McLaren HEALTH CARE		Policy Title:	Relying on an External IRB as an IRB of Record
Effective Date:	October 17. 2014	**Policy Number:**	MHC_RP0128
Review Date:	August 18, 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. The purpose of the policy is to establish guidelines for when a McLaren investigator relies on an institutional review board (IRB) other than the McLaren Health Care (MHC) IRB for review of research involving human subjects.

2. Scope

2.1. This policy applies to each study that a McLaren investigator intends to submit to an external IRB.

3. Definitions

3.1. Appendix I *"Definitions"*

4. Policy

4.1. McLaren Health Care IRB may enter into formal agreements with other institutions that are not legal entities of MHC to rely on other institutions for research review, or to share IRB review. MHC enters these types of arrangements through a Memorandum of Understanding (MOU), IRB Authorization Agreement (IAA)/Reliance Agreement, or other written contract with the institution(s) in question.

4.2. McLaren Health Care IRB does not act as the reviewing IRB for multisite studies.

4.3. McLaren may rely on an external IRB to oversee the management and review of certain for *s*tudies meeting one or more of the following criteria qualify for external IRB review:

4.3.1. Multi-site or cooperative research where all sites agree to use an external IRB.

4.3.2. Industry-funded and/or supported when using an external IRB is a requirement from the sponsor to use external IRB and for participation requirement.

4.3.3. Federally funded research.

4.3.4. . When research is subject to the NIH single IRB policy, the requirement for single IRB review applies to awardees in the United States and participating research sites in the United States that conduct the same protocol. The NIH policy does not apply to organizations outside the United States. Awardee organizations are responsible for ensuring that IRB reliance/authorization agreements are in place, and that the documentation of the agreement is maintained.

4.3.5. When prisoners are involved in research according to MHC_RP0116_Vulnerable Subjects in Research.

4.3.6. NCI- CIRB reviews and oversees all its member cooperative group sponsored pediatric and adult research.

4.3.7. Studies that do not meet the above criteria may be reviewed externally if the has been authorized to use an external IRB with the express written approval of the Vice President of Clinical Excellence and Research.

4.4. When entering such a relationship, the McLaren HRPP will evaluate whether the external IRB has equivalent human subject protections in place. The external IRB must meet all the following criteria:

4.4.1. Currently registered with OHRP/FDA.

4.4.2. In good standing with OHRP/FDA (no recent warning letters, no open investigations).

4.4.3. AAHRPP accredited.

4.4.4. Located within the U.S.

4.5. The McLaren HRPP and Institutional Official or their designee retain final authority to determine whether a research study can be submitted to an external IRB for review.

4.6. The MHC IRB will retain certain responsibilities for local oversight and review of the research in order to comply with McLaren requirements and all pertinent federal, state, and local laws, and regulations.

4.7. All investigators and research personnel must follow McLaren requirements for disclosing Conflicts of Interest (COI).

4.7.1. McLaren policies, through HRPP, apply for disclosing significant financial conflicts of interest.

4.7.2. Prior to the review decision by the external IRB the McLaren Research COI Committee will review disclosures to identify financial COI, approve the management plan (when applicable), and share it with the external IRB.

4.8. All investigators and research personnel must meet McLaren requirements for training and education.

4.9. All research activities at MHC must follow HRPP requirements pertaining to monitoring and research record retention.

4.10. A fully executed IRB Authorization Agreement (IAA) is required before McLaren may rely on an external IRB for review.

4.10.1. The IAA may be written to cover one research project; research projects on a case-by-case basis; or a program of research.

4.10.2. The IAA will outline the responsibilities of the external IRB, MHC IRB, and the researchers.

4.11. McLaren, through the MHC HRPP, requires communication and collaboration with all ancillary departments that are included or impacted by research projects.

4.11.1. When an investigator plans to conduct human subject research at MHC and its subsidiaries, communication with the impacted departments is required for the protection of human research subjects.

4.11.2. Investigators must obtain permission to allow research to be conducted in each impacted department as appropriate (e.g., project impact statements) and define in the IRB electronic system application.

4.12. If a research study has already been reviewed and approved by the MHC IRB, it may not be transferred to an external IRB without the express written approval of the Vice President of Clinical and Research and Institutional Official.

5. Procedure When MHC IRB relies on an External IRB

5.1. Establishing Agreement:

5.1.1. All investigators must submit a “Request to use an External IRB” application and all the applicable supporting documents through the McLaren IRB electronic application system before a protocol can be submitted to the external IRB.

5.1.2. The assigned IRB analyst reviewer will first determine if a reliance agreement/IAA exists between MHC IRB and the reviewing external IRB.

5.1.3. If a reliance agreement/IAA does not already exist, the Corporate Manager of Research Integrity or designee will assess whether the external IRB is qualified as an IRB of record.

5.1.3.1. An IAA/reliance agreement is initiated, either by the external IRB or McLaren HRPP.

5.1.3.2. The IAA/reliance agreement will document the responsibilities and agreement of all parties.

5.1.4. The MHC IRB requires a written agreement to be completed between organizations involved in a reliance relationship. The written agreement describes which organization (reviewing or relying) is responsible for the following:

5.1.4.1. Determining whether the relying organization applies its FWA to some or all research and ensuring the IRB review is consistent with the requirements of the relying organization's FWA.

5.1.4.2. Conducting scientific review.

5.1.4.3. Human subjects research education qualifications of investigators and research staff.

5.1.4.4. Reviewing potential non-compliance, including complaints, protocol deviations, and results of audits:

5.1.4.4.1. Identifying which organization is responsible for deciding whether each allegation of noncompliance has a basis in fact.

5.1.4.4.2. Identifying which organization's process is used to decide whether each incident of noncompliance is serious or continuing.

5.1.4.4.3. Determining which organization is responsible for reporting serious or continuing non-compliance; unanticipated problems involving risks to participants or others; and suspensions or terminations of IRB approval.

5.1.4.4.4. Managing organizational COI related to the research for investigators and research staff.

5.1.4.5. When applicable, who is responsible for meeting the additional requirements of the NIH Genomic Data Sharing Policy.

5.1.4.6. Determining whether the reliance on a single IRB is appropriate versus conducting local IRB review in accordance with NIH policy on exceptions from single IRB review.

5.1.4.7. The Revised Common Rule's Cooperative Research Provision (45 CFR 46.114) applies to all institutions located in the United States that are engaged in cooperative research conducted or supported by a Common Rule department or agency. These institutions must rely on approval by a single IRB for the portion of the research conducted in the United States.

5.2. Administrative Review

5.2.1. If it is determined that the **external IRB is qualified to serve as the IRB of record** the IRB analyst reviewer will conduct an *administrative review* to ensure that the local and regulatory requirements are met before processing granting approval to use external IRB letter to PI.

5.2.1.1. The IRB analyst reviewer will follow the steps outlined in the IRB *analyst checklist – Request to Use External IRB.*

5.2.1.2. If seeking an *exception to the criteria for external IRB review*, the researcher must provide the rationale as a written attachment at the time of the request for external IRB.

5.2.1.3. Review potential *conflict of interest.*

5.2.1.4. Ensure that all McLaren researchers and research personnel are appropriately qualified to conduct the protocol and compliant with McLaren *training requirements*.

5.2.1.5. Ensure that a completed *Project Impact Statement* is on file with the MHC IRB office for all impacted departments.

5.2.1.6. Review consent documents and protocol for *McLaren required language and standard format.*

5.2.1.7. Assign McLaren IRB HIPAA privacy officer to *review HIPAA language*.

5.2.1.8. If questions arise during the review, the assigned IRB analyst reviewer will *communicate with the PI* via IRB electronic application system.

5.2.1.9. Once MHC IRB accepts the administrative review, IRB analyst reviewer will issue an *acceptance letter to the PI*.

5.2.1.10. An *IRB fee* will be charged for each request to use an external IRB to off-set administrative costs associated with the review process and interactions with the external IRB.

5.2.1.11. The approved request to use external IRB will be added to the MHC *IRB Agenda*.

5.2.2. If it is determined that the external IRB is NOT qualified to serve as the IRB of record:

5.2.2.1. If the study is not eligible for external IRB review but qualifies for review by the MHC IRB, the electronic submission must be withdrawn and resubmitted to be reassigned for MHC IRB review.

5.2.2.2. The PI will be notified by the McLaren IRB office.

5.3. After MHC IRB initial administrative review and acceptance:

5.3.1. If the request to use an external IRB is accepted, the PI and research team are to communicate directly with the external IRB regarding the study and will submit the initial application form, along with all the supporting documents, to the external IRB for review and approval.

5.3.2. Once the project is approved by the external IRB, the McLaren PI must provide the external IRB approval letter and the IRB-approved consent form to the MHC IRB.

5.3.2.1. MHC IRB and the external IRB will collaborate to develop a mechanism to keep MHC IRB current on *all subsequent approvals* granted by the external IRB.

5.4. Changes to Research and After Approval Granted by the External IRB:

5.4.1. Once approval is granted by the external IRB, McLaren will recognize the external IRB as an IRB of record for the study(ies) for which the IAA was developed.

5.4.2. The PI and research team are to communicate directly with the IRB of record and will submit all the required applications (i.e., continuing reviews, changes/amendments, etc.) to the IRB of record for review and approval.

5.4.3. Any reportable unanticipated problems involving risks to subjects or others, or serious or continuing non-compliance that involve McLaren personnel and/or research participants, must be reported to the MHC IRB concurrently with the submission to the external IRB.

5.4.3.1. It is the PIs responsibility to ensure these reports are made available to the MHC IRB.

5.4.4. The investigator is required to submit a “Request to use an External IRB Modification” application and all the applicable supporting documents through the IRB electronic application system before a protocol can be submitted to the external IRB for modification of the following:

5.4.4.1. Change in personnel.

5.4.4.1.1. Change in PI to a new PI must occur **before** leaving PI leaves the health care system. Failure to do so will be considered non-compliance.

5.4.4.2. Change or reporting of COI of PI and research personnel.

5.4.4.3. Change in HIPAA language.

5.4.4.4. Change in research sites.

5.4.4.5. Other local context changes

5.4.4.6. Once MHC IRB accepts the administrative review, IRB analyst reviewer will issue a modification *acceptance letter to the PI*.

6. Responsibilities:

6.1. Principal Investigator (PI)

6.1.1. The investigator is required to obtain all applicable institution/compliance reviews and ancillary committee approvals (e.g., department/division, Protocol Review Committee, Protocol Review Committee, etc.) prior to starting any human subject research activities.

6.1.2. Comply with the requirements of the external IRB and directives per the IAA Including, but not limited to:

6.1.2.1. Initial and continuing review,

6.1.2.2. Record keeping, and

6.1.2.3. Reporting (e.g., data safety monitoring reports, protocol deviations, noncompliance, complaints, unanticipated problems).

6.1.3. All information required or requested by the reviewing IRB must be provided in a timely manner.

6.1.4. Comply with all McLaren requirements and policies pertaining to education/training, monitoring, record retention, COI, and consenting process including, but not limited to, initial and continuing review, record keeping, and reporting (e.g., data safety monitoring reports, protocol deviations, noncompliance, complaints, unanticipated problems). All information required or requested by the reviewing IRB must be provided in a timely manner.

6.1.5. Notify the MHC IRB office of any:

6.1.5.1. Determination of serious and/or continuing non-compliance

6.1.5.2. Determination of unanticipated problem involving risk to subjects or others.

6.1.6. Execute the research plan as described in the application and as approved by the IRB of record.

6.1.7. Promptly report any proposed changes in research to the IRB of record.

6.1.7.1. The PI must not initiate changes in research (including changes in the consent form) without prior IRB approval, except where necessary to eliminate apparent immediate hazards to the subjects.

6.1.8. Must not enroll individuals in research prior to review and approval by the external IRB and meeting all other applicable requirements and approvals for the study.

6.1.9. Assure that the MHC IRB fees are paid by the sponsor.

6.1.9.1. If the sponsor fails to pay the IRB fees within the required time frame, the PI will be responsible for the fees.

6.1.10. Provide a completed project impact statement(s) to the MHC IRB prior to initiating the study.

6.1.11. Ensuring that all investigators and research staff have appropriate qualifications and expertise to conduct the research, and are knowledgeable regarding applicable laws, regulations, policies, and other requirements.

6.1.12. Maintain appropriate resources and all required institutional credentialing of research staff.

6.1.13. Ensuring the consent form (typically the Costs, Payment and Compensation for Injury sections) is consistent with the executed clinical trial agreement, once available.

6.1.14. If medical records are to be accessed at any MHC sites:

6.1.14.1. Develop an approved HIPAA Authorization Form or obtain a Waiver of Authorization.

6.1.15. Develop plans for data security at all MHC sites (if applicable).

6.1.15.1. Physical materials – locked file cabinets, limited access, etc.

6.1.15.2. Electronic data – passwords, encryption, firewalls, access, etc.

6.1.16. Develop a plan for a secure central database (if applicable).

6.1.16.1. Secure data transmission or transportation.

6.1.16.2. Security parameters for central database.

6.1.16.3. Limited access to identifiable data.

6.1.16.4. Who will have access to data for research purposes and in what form? (e.g., anonymous).

6.1.17. Develop a communication plan with all MHC research sites (if applicable).

6.1.17.1. Develop a mechanism of reporting and responding to unanticipated problems, adverse events, and complaints from all sites.

6.1.18. Disclose any potential financial conflict of interest and comply with any conflict-of-interest management plans.

6.1.19. PI must submit any reportable unanticipated problems involving risks to subjects or others, or serious or continuing non-compliance that involve McLaren personnel and/or research participants, to the MHC IRB concurrently with the submission to the IRB of record promptly and in accordance with the reviewing IRBs timeframes.

6.1.20. Once the research is complete, the PI must notify the MHC IRB.

6.2. External IRB (Reviewing IRB):

6.2.1. Conducting review of research according to all applicable regulations and laws. Fulfill requirements stipulated in the IAA.

6.2.2. Reviewing modifications, continuing reviews, unanticipated problems involving risks to subjects or others (UPIRSO) or any serious or continuing noncompliance, and information intended for use by current or prospective study participants.

6.2.3. Communicate with the MHC sites, investigators, and/or MHC IRB, to:

6.2.3.1. Obtain information regarding reports of unanticipated problems, noncompliance, termination or suspension, and emergency use of investigational drugs or devices.

6.2.3.2. Coordinate corrective action plans as necessary.

6.2.3.3. Fulfill any other activity necessary to protect research subjects.

6.2.3.4. Work together with the MHC IRB to investigate reports of reportable unanticipated problems, noncompliance, termination or suspension, and

emergency use of investigational drugs or devices and plan responses accordingly.

6.3. MHC HRPP

6.3.1. Maintain responsibility for the local oversight to ensure compliance with McLaren requirements, and all pertinent federal, state, and local laws and regulations, including, but not limited to:

6.3.1.1. Fulfill requirements stipulated in the IAA.

6.3.2. Ensure that the protocol is conducted in accordance with federal and local regulations and policies through routine review/audit by EQuIP policy and procedures.

6.3.3. Work together with the IRB of record to investigate reports of reportable unanticipated problems, noncompliance, termination or suspension, and emergency use of investigational drugs or devices and plan responses accordingly.

6.3.3.1. All reports of UPIRSOs, non-compliance, terminations or suspension and emergency use of test article will be reviewed concurrently by the IRB chair or designee via forwarding of email notification of report directly to IRB chair or designee.

6.3.3.1.1. IRB Analyst will forward IRB chair or designee response to PI.

6.3.3.1.2. IRB Analyst will upload response from IRB Chair or designee in IRB protocol file.

6.3.3.1.3. If necessary and if requested by reviewing IRB, MHC Chair will respond to determination or CAPA made by the reviewing IRB.

6.3.3.1.4. In addition to the reviewing IRB, the MHC IRB may issue a letter directly to the PI commenting on the reviewing IRB determination or actions.

6.3.4. Providing the reviewing IRB with requested information about local requirements or local research context issues relevant to the IRB's determination, prior to IRB review.

6.3.5. Notifying the reviewing IRB when local policies that impact IRB review are updated.

6.3.6. Ensuring that officials of the relying organization may not approve the research subject to the reliance agreement if it has not been approved by the reviewing IRB.

6.3.7. Providing the contact person and providing contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB.

7. Previous Revisions: 10/17/14, 10/20/15, 8/18/20, 12/1/21, 1/18/23

8. Supersedes Policy: None

9. Approvals:

MHC Institutional Review Board initial approval: 10/17/14

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

Signature on File *3/22/2024*

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Justin Klamerus, MD, MMM Date
Executive Vice President/Chief Clinical Officer
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