McLaren HEALTH CARE		**Policy Title:**	Education and Quality Improvement Program - EQuIP
Effective Date:	October 8, 2015	**Policy Number:**	MHC_RP0301
Review Date:	October 8, 2015	**Section:**	Human Research Protections Program
Revised Date:		**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The Human Research Protection Program oversees the Office of Research Compliance and Quality Assurance and the Office of Education, Training, and Resources which are jointly known as the Education and Quality Improvement Program (EQuIP).

1.2. The purpose of this policy is to describe the activities of the EQuIP within the McLaren Health Care Human Research Protection Program (HRPP).

1.2.1. The purpose of EQuIP is to measure, evaluate, and improve the effectiveness, quality, and compliance of HRPP with organizational policies and procedures and applicable federal regulations, state, and local laws on an ongoing basis.

2. Scope

2.1. This policy applies to all Quality Assurance (QA) and Quality Improvement (QI) activities performed by EQuIP at McLaren Health Care and its subsidiaries.

2.1.1. Quality assurance and quality improvement occurs at all levels of the HRPP.

2.2. The scope of the EQuIP QA/QI activities focuses primarily on, compliance through QA/QI reviews and audits, policies and procedures, education, and other activities designated by the Corporate Director of HRPP.

3. Definitions

3.1. Best Practices: A method or technique that has consistently shown results superior to those achieved with other means and that is used as a benchmark. In addition, a "best" practice can evolve to become better as improvements are discovered. Best practices are used to

maintain quality as an alternative to mandatory legislated standards and can be based on self-assessment or benchmarking.

3.2. Corrective Actions Preventative Action Plan (CAPA): A systematic plan to align research conduct in line with federal regulations, laws, and institutional policies.

3.2.1. Corrective Action is the action taken to eliminate the causes of an existing non-compliance issue or other undesirable situation in order to prevent recurrence.

3.2.2. Preventative Action is action taken to eliminate the cause of a potential non-compliance or other undesirable situation in order to prevent occurrence.

3.3. Directed For-Cause Audit: A systematic review, inspection, or verification of compliance regarding research and/or investigators-initiated at the request of the MHC IRB chairperson, designee or authorized official. Directed audits may be conducted in response to subject or sponsor complaint.

3.4. Education and Quality Improvement Program (EQuIP): A program that encompass the HRPP Offices of Research Compliance and Quality Improvement with the Office of Education, Training, and Resources.

3.5. Good Clinical Practice (GCP): Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of the trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

3.6. QA/QI Plan: A plan that incorporates routine QA/QI review activities as required to achieve the specific objectives for compliance improvement that have been identified. The plan is adjusted throughout the year to address new input received from the EQuIP monitoring and evaluation activities described above and to respond to changes in external requirements. The Corporate HRPP Director approves the plan.

3.7. QA/QI Routine Reviews: A quality assurance and quality improvement effort to ensure optimal conduct of human subject research within the framework of institutional policy and regulatory requirements and to provide educational resources to Investigators and members of the study team.

3.8. Quality Assurance (QA): An evaluation of whether or not activities meet defined standards. In the context of research, QA is a retrospective, objective, and systematic review of trial related activities to ensure that the trial is performed in compliance with federal regulations, MHC institutional policies, and Good Clinical Practices.

3.9. Quality Improvement (QI): Systematic efforts or activities aimed at improving human subject research conduct through analysis and interpretation of performance demonstrated through QA/QI reviews and audits.

3.10. Research Community: Investigators, research coordinators, contracted research personnel, IRB office, IRB members, and others who have a role in the human research study.

3.11. Refer to Appendix I "Definitions" for additional definitions.

4. Policy

4.1. McLaren's 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.

4.2. EQuIP will provide post-approval monitoring and internal oversight, education and training to all involved in human subject research to assure that all HRPP operations are supported, consistent, and continue to protect the rights and welfare of research participants.

4.3. In line with AAHRPP accreditation standards, EQuIP will evaluate the quality, effectiveness, and efficiency of the MHC HRPP.

4.4. In line with AAHRPP accreditation standards, EQuIP will evaluate compliance with institutional policies and procedures and applicable laws and regulations.

4.5. EQuIP will identify strengths and weaknesses and will increase compliance through:

- **4.5.1.** Quality Assurance, Performance Measurement, and Quality Evaluation.
- **4.5.2.** Assessment of Current Processes, Practices, and Metrics.
- **4.5.3.** Quality Improvement, Training, and Education.

5. Procedures

5.1. Quality Assurance, Performance Measurement, and Quality Evaluation will be conducted at:

5.1.1. Research Sites:

5.1.1.1. Routine and random QA/QI reviews are done to monitor/observe research conduct and compliance of the Principle Investigators (PI), Sub-Investigator, and research staff.

5.1.1.2. The calendar plan of QA/QI monitoring activities is outlined in the QA/QI Plan.

5.1.1.2.1. The plan will define at least one goal to assess compliance of the HRPP.

5.1.1.2.2. The plan will define at least one goal to assess the quality, efficiency and effectiveness of the HRPP.

5.1.1.3. The scope of the QA/QI reviews is outlined in the policy *MHC_RP0301 QA/QI Routine Review*.

5.1.1.4. Directed for-cause audits of specific research and/or investigators at the request of the IRB or Institutional Official (IO) will be performed as necessary to support IRB review and ensure human subjects protections.

5.1.1.5. The scope of the audit is based on the Directed For-Cause Audit Policy.

5.1.2. IRB Office:

5.1.2.1. IRB QA/QI reviews will be done to assess IRB compliance with applicable institutional policies and procedures, federal regulations, state, and local laws.

5.1.2.2. The calendar plan and type of IRB QA/QI reviews is outlined in the QA/QI Plan.

The plan will define at least one goal to assess compliance of the HRPP.

The plan will define at least one goal to assess the quality, efficiency and effectiveness of the HRPP.

5.1.2.3. The scope of the IRB QA/QI review is outlined in the policy *MHC_RP0304_IRB QA Review.*

5.2. Assessment of Current Processes and Policies will be performed by using the following methods:

5.2.1. Analyzing HRPP Satisfaction Surveys, investigator QA/QI reviews and audits, and IRB QA/QI reviews.

5.2.2. Conducting IRB member assessment.

5.2.3. Reviewing IRB meeting minutes and IRB study files.

5.2.4. Reviewing and revising, when needed, HRPP policies and procedures.

5.2.5. QA/QI reviews of the research investigators and IRB, based on the annual risk assessment, compliance review, and education plan.
5.2.6. Directed for-cause audits as directed by the Corporate HRPP Director, IRB Chairman, IRB board members, or IO.
5.2.7. Training and education of research community:
5.2.7.1. Via live or archived webinars.
5.2.7.2. Formal and informal in-person education sessions per policy and QA/QI Plan.
5.2.7.3. Templates, tools, and resources listed on HRPP website.

5.3. Metrics will be performed to assess the overall HRPP program to determine if the additional resources are needed and/or to provide continuing education to investigators, research staff, and IRB members.
5.3.1. The following metrics will be assessed, evaluated, and submitted to Corporate Director:
5.3.1.1. Number of active protocols (exempt, expedited, full board).
5.3.1.2. Mean number of days from submission to review and approval for new studies for full board and expedited.
5.3.1.3. Mean number of days from submission to exempt determination.
5.3.1.4. Number of protocol deviations.
5.3.1.5. Number of complaints from research participants received.
5.3.1.6. Number of cases of alleged non-compliance investigated.
5.3.1.7. Number of determinations of serious non-compliance.
5.3.1.8. Number of determinations of continuing non-compliance.
5.3.1.9. Number of unanticipated problems investigated.
5.3.1.10. Number of unanticipated problems involving risks to participants or others.
5.3.1.11. Number of "for cause" audits of investigator protocols.
5.3.1.12. Number of random audits of investigator protocols.
5.3.1.13. Number of "for cause" audits of IRB records conducted.
5.3.1.14. Number of random QA/QI review of IRB records conducted.
5.3.1.15. Number of FDA inspections of investigators or the IRB(s).

5.3.2. Metrics will be used to determine if AAHRPP standards I-5 are met.

5.3.3. Metrics will be used to determine if the QA/QI Plan goals have been met.

5.3.4. Examination of trends and aggregate results will be utilized to determine exactly where changes are needed or if more education is in order.

5.4. QI and Education Specialist along with the Corporate HRPP Director will create the QA/QI Plan.

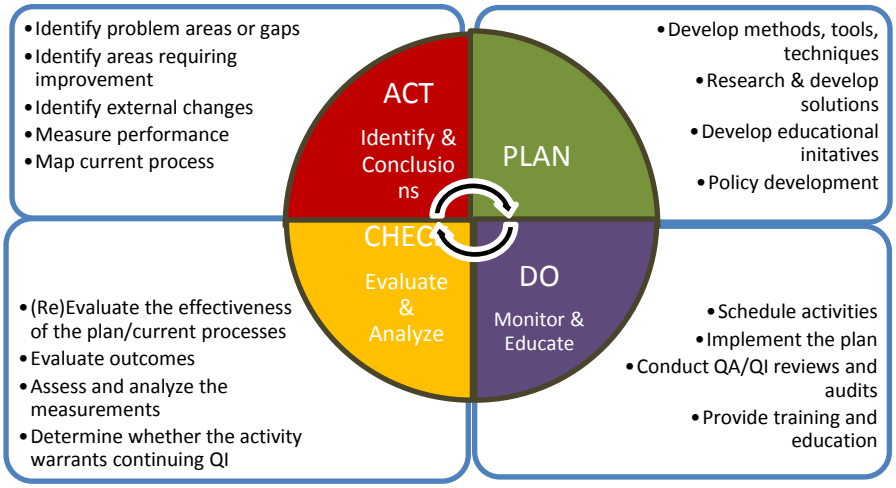
5.5. QI and Education Specialist will meet with the Corporate HRPP Director on a regular basis to provide update on QA/QI activities and metrics.

5.6. The IRB will receive findings of the audits, which it requested, and any other reviews, that suggests evidence of serious or continuing non-compliance with regulations or policies and procedures related to human subjects' research according to policy *MHC_RP0121_Reporting Adverse Events and Unanticipated Problems Involving Risks to Subjects and Others (UPIRSO).*

5.7. Quality assurance reports listing each review, its findings, and any recommendations and actions will be reported to the Institutional Official and Corporate Compliance quarterly.

5.8. All EQuIP activities undertaken to assess HRPP quality, efficiency, and effectiveness will be documented in writing, filed electronically, and filed in EQuIP office file cabinet.

5.9. The Deming Method (Plan, Do, Check, Act or PDCA) of continuous quality improvement to EQuIP activities will be applied:



6. Responsibilities

6.1. Quality Improvement and Education Specialist:

6.1.1. Responsible for evaluating research studies for compliance with applicable federal regulations and/or agency specific requirements, state or local laws, and institutional policies and procedures.

6.1.2. Perform internal monitoring of the HRPP and IRB to assure compliance with the federal, state laws, institutional policies.

6.1.3. Responsible for implementing QA/QI activities.

6.1.4. Responsible for implementing QA/QI monitoring tools.

6.1.5. Responsible for preparing and presenting reports to the Corporate HRPP Director.

6.1.6. Responsible for providing on-going support and education to the research community to ensure compliance with applicable institutional, FDA, OHRP, HIPAA, and GCP requirements and guidelines.

6.1.7. Train and provide training resources to researchers and IRBs on human research regulations, policies, and procedures.

6.2. Principal Investigator (PI):

6.2.1. Responsible for the conduct and oversight of their research study, including oversight of personnel and for protecting the right, safety, and welfare of the subjects enrolled in the research.

6.2.2. Responsible for making available study documents for review or audit and addressing concerns or deficiencies via interview and/or CAPA plan.

6.3. IRB:

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

6.3.2. Responsible for generating IRB minutes based on the current policies and procedures.

6.3.3. Responsible for making available time and study documents as well as addressing concerns or deficiencies via interview and/or CAPA plan.

6.3.4. The IRB chair and/or any member of the IRB is responsible for notifying the Corporate HRPP Director and/or QI and Education Specialist of any suspected or known non-compliance or unanticipated problems involving risk to participants or others so that an audit can be conducted.

6.4. Corporate Director of HRPP:

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

6.4.2. 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.

6.4.3. Responsible for developing training requirements, as required and appropriate, for investigators, subcommittee members, and research staff, and ensuring that training is completed on a timely basis.

6.4.4. Instituting Corrective Action Plans based upon audit findings.

7. References

7.1. International Conference on Harmonization Good Practice Guidelines
7.2. AAHRPP Element I.5.B
7.3. AAHRPP Element I.5.A
7.4. MHC_RP0302_Routine and Random QA/QI Review
7.5. MHC_RP0303_Directed For-Cause Audit
7.6. MHC_RP0304_IRB QA/QI Review
7.7. MHC_RP0121_Reporting Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO)
7.8. MHC_RP0125_Investigator Responsibilities
7.9. MHC HRPP Manual
7.10. The W. Edward Deming Institute

8. Previous Revisions:

8.1. None

9. Supersedes Policy:

9.1. None

10. Approvals:

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Date