McLaren HEALTH CARE		Policy Title:	Investigator Responsibilities
Effective Date:	December 21, 2012	**Policy Number:**	MHC_RP0125
Review Date:	August 17, 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. Establish guidelines outlining the responsibilities of the principal investigator (PI) and research team when conducting human subjects' research.

1.2. Ensure investigators and research personnel recognize their responsibilities associated with the conduct of human subject 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-subject 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.

4.2.1. PI must delegate to staff who are appropriately trained and qualified to perform the function.

4.2.2. PI must delegate staff prospectively (e.g., delegation of duty of log).

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).

4.4. PIs are responsible for conducting clinical trials in accordance with ICH-GCP E6 guidelines when these guidelines are applicable. (e.g., sponsor required)

5. Responsibilities:

5.1. Principal Investigators

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

5.1.1.1. Develop and conduct research in accordance with the ethical Principals in the Belmont Report.

5.1.1.2. Develop a research plan that is scientifically sound and minimizes risk to the subjects and the research design is sound enough to meet the study's objectives before agreeing to enroll participants.

5.1.1.3. Ensure the risks of the research are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

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. Any equipment necessary to conduct the research and protect the safety of participants and staff.

5.1.2.3. Sufficient time to conduct and complete the research.

5.1.2.4. Adequate numbers of qualified staff.

5.1.2.5. Adequate facilities.

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

5.1.2.7. Availability of medical or psychological resources that subjects might require because of the research.

5.1.3. Ensure that research staff are appropriately supervised and qualified including but not limited to:

5.1.3.1. Appropriate training, education, expertise, credentials and,

5.1.3.2. When relevant privileges to perform procedures assigned to them during the study

5.1.3.3. When relevant study procedures are performed by individuals who are licensed or otherwise qualified under the laws of MI and policies of Research Integrity Department (e.g., Chemotherapy Nurse).

5.1.4. Assure that all key personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles 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 by using procedures which are:

5.1.6.1. Consistent with sound research design and which do not unnecessarily expose subjects to risk and.

5.1.6.2. Already being performed on the subjects for diagnostic or treatment purposes, if appropriate.

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 said study.

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 avoiding practices that place participants at risk for coercion or undue influence.

5.1.10. Obtain and document informed consent as required by the IRB and ensure 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 the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making ability, 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, concerns, 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 or 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 Research Integrity Policy MHC_RP0129_ Concerns Questions and Complaints About Human Research Studies

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 *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 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 MHC Protocol Review Committee (PRC) before submission to the IRB.

5.1.23. Notifications

5.1.23.1. Notifying the IRB audit correspondence from or sent to Food and Drug Administration (FDA); and any sanctions or actions taken against the Investigator, the Sponsor, or the research. (Note: for FDA regulated research only)

5.1.23.2. Notifying the IRB immediately of any correspondence with regulatory authorities.

5.2. Academic or Faculty Advisors

5.2.1. The academic/faculty advisor is an active mentor to the student researcher and shares the responsibility for the ethical conduct of the research with the student.

5.2.2. The IRB holds the Faculty Advisor(s) responsible for the overall management of an approved research protocol in conjunction with the student PI. Management of the research encompasses the ethical, administrative, fiscal, and applied elements of a project. *In keeping with these responsibilities, faculty advisors are* ***required*** *to complete the same CITI training required of all PIs on human subjects' research protocols.*

5.2.3. Investigators who are undergraduate, graduate students, post-doctoral or medical residents completing a research project for their academic or medical residency program will need to identify a faculty advisor on their request for protocol approval applications.

5.2.4. Program director or faculty can serve as the academic/faculty advisor for each protocol submitted by the resident to MHC IRB for approval.

5.2.5. College and university faculty can serve as the academic/faculty advisor for each protocol submitted by the resident to MHC IRB for approval.

5.2.6. In some circumstances designated MHC individuals affiliated with their academic institution can serve as the academic/faculty advisor

5.2.7. Faculty Advisors supervising students/medical residents as a PI are required to:

5.2.7.1. Acknowledge and accept their responsibility for protecting the rights and welfare of human research participants, by electronically signing the IRB Protocol Submission and being listed as a research personnel on the protocol.

5.2.7.2. Fulfill the human subjects research training requirement (CITI Training) and understand the ethical standards and regulatory requirements governing research activities with human subjects.

5.2.7.3. Collaborate with student or medical resident during the preparation of the IRB proposal and ensure the proposed research complies with the ethical principles outlined in the Belmont Report, human subject research regulations including 45CFR46, institutional and HRPP/IRB policies, and other applicable laws and regulations.

5.2.7.4. Academic advisors are required to review all proposals before they are submitted to the MHC IRB for review.

5.2.7.5. Ensure all research activities have IRB approval and any other ancillary approvals required by the institution before human subjects are involved and implement the research activity as it was approved by the IRB.

5.2.7.6. Consult with the student PI on a regular basis to monitor research progress and ensure ongoing compliance with the approved protocol.

5.2.7.7. Ensure that the confidentiality and security of all information obtained from and about human subjects, and that the privacy of subjects is maintained, as specified in the approved protocol.

5.2.7.8. Ensure that student PIs promptly report any conflict of interest, protocol deviations, unanticipated problems involving risks to participants or others and other reportable events to the MHC IRB in a timely manner.

5.2.7.9. Ensure that a Final Report is submitted to the IRB upon completion of the research. If the student PI is unable or unwilling to do so, the responsible Faculty Advisor will be required to do so prior to when the PI graduates or otherwise leaves MHC, and

5.2.7.10. Ensure the student PI complies with the additional responsibilities listed as investigator responsibilities.

5.2.7.11. 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. The program director is responsible for ensuring that the PI has sufficient resources and facilities to conduct the proposed research.

5.2.8. 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.

5.2.9. Academic advisors are required to review all proposals before they are submitted to the MHC IRB for review.

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

5.2.11. 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.

5.2.11.1. 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) online human subject research training program. Initial training is valid for a three-year period.

6.1.1.1. Upon request, the Corporate Manager of Research Integrity will review training provided by another affiliate to determine whether it meets the requirements of the HRPP Manual.

6.1.1.1.1. Such training will only be accepted if the Director of Corporate Research Administration has determined that it meets appropriate requirements.

6.1.1.2. When training from another affiliate 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 conflict of interest (COI) training through CITI prior to the start of any study activities.

6.1.2.1. The COI training certificate is valid for three 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 education requirements.

6.1.4. 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.

6.1.4.1. Co-investigators and members of the research team will not be able to participate in the study until they complete the education requirements.

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 initial education certification long as they are involved in human subject research.

6.2.1.1.1. Investigators and members of their research team will complete a refresher course in CITI containing six required GCP modules and three 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 the MHC HRPP should convey them to the Institutional Official, 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 Manager of Research Integrity will be available to address investigators' questions, concerns, and suggestions.

8. Temporary Delegation of Duties to Another Investigator or PI Leaving McLaren Health Care or PI role

Temporary Delegation

8.1. If the PI is going to be temporarily unavailable (e.g., vacation, leave of absence, medical or family leave) the PI must delegate oversight of the study to a sub-investigator.

8.2. In the case where there is no sub investigator on the study, a qualified on-site PI must be formally appointed by VP of Clinical Excellence and Research. The new PI must be qualified and willing to assume all PI responsibilities. Notify MHC IRB of a replacement PI via a modification in IRB electronic system.

PI Leaving McLaren Health Care or No Longer Able to be PI.

8.3. When the PI can no longer provide oversight over a study (e.g., leaving the institution, no longer willing to conduct study) the PI is required to arrange timely transfer of responsibilities to a new PI. These activities should be undertaken putting the interests of subjects/patients first. These activities should be completed BEFORE you leave the MHC. Notify MHC IRB of a replacement PI via a modification in IRB electronic system.

8.3.1. If the study is with an external IRB, MHC IRB must be notified FIRST.

8.3.2. Notification of sponsor, funding agency and department head is required.

9. References:

9.1. Appendix I "Definitions"

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

9.3. MHC_RP0123 *"Complaints and Non-Compliance in Human Subject Research"*

10. Previous Revisions: 3/23/13, 11/23/15, 2/25/16, 12/12/21, 1/18/23

11. Supersedes Policy: None

12. Approvals:

MHC Institutional Review Board initial review: 12/21/12

MHC Institutional Review Board acknowledgement: 1/7/13,12/18/15, 4/14/16

Signature on File *3/22/2024*

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