McLaren HEALTH CARE		Policy Title:	QA/QI Review of IRB Files and Operations
Effective Date:	October 8, 2015	**Policy Number:**	MHC_RP0304
Review Date:	August 20, 2020	**Section:**	Research Integrity
Revised Date:	January 20, 2023	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Office, HRPP		

1. Purpose

1.1. The purpose of this policy is to establish the process for the McLaren Health Care (MHC) Education and Quality Improvement Program (EQuIP) to perform QA/QI reviews on the activities of the McLaren Health Care Institutional Review Board.

2. Scope

2.1. This policy applies to all activities performed by the McLaren Health Care Institutional Review Board.

3. Definitions

3.1. Refer to Appendix I *"Definitions"*

4. Policy

4.1. As part of the McLaren's AAHRPP Quality Improvement and Quality Assurance Program, EQuIP is authorized to conduct reviews of IRB records for process improvement and quality assurance.

4.2. McLaren's Human Research Protection Program (HRPP) is committed to a consistent, proactive effort to continually ensure the human subject research conducted at McLaren occurs in accordance with all applicable federal regulations and/or agency specific requirements, state and local laws, and institutional policies and procedures.

4.3. Reviews of IRB files will be conducted to:

4.3.1. Evaluate efficiency and effectiveness of the MHC IRB.

4.3.2. Assess IRB compliance with applicable institutional policies and procedures, federal regulations, state, and local laws.

4.3.3. Ensure the highest degree of research standards are being maintained in regards to the safety of human subject research.

4.3.4. Evaluate MHC IRB's compliance, organization, record keeping, and documentation within a selected investigator protocol.

4.3.5. Gather metrics and to ensure consistent and adequate IRB review and documentation for the following:

4.3.5.1. Meeting Minutes.

4.3.5.2. Expedited Reviews.

4.3.5.3. Data Safety Monitoring Plans.

4.3.5.4. Informed Consent.

4.3.5.5. Approval Timelines.

5. Procedures

5.1. Study Specific IRB Review

5.1.1. Once a QA/QI review or audit of a research study is scheduled with the Primary Investigator, the QI and Education Specialist will conduct a preliminary review of the MHC IRB files. The Clinical and Non-Clinical Study QA/QI Review worksheet will be utilized to capture information.

5.1.1.1. Information captured will include, but not limited to:

5.1.1.1.1. Review of IRB files to ensure retention of appropriate documentation and completeness of IRB electronic application system.

5.1.1.1.2. Verification that applicable investigator files match the IRB files (i.e., approval letters, approved documents).

5.1.2. When the study review is complete, the QI and Education Specialist will discuss all noted deficiency observations with the Corporate Manager of Research Integrity.

5.1.3. A formal report letter listing the findings and recommendations will be sent to the IRB Chair.

5.1.4. If a Corrective Actions and Preventative Actions plan (CAPA) is necessary to address deficiencies, the CAPA plan will be formulated through the HRPP management.

5.2. IRB Process QA Review

5.2.1. The Corporate Manager of Research Integrity will determine which processes will undergo QA review and the frequency of QA reviews. Types of QA review may include, but not limited to:

5.2.1.1. IRB Meeting Minutes QA Review: The minutes will be reviewed to determine the following, but not limited to:

5.2.1.1.1. Documentation of discussions regarding controverted issues.

5.2.1.1.2. Quorum was met and maintained.

5.2.1.1.3. IRB composition.

5.2.1.1.4. Conflict of interest policy followed.

5.2.1.1.5. Assessment of privacy provisions according to HIPAA.

5.2.1.1.6. Documentation surrounding the discussion for protections of vulnerable populations.

5.2.1.1.7. Documentation that studies met regulatory criteria for approval.

5.2.1.1.8. Documentation of evaluation of continuing review discussion.

5.2.1.2. Expedited QA Review: The protocol will be reviewed to ensure criteria for expedited review was met.

5.2.1.3. Data Safety Monitoring Plans QA Review: Selected protocols will be reviewed to ensure that all requirements were met before approval.

5.2.1.4. Informed Consent QA Review: Selected informed consent documents will be reviewed to ensure all required consent elements were adequately reviewed before approved.

5.2.1.5. Timelines QA Review: Calculations will be made of the number of business days between, but not limited to:

5.2.1.5.1. Protocol submission and IRB reviewer assignment.

5.2.1.5.2. IRB reviewer assignment and IRB approval.

5.2.1.5.3. Protocol submission and IRB approval.

5.2.2. Each process will be reviewed using the corresponding QA review checklist (i.e., IRB Meeting Minutes QA Checklist) that is based on pertinent federal regulations and relevant IRB policies.

5.2.3. Completed QA reviews will be forwarded to the Corporate Manager of Research Integrity for review and further follow-up instructions.

5.2.4. Any corrective actions such as re-training of the staff will occur as appropriate.

6. Responsibilities

6.1. Quality Improvement (QI) and Education Specialist:

6.1.1. Responsible for conducting reviews of IRB records to ensure compliance with applicable federal regulations and/or agency specific requirements, state or local laws, and institutional policies and procedures.

6.1.2. Generate QA checklists and written reports with the results of the review identifying deficiencies or deviations from federal regulations, local laws, and institutional policies.

6.2. IRB:

6.2.1. Responsible for assuring that research studies are approved in accordance with federal, state, and local regulations as well as the HRPP policies and procedures.

6.2.2. Responsible for generating IRB minutes for the IRB meetings.

6.2.3. Responsible for making available time as well as addressing concerns or deficiencies via CAPA plan.

6.2.4. Corporate Manager of Research Integrity:

6.2.4.1. Responsible for developing, managing, and evaluating policies and procedures that ensure compliance with all state and federal regulations governing research.

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

6.2.4.3. Instituting Corrective Action Plans based upon audit findings.

7. References

7.1. MHC_RP0301_EQuIP Overview

7.2. MHC_RP0302_QA/QI Routine Review

7.3. MHC_RP303_Directed For Cause Audit

7.4. MHC_RP101_Authority and Responsibility of IRB

7.5. QA Review Checklist

8. Previous Revisions: 11/28/21

9. Supersedes Policy: None

10. Approvals:

Signature on File *1/31/23*

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