McLaren HEALTH CARE		**Policy Title:**	Investigator Responsibilities
Effective Date:	December 21, 2012	**Policy Number:**	MHC_RP0125
Review Date:	April 14, 2016	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	February 25, 2016	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is to:

1.1.1. Establish guidelines outlining the responsibilities of the Principal Investigator (PI) and research team when conducting human subjects' research.

1.1.2. Ensure that investigators and research personnel recognize their responsibilities associated with the conduct of human subject's research.

2. Scope

2.1. This policy outlines responsibilities of the PI, research team, and program directors, in accordance with federal regulations, state and local laws, and institutional policies and procedures.

2.2. Any individual who is involved in conducting a human subject research study that is under the jurisdiction of the McLaren Human Research Protections Program (MHC HRPP).

2.3. Any individual (i.e. all investigators, research staff, employees, program directors, students) engaged in conducting human subject research.

3. Definitions

3.1. Refer to Appendix I "Definitions"

4. Policy

4.1. The PI is ultimately responsible for the conduct of human-subjects research and for protecting the rights, safety, and welfare of the subjects enrolled in the research.

4.2. The PI may delegate research responsibility. However, PI must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

4.3. The PI must ensure that all human-subjects research is conducted in an ethical manner and in accordance with all federal, state, and local laws and regulations,

institutional policies, and requirements, or determinations of the McLaren Health Care Corporate Institutional Review Board (MHC IRB).

4.3.1. Protocols that require skills beyond those held by the PI must be modified to meet the investigator's skills or have one or more additional qualified investigators as sub-investigator(s).

5. Responsibilities:

5.1. Principal Investigators

5.1.1. In order to satisfy the requirements of this policy, investigators who conduct research involving human subjects must:

5.1.1.1. Develop and conduct research that is in accordance with the ethical principles in the Belmont Report;

5.1.1.2. Develop a research plan that is scientifically sound and minimizes risk to the subjects.

5.1.2. Have sufficient resources necessary to protect human subjects, including:

5.1.2.1. Access to a population that would allow recruitment of the required number of subjects;

5.1.2.2. Sufficient time to conduct and complete the research;

5.1.2.3. Adequate numbers of qualified staff;

5.1.2.4. Adequate facilities;

5.1.2.5. A process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions;

5.1.2.6. Availability of medical or psychological resources that subjects might require as a consequence of the research.

5.1.3. Assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified to perform such under the laws of MI and the policies of MHC HRPP;

5.1.4. Assure that all key personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principals upon which they are based;

5.1.5. Protect the rights and welfare of prospective subjects;

5.1.6. Ensure that risks to subjects are minimized:

5.1.6.1. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and;

5.1.6.2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

5.1.7. When investigational drugs or devices are used, the investigator is responsible for providing a plan for their storage, security, dispensing, accounting, and disposal.

5.1.8. When the research requires an IND, the PI must not begin the research until a valid IND is in effect. This includes recruiting, obtaining consent, and screening participants for a specific study that is subject to the IND.

5.1.8.1. The IND goes into effect 30 days after the FDA receives the IND, unless the sponsor receives earlier notice from the FDA.

5.1.9. Recruit subjects in a fair and equitable manner.

5.1.10. Obtain and document informed consent as required by the IRB and ensuring that no human subject is involved in the research prior to obtaining their consent.

5.1.11. Have plans to monitor the data collected for the safety of research subjects.

5.1.12. Protect the privacy of subjects and maintain the confidentiality of data.

5.1.13. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, include additional safeguards in the study to protect the rights and welfare of these subjects.

5.1.14. Have a procedure to receive complaints or requests for additional information from subjects and respond appropriately:

5.1.14.1. Informed consent must have contact information for the subjects to obtain answers to questions about the research study, such as scientific issues, how to do any part of it, or to report an injury to voice concerns or complaints about the research;

5.1.14.2. Informed consent form must have contact information for the subjects to voice concerns or complaints about the research, to obtain answers to questions about their rights as a research participant.

5.1.14.3. Investigator must promptly notify the IRB office of any complaints received by the subject.

5.1.14.3.1. IRB Office will follow HRPP Policy *MHC_RP0123_Complaints and Non-Compliance in Human Subject Research.*

5.1.15. Ensure that pertinent laws, regulations, and institutional procedures and guidelines are observed by participating investigators and research staff;

5.1.16. Ensure that all research involving human subjects receives IRB review and approval in writing before commencement of the research;

5.1.17. Comply with all IRB decisions, conditions, and requirements;

5.1.18. Ensure that protocols receive timely continuing IRB review and approval;

5.1.19. Report unanticipated problems involving risk to subjects or others and any other reportable events to the IRB per Policy *MHC_RP0121 "Reporting Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO)";*

5.1.20. Obtain IRB review and approval in writing before changes are made to approved protocols or consent forms;

5.1.21. Seek IRB assistance when in doubt about whether proposed research requires IRB review;

5.1.22. When applicable, Investigator-Initiated studies (except for registries, expedited and exempt studies) must go through the Protocol Review Committee (PRC) before submission to the IRB.

5.2. Academic Advisors

5.2.1. Academic Advisors at each subsidiary hospital are responsible for ensuring that their residents acting as Principal Investigators (PI) are qualified by training and experience to conduct the proposed research. In addition, program directors are responsible for ensuring that the PI has sufficient resources and facilities to conduct the proposed research.

5.2.2. Program director must serve as the Academic Advisor for each protocol submitted by the resident to MHC IRB for approval.

5.2.3. Academic Advisors will accept responsibility for assuring adherence to the federal and state regulations and institutional policies governing the protection of human subjects of research, including applicable institutional credentialing requirements.

5.2.4. Academic Advisors are required to review all proposals before they are submitted to the MHC IRB for review.

5.2.5. By serving as an Academic Advisor, an individual indicates that the study is found to be scientifically sound and can reasonably be expected to answer the proposed question.

5.2.6. Academic Advisors are responsible for assuring that their residents have the resources required to conduct the research in a way that will protect the rights and welfare of participants.

5.2.6.1. Such resources include but are not necessarily limited to personnel, space, equipment, and time.

6. Training / Ongoing Education of Investigators and Research Team

6.1. Initial Education

6.1.1. Investigators and research staff must complete the online Collaborative Institutional Training Initiative (CITI) human subjects' online training program. Initial training is valid for a three-year period.

6.1.1.1. Training provided by another affiliate will be accepted by the Corporate Director of the HRPP as long as it meets the training requirement.

6.1.1.2. Corporate Director of HRPP will review training upon request to determine whether or not it meets the requirements of the HRPP Manual.

6.1.1.3. If other training is accepted, the Investigator will be required to complete CITI training at the time of the next renewal.

6.1.2. All investigators, including academic advisors are required to complete COI training through CITI prior to the start of any study activities. COI training certificate is good for four years.

6.1.3. Approval letters for new research protocols and applications for continuing review will not be issued by the MHC IRB Office if the Academic Advisor has not completed the education requirement.

6.1.4. While research protocols and applications for continuing review will be accepted and reviewed if the Principal Investigator and Academic Advisor hold a current certification of training, co-investigators and members of the research team will not be able to participate in the study until they complete the education requirement.

6.2. Continuing Education

6.2.1. To ensure that oversight of human research is ethically grounded, training is continuous for investigators and research teams throughout their involvement in human subject protection and research.

6.2.1.1. All investigators and members of their research teams must meet continuing education requirements every three (3) years after certification of Initial Education for as long as they are involved in human subject research.

6.2.1.1.1 Investigators and members of their research team will complete 6 required GCP modules and 3 additional modules of their choice.

6.2.1.2. Investigators must submit evidence of continuing education prior to the expiration of their training certification.

6.2.1.3. New research protocols and applications for continuing review will not receive final approval until principal investigators and Academic Advisors have submitted satisfactory evidence of continuing education.

6.2.1.4. There is no exception to this requirement.

6.2.2. Investigators who also serve as the IRB Chair, IRB members, or IRB Office staff will satisfy the training requirements for IRB members.

7. Investigator Concerns

7.1. Investigators who have concerns or suggestions regarding McLaren's HRPP should convey them to the Institutional Official regarding the issue, when appropriate.

7.2. The Institutional Official will research the issue, and when deemed necessary, convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted.

7.3. The Chair of the IRB or the Corporate Director of HRPP will be available to address investigators' questions, concerns, and suggestions.

8. References:

8.1. Appendix I "Definitions"

8.2. MHC_RP0121 *"Reporting Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO)"*

8.3. MHC_RP0123_"*Complaints and Non-Compliance in Human Subject Research*"

9. Previous Revisions: March 23, 2013, November 23, 2015

10. Supersedes Policy: None

11. Approvals:

MHC Institutional Review Board initial review:	December 21, 2012
MHC Institutional Review Board acknowledgement:	January 7, 2013 December 18, 2015 April 14, 2016

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Michael McKenna, MD Date
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Institutional Official of Research