McLaren HEALTH CARE		Policy Title:	Human Research Protections Program
Effective Date:	February 16, 2011	**Policy Number:**	MHC_RP0201
Review Date:	August 18, 2020	**Section:**	Research Integrity
Revised Date:	March 25, 2023	**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 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 at any location within McLaren Health Care Corporation and its subsidiary hospitals.

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

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

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

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

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

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 the McLaren HRPP and research community, including researchers, research staff, IRB members, chairs, IRB staff, the Institutional Official, employees,

and students. All involved are responsible for ensuring the ethical and equitable treatment of all human subjects in research conducted at MHC.

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

4.3. McLaren Health IRB commits to compliance with the International Conference on Harmonisation-Good Clinical Practices ("ICH-GCP") E6 to the extent ICH-GCP E6:

4.3.1. is consistent with applicable FDA and DHHS regulations

4.3.2. defined in clinical trial contract agreement with sponsors

4.3.3. required by funding agency

4.4. MHC fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for or participating in research

4.5. In the review and conduct of research, actions by MHC and its subsidiary hospitals will be guided by the principles of respect for persons, beneficence 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).

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

4.7. MHC has established a Human Research Protections Program to:

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

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

4.7.3. Assist the research community in ensuring compliance with relevant regulations.

4.7.4. Provide timely and high-quality education, review, and monitoring of human research projects

4.7.5. To facilitate excellence in human subjects' research.

4.8. MHC HRPP includes mechanisms to:

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

4.8.2. Dedicate resources sufficient to do so

4.8.3. Exercise oversight of research protection

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

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

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

5. Procedure

5.1. MHC has designated an Institutional Official (IO) who has overall responsibility for the MHC HRPP. The IO delegates operational responsibilities of the HRPP to the VP of Clinical Excellence and Research.

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

5.2.1. 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.

5.3. To conduct its responsibility effectively, MHC maintains a corporate institutional review board (IRB) to review research protocols involving human subjects.

5.3.1. 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 at MHC and its subsidiary hospitals.

5.3.2. The MHC IRB has the authority to:

5.3.2.1. Approve, require modifications to secure approval of, or disapprove all research activities overseen and conducted at MHC, regardless of location of the research activities.

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

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

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

5.3.2.5. Determine whether an activity meets the criteria of human subject research.

5.3.2.6. Evaluate financial interests of investigators and research staff and have the final authority to determine whether the financial interest and management plan, if any, allow the human research to be approved.

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

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

5.6. 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.

5.7. 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.

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

5.9. Written Policies and Procedures:

5.9.1. 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.

5.9.2. The policies and procedures are reviewed corporate level guidelines and revised as necessary by the Corporate Manager of Research Integrity and the IO or designee.

5.9.3. The IO is the signatory of the policies and procedures.

5.9.4. The Corporate Manager of Research Integrity will keep the organization's research community apprised of new information that may affect the HRPP, including laws, regulations, policies, procedures, and emerging ethical and scientific issues on its website and through electronic mailing lists.

5.9.5. All Research Integrity policies and procedures are made available to investigators and research staff and are posted on the MHC Research Integrity website (www.mclaren.org). Copies will be available upon request.

5.9.6. Changes to the policies and procedures are communicated to PIs and research staff through by not limited to: e-mail announcements and the MHC Research Integrity website.

5.9.7. Changes to the policies and procedures are communicated to IRB members and IRB staff through IRB meetings, e-mail announcements, and the MHC Research Integrity website.

5.9.8. The human research program is evaluated annually, See policy MHC_RP0202 Annual Evaluation of the HRPP

6. Responsibilities:

6.1. Institutional Official (IO):

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

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 that the IRB is free from inappropriate influence.

6.1.2.4. Overseeing the conduct of research led by all MHC investigators.

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

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

6.1.2.7. Support for evaluation of Conflict of Interest.

6.1.2.8. Support for community outreach.

6.1.3. The Corporate Manager of Research Integrity is appointed by and reports to the VP of Clinical Excellence and Research and is responsible for:

6.1.3.1. 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.

6.1.3.2. Advising the IO or designee on key matters regarding research at MHC and its subsidiary hospitals.

6.1.3.3. Implementing MHC HRPP policy.

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

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

6.1.3.6. Ensuring that MHC IRB is listed on the institution's FWA and ensuring that MHC IRB maintains current registration with OHRP.

6.1.3.7. Assisting investigators in their efforts to carry out the organization's research mission.

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

6.1.3.9. 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.

6.1.3.10. 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.

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

6.1.3.12. Overseeing the Conflict-of-Interest Committee.

6.1.3.13. Day-to-day responsibility for the operation of the Research Integrity department , including supervision of the staff.

6.1.3.14. Responding to researcher and staff questions.

6.1.3.15. Working closely with the chair of the IRB on the development of policies and procedures, as well as organizing and documenting the review process.

6.1.3.16. In consultation with the IO or designee, notifying federal agencies and sponsors regarding compliance issues.

6.1.3.17. Instituting corrective action plans based upon audit findings.

6.2. Institutional Review Board (IRB)

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

6.2.2. 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.

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

6.2.4. Review and approve informed consent process, procedures to identify and recruit individuals to participate, and any adverse events or unanticipated problems involving risk to subjects or others.

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

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

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

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

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

6.2.10. 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.

6.2.11. The IRB has the final authority to decide whether the Conflict of Interest (COI) and its management plan, if any, are adequate for the approval of the research.

6.2.12. 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), serious or continuing non-compliance with federal regulations or IRB requirements, and any suspension and termination of IRB approval.

6.3. IRB Staff:

6.3.1. Familiarize themselves with all policies and procedures of the HRPP and implement them as applicable.

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

6.4.1. Familiarize themselves with all policies and procedures of the HRPP and implement them as applicable.

6.5. Research QI, Compliance and Education Specialist:

6.5.1. Familiarize themselves with all policies and procedures of the HRPP and implement them as applicable.

6.6. Researchers and Research Staff including Students involved in the Conduct of Research

6.6.1. Familiarize themselves with all policies and procedures of the HRPP and implement them as applicable.

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

7. References:

7.1. Appendix I “Definitions”

7.2. 21 CFR §56.106 and §56.107

7.3. 45 CFR §46.107 and 45 CFR §46 Subpart E

7.4. ICH-GCP E6, R2

7.5. Belmont Report

8. Previous Revisions: 2/6/11, 12/15/21, 1/20/23

9. Supersedes Policy: None

10. Approvals:
December 20, 2012, December 3, 2015

Signature on File *4/7/2023*

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