McLaren HEALTH CARE		**Policy Title:**	Human Research Protections Program
Effective Date:	February 16, 2011	**Policy Number:**	MHC_RP0201
Review Date:	December 3, 2015	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	November 19, 2015	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is to provide guidance to the human subjects' research community regarding the McLaren Health Care Corporation (MHC) Human Research Protection Program (HRPP).

2. Scope

2.1. This policy applies to all individuals conducting human subject research under the auspices of McLaren Health Care Corporation and its subsidiary hospitals with the exception of Karmanos Cancer Institute/Karmanos Cancer Hospital;

2.2. The MHC HRPP pertains to all human subjects research conducted at McLaren with at least one of the following:

2.2.1. Using any property, patient population or facility of MHC or its subsidiary hospitals or clinics; and

2.2.2. By or under the direction of any employee, student, or agent of the MHC (full-time, part-time, visiting, consulting, and/or without compensation) in connection with his/her MHC assignment; or

2.2.3. By or under the direction of an IRB Authorization Agreement(s) or an Individual Investigator Agreements (IIA).

3. Definitions

3.1. Refer to Appendix I "Definitions"

4. Policy

4.1. The protection of the rights and welfare of human subjects is a partnership between McLaren's HRPP and research community, including researchers, research staff, IRB members and chairs, IRB staff, the organizational official, employees, and

students are responsible for ensuring the ethical and equitable treatment of all human subjects in research conducted under its auspices.

4.2. All human subjects research at McLaren will be conducted in accordance with the policy and regulations found in the Common Rule and 21 CFR 50 and 56.

4.2.1. MHC subsidiary hospitals follow ICH-GCP guidelines as adopted by FDA.

4.3. MHC fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for or participating in research conducted by or under the auspices of MHC and its subsidiary hospitals.

4.4. In the review and conduct of research, actions by MHC and its subsidiary hospitals will be guided by the principles (i.e. respect for persons, benefice and justice) set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects in Research (often referred to as the Belmont Report).

4.5. The actions of MHC and its subsidiary hospitals will also conform to all applicable federal, state, and local laws and regulations.

4.6. In order to fulfill this mission, MHC has established a Human Research Protections Program to:

4.6.1. Safeguard and promote the welfare of human research subjects by ensuring that their rights, safety, and well-being are protected;

4.6.2. Provide guidance and support to the research community in the conduct of research with human subjects;

4.6.3. Assist the research community in ensuring compliance with relevant regulations;

4.6.4. Provide timely and high quality education, review, and monitoring of human research projects; and

4.6.5. To facilitate excellence in human subjects research.

4.7. MHC HRPP includes mechanisms to:

4.7.1. Establish a formal process to monitor, evaluate, and continually improve the protection of human research participants.

4.7.2. Dedicate resources sufficient to do so;

4.7.3. Exercise oversight of research protection;

4.7.4. Educate investigators and research staff about their ethical responsibility to protect research participants;

4.7.5. When appropriate, intervene in research and respond directly to concerns of research participants;

4.8. McLaren's HRPP along with the research community is responsible for ensuring compliance with federal regulations, state and local laws, and institutional polices.

4.9. MHC has designated an Institutional Official (IO) who has overall responsibility for MHC HRPP.

5. Procedure

5.1. The Institutional Official and the HRPP have adopted standard operating procedures to protect the rights and welfare of human research participants.

5.1.1. These procedures serve as governing procedures for the conduct and review of all human subject research conducted under the auspices of MHC and its subsidiary hospitals.

5.2. To conduct its responsibility effectively, MHC maintains a Corporate Institutional Review Board (IRB) to review research protocols involving human subjects.

5.2.1. The MHC IRB is an autonomous administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of MHC and its subsidiary hospitals.

5.2.2. The IRB has the following authority to:

5.2.2.1. Approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of MHC and its subsidiary hospitals, regardless of location of the research activities.

5.2.2.2. 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.

5.2.2.3. Observe, or have a third party observe, the consent process, and

5.2.2.4. Observe, or have a third party observe, the conduct of research.

5.2.2.5. Determine whether an activity is Human Research.

5.2.2.6. Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.

5.3. All MHC IRB approved research studies are subject to ongoing review, which must be conducted at least annually by the IRB.

5.4. If approval by the IRB lapses, all research activities must stop.

5.5. The Investigator can petition the IRB to continue an individual participant's research intervention/interaction during a period of lapsed IRB approval if the Investigator believes there is a safety concern or ethical issue such that it is in the best interests of the individual participant to do so.

5.6. The IRB has jurisdiction over all human subjects research conducted under the auspices of MHC and its subsidiary hospitals, regardless of funding source or performance site.

5.7. Research under the auspices of the institution includes research:

5.7.1. Conducted at any subsidiary hospitals or clinical of MHC.

5.7.2. Conducted by or under the direction of any employee or agent of the institution (including residents and students) in connection with his/her institutional responsibilities.

5.7.3. Conducted by or under the direction of any employee or agent of the institution (including residents and students) using any property or facility of the institution, or

5.7.4. Involving the use of the institution's non-public information.

5.8. MHC and its subsidiary hospitals may review any research protocols and have the right to disapprove the implementation of a research protocol that has been approved by the IRB.

5.9. No one at the MHC or its subsidiary hospitals shall approve the implementation of any research protocol nor may it override the decision of the IRB concerning a research protocol that has not been approved by the IRB.

5.10. Written Policies and Procedures:

5.10.1. Standard Operating Policies and Procedures for MHC HRPP detail the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by MHC IRB.

5.10.2. The policies and procedures are reviewed regularly and revised (if applicable) by the Corporate Director of the HRPP and IO.

5.10.3. The IO will approve all revisions of the policies and procedures.

5.10.4. The Corporate Director of the HRPP will keep the Organization research community apprised of new information that may affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues on its website and through campus electronic mailing lists.

5.10.5. The HRPP policies and procedures are made available to all Investigators and research staff and are posted on MHC HRPP website (www.mclaren.org) and copies will be available upon request.

5.10.6. Changes to the policies and procedures are communicated to PIs and research staff through a quarterly Newsletters, e-mail announcements, or using the MHC HRPP website.

5.10.7. Changes to the policies and procedures are communicated to IRB members and IRB staff through IRB meetings, e-mail announcements, or using the MHC HRPP website.

6. Responsibilities:

6.1. Institutional Official (IO):

6.1.1. The IO is the signatory of the Federal-wide Assurance (FWA) for the McLaren Health Care Corporation and assumes the obligations of the Institution's FWA.

6.1.2. The IO holds ultimate responsibility for:

6.1.2.1. All areas of research compliance, including but not limited to, conflict of interest, scientific misconduct, and non-compliance in research involving human subjects;

6.1.2.2. Oversight of the Institutional Review Board (IRB);

6.1.2.3. Ensuring respect for the authority of the IRB and its decisions and must ensure that the IRB is free from inappropriate influence;

6.1.2.4. Oversight over the conduct of research conducted by all MHCC subsidiary hospital investigators;

6.1.2.5. Assuring the IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations;

6.1.2.6. Assuring that all investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations;

6.1.2.7. Oversight of the development and implementation of an educational plan for IRB members, staff, and investigators;

6.1.2.8. Support for evaluation of Conflict of Interest; and,

6.1.2.9. Support for Community Outreach.

6.2. Corporate Director, Human Research Protections Program

6.2.1. The Corporate Director of the HRPP is selected by and reports to the IO and is responsible for:

6.2.1.1. Developing, managing, and evaluating policies and procedures that ensure compliance with all state and federal regulations governing research. This includes monitoring changes in regulations and policies that relate to human research protection and overseeing all aspects of the HRPP program.

6.2.1.2. Advising the IO on key matters regarding research at MHC and its subsidiary hospitals.

6.2.1.3. Implementing the institution's HRPP policy.

6.2.1.4. Submitting, implementing, and maintaining an approved FWA through the Department of Health and Human Services Office of Human Research Protection (OHRP).

6.2.1.5. Ensuring compliance with the FWA, federal regulations, state statutes, local laws, IRB decisions, institutional policies, and ethical principles for protecting human research participants.

6.2.1.6. Ensuring that MHC IRB is listed on Institution's FWA and ensuring that MHC IRB maintains current registration with OHRP.

6.2.1.7. Managing the finances of McLaren's HRPP.

6.2.1.8. Assisting investigators in their efforts to carry out the Organization's research mission.

6.2.1.9. Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program.

6.2.1.10. Developing training requirements as required and as appropriate for investigators, subcommittee members, and research staff, and ensuring that training is completed in a timely manner.

6.2.1.11. Serving as the primary contact at MHC for the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services and other federal regulatory agencies.

6.2.1.12. Serving as the primary contact at MHC between research community and public at large on issues related to protecting human participants in research.

6.2.1.13. Overseeing the Conflict of Interest Committee.

6.2.1.14. Day-to-day responsibility for the operation of the HRPP office, including supervision of HRPP staff.

6.2.1.15. Responding to researchers and staff questions.

6.2.1.16. Working closely with the Chair of the IRB and on the development of policy and procedures, as well as organizing and documenting the review process.

6.2.1.17. In consultation with the IO, notifying federal agencies and sponsors regarding compliance issues.

6.2.1.18. Instituting corrective action plans based upon audit findings.

6.3. Institutional Review Board (IRB)

6.3.1. Protect the safety, rights, and welfare of individuals participating in human subjects research;

6.3.2. 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;

6.3.3. Conduct prospective and continuing review of human subjects research, including review of the protocol, grant application (as applicable);

6.3.4. Informed consent process, procedures to identify and recruit individuals to participate, and any adverse events or unanticipated problems involving risk to subjects or others;

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

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

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

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

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

6.3.10. 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

6.3.11. 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.

6.3.12. 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.

6.4. IRB Staff:

6.4.1. Familiarizes themselves with all policies and procedures of the HRPP and follows and/or implements them as applicable.

6.5. IRB Chair, Vice Chair, and IRB Members:

6.5.1. Familiarizes themselves with all policies and procedures of the HRPP and follows and/or implement them as applicable.

6.6. Researchers and Research Staff

6.6.1. Familiarizes themselves with all policies and procedures of the HRPP and follows and/or implement them as applicable.

6.6.2. Responsible for conducting research involving human subjects according to federal regulations, state law, and institutional policies.

7. References:

7.1. Appendix I “Definitions”

8. Previous Revisions: February 16, 2011

9. Supersedes Policy: None

10. Approvals:

December 20, 2012
December 3, 2015

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Phil Incarnati
President / CEO
McLaren Health Care Corporation

Date