McLaren HEALTH CARE		Policy Title:	Authority and Responsibility of the IRB
Effective Date:	January 16, 2012	Policy Number:	MHC_RP0101
Review Date:	December 21, 2012	Section:	Human Research Protections Program (HRPP)
Revised Date:	December 03, 2012	Oversight Level:	Corporate
Administrative Responsibility:	Corporate Director, HRPP 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 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 HRPP;

      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 in reviewing all human subjects' protocols.

4.3. Research that has been reviewed and approved by the MHC Corporate IRB may be subject to review and disapproval by officials of the institution. However, those officials may NOT approve research if it has not been approved by the MHC Corporate 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 Corporate IRB before initiating the changes or modifications

5. Procedure

5.1. The Board of Trustees of each subsidiary hospital of McLaren Healthcare Corporation has authorized McLaren Health Care Corporate Institutional Review Board (MHC IRB) to review non-exempt research involving human subjects conducted by faculty, staff, and students at McLaren Healthcare and its subsidiary hospitals. This reflects in a Letter of Resolution for their hospital

5.2. MHC IRB was established to ensure the protection of human subjects in human subject research conducted under the auspices of the 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/or members of the faculty or staff of the MHC and its subsidiary hospitals that provides 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 or Corporate Director of the HRPP.

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 if Human Research Protections Program, Corporate Director of the HRPP or 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 subjects research;

6.2. Monitor human subjects 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 subjects 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 that 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 16, 2012

9. Supersedes Policy: None

10. Approvals:

MHC Institutional Review Board initial review: February 17, 2012

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Michael McKenna, MD
Executive Vice President/Chief Medical Officer
Institutional Official of Research

Date