply or appear to imply approval of this activity, may be signed by the Institutional Official, VP of Clinical Excellence and Research or Corporate Manager of Research Integrity.

5.5. Correspondence with External Agencies

5.5.1. Any letters, memos or emails sent to agencies of the federal government, funding agencies (whether private or public), or their agents will be signed by either the President and CEO of McLaren Health Care, Institutional Official of Human Research Protections Program, Corporate Manager of Research Integrity, or the IRB Chair.

5.6. Decisions Made by Chair

5.6.1. Any letters, memos or email sent representing the decision or opinions of the IRB Chair or his/her respective designees, as long as such correspondence does not imply review and approval of research projects, may be signed by the IRB Chair or designee.

6. Responsibility of the IRB:

6.1. Protect the safety, rights, and welfare of individuals participating in human subject research.

6.2. Monitor human subject research studies to ensure they are conducted in an ethical manner and in compliance with federal regulations, state and local law, and institutional policies and procedures.

6.3. Conduct prospective and continuing review of human subject's research, including review of the protocol, grant application (as applicable), informed consent process, procedures to identify and recruit individuals to participate, and any adverse events or unanticipated problems involving risk to subjects or others.

6.4. Notify investigators and the institution, in writing, of its decision to approve, disapprove, or require modifications to research.

6.5. Notify the investigator of the reason(s) for the disapproval of research involving human subjects.

6.6. Allow the PI to respond in writing or in person to the concerns of the IRB.

6.7. Ensure the PI and all study team members have appropriate expertise and experience to conduct research.

6.8. Evaluate the time and resources of the PI and study team committed to the conduct of research.

6.9. Perform periodic audits of the study files held by the PI to ensure adequate time, personnel, and other resources and facilities are appropriate for the conduct of the research; and

6.10. The IRB has the final authority to decide whether a Conflict of Interest (COI) and its management plan, if any, allow the research to be approved.

6.11. Prompt reporting to appropriate officials and entities (institutional, federal and state agencies, regulatory bodies, Office of Human Research Protections Program, U.S. Food and Drug Administration, sponsor agency, etc.) of any unanticipated problems involving risks to subjects or others (UPIRSO), of any serious or continuing non-compliance with federal regulations or IRB requirements, and of any suspension and termination of IRB approval.

7. References

7.1. 21 CFR 56.

7.2. 45 CFR 46.

7.3. Appendix I “Definitions”

8. Previous Revisions: March 12, 2012, 1/11/2023

9. Supersedes Policy: None

10. Approvals:

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

Signature on File *3/22/2024*

_____ _____

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