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:	April 14, 2016	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	June 11, 2020	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Official		

1. Purpose

1.1. The purpose of the policy is to establish guidelines 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 may rely on an external IRB to oversee the management and review of certain protocols when it is a requirement from the sponsor to use external IRB or when prisoners are involved in research according to MHC_RP0116_Vulnerable Subjects in Research.

4.2. When entering into such a relationship, McLaren's HRPP will evaluate whether the external IRB has equivalent human subject protections in place. The external IRB must meet specific criteria:

4.2.1. The external IRB is currently registered with OHRP/FDA.

4.2.2. The external IRB is in good standing with OHRP/FDA (no recent warning letters, no open investigations).

4.2.3. The external IRB is AAHRPP accredited.

4.2.4. The external IRB is located within the U.S.

4.3. McLaren's Corporate HRPP and Institutional Official or their designee retains final authority to determine whether a research study can be submitted to an external IRB for review.

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

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

4.5.1. McLaren's policies, through HRPP, apply for disclosing significant financial conflicts of interest.

4.5.2. McLaren's Research COI Committee will review disclosures to identify financial COI and approve (when applicable) the management plan and share it with the external IRB.

4.6. All investigators and research personnel must follow McLaren's requirements for training and education.

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

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

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

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

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

4.9.1. 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.

4.9.2. Investigator must obtain permission to allow research to be conducted at each impacted department as appropriate (e.g., project impact statements).

5. Procedure

5.1. Before IRB approval:

5.1.1. Investigator is required to submit a "Request to use an External IRB" application and all the applicable supporting documents to the McLaren HRPP office before a protocol can be submitted to the external IRB.

5.1.2. Corporate Manager or designee will assess whether an external IRB is qualified as an IRB of record.

5.1.2.1. If it is determined that the external IRB is qualified to serve as the IRB of record:

5.1.2.1.1. An IAA is initiated, either by the external IRB or McLaren's HRPP.

5.1.2.1.2. The IAA will document the responsibilities and agreement of all parties.

5.1.2.1.3. A request to use external IRB will be assigned to a reviewer within the MHC IRB office.

5.1.2.1.4. The reviewer will conduct an administrative review to ensure that all of the local and regulatory requirements are met prior to submitting a study to the external IRB.

5.1.2.1.5. The reviewer will make '*reasonable'* efforts to complete their administrative review within 3 business days of notice of assignment. Turn around may be affected by:

5.1.2.1.5.1. Completeness of application received (i.e. PRC letter, complete ICF, etc.)
5.1.2.1.5.2. Responsiveness of answers to questions posed to PI or designee
5.1.2.1.5.3. Time of day application received by IRB office (i.e. application received late near end of business day may not be reviewed until next business day

5.1.2.1.6. If questions arise during the review, the assigned reviewer will communicate with the PI via e-mail.

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

5.1.2.1.8. Once MHC IRB accepts the administrative review, IRB staff will issue an acceptance letter to the PI.

5.1.2.1.9. MHC IRB office will maintain an electronic copy of the original request form with the supporting documents and the acceptance letter.

5.1.2.1.10. A request to use external IRB will be added to the MHC IRB Agenda.

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

5.1.2.2.1. The PI will be notified by the McLaren HRPP office.

5.2. After MHC IRB administrative review and acceptance:

5.2.1. 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.

5.2.2. 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.

5.2.2.1. 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.

5.3. After approval granted by the external IRB:

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

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

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

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

6. Responsibilities:

6.1. Principal Investigator (PI)

6.1.1. Comply with the external IRB's requirements and directives per the IAA.

6.1.2. Comply with all McLaren requirements and policies pertaining to education/training, monitoring, record retention, COI, and consenting process.

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

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

6.1.4.1. 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.

6.1.5. Must not enroll individuals in research prior to review and approval by the external IRB.

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

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

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

6.1.8. Ensure all investigators and research staff at all McLaren sites have required human subjects training and other training as needed.

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

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

6.1.10.1. Develop an approved HIPAA Authorization Form or obtain Waiver of Authorization.

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

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

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

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

6.1.12.1. Secure data transmission or transportation.

6.1.12.2. Security parameters for central database.

6.1.12.3. Limited access to identifiable data.

6.1.12.4. Who has access to data for research purposes and in what form. (e.g., anonymous).

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

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

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

6.1.15. 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.

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

6.2. External IRB:

6.2.1. Fulfill requirements stipulated in the IAA.

6.2.2. Communicate with the MHC sites, investigators, and/or MHC IRB, in order to:

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

6.2.2.2. Coordinate corrective action plans as necessary.

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

6.2.2.4. 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. Fulfill requirements stipulated in the IAA.

6.3.2. Conduct an administrative review of the "*Request to Use External IRB*" application.

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

6.3.3.1. Review potential conflict of interest.

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

6.3.3.3. Monitor and/or audit protocol records and consent process.

6.3.3.4. Ensure that the protocol is conducted in accordance with federal and local regulations and policies.

6.3.4. Ensure that a completed Project Impact Statement(s) is / are on file with the MHC IRB office for all impacted departments.

6.3.5. Provide a letter to the PI electronically to inform him/her of the MHC IRB acceptance.

6.3.6. 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.

7. Previous Revisions: October 17, 2014
October 20, 2015
March 8, 2016

8. Supersedes Policy: None

9. Approvals:

MHC Institutional Review Board initial approval: October 17, 2014

MHC Institutional Review Board acknowledgement: December 18, 2015
April 14, 2016

_____ _____

Michael McKenna, MD
Executive Vice President/CMO
Institutional Official

Date