McLaren HEALTH CARE		Policy Title:	Investigator Requested Services
Effective Date:	October 8, 2015	Policy Number:	MHC_RP0305
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. This policy outlines EQuIP services that can be provided to the research investigators and research staff.

1.2. The purpose of the EQuIP services:

1.2.1. To promote quality improvement amongst all research professionals.

1.2.2. To educate researchers about techniques used to improve the quality of human participant research.

1.2.3. To make available means to self-assess researchers' compliance with state and federal regulations.

1.2.4. Foster open communication between research sites and the HRPP.

2. Scope

2.1. This policy applies to all industry sponsored, government funded, and investigator initiated studies conducted at McLaren Health Care and any of its subsidiaries.

3. Definitions

3.1. Directed For-Cause Audit: An in-depth examination of any or all components of a research study, including but not limited to, all records, documents, observation of processes, and interviews with investigators, research staff team members and participants for the purpose of determining if the rights and welfare of participants are being upheld according to federal regulatory requirements, laws, and HRPP policy.

3.2. Corrective Action 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. 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.

3.4. QA/QI Routine Reviews: A Quality Assurance (QA) and Quality Improvement (QI) 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.

3.5. Quality Assurance: 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.

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

3.7. 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. As part of the McLaren's AAHRPP Quality Improvement and Quality Assurance Program and the Office of Research Compliance and Quality

Improvement, through EQuIP, will evaluate and educate research sites at their own request to help improve the quality of the research and communication between the HRPP office and the research site.

4.2.1. Services are provided to evaluate study conduct, educate, and promote compliance with institutional policies, state and local laws, and federal regulation.

4.3. All services/consultation requests must be requested via the Service Request Form.

4.4. Services/consultations can include, but not limited to:

4.4.1. QA/QI Routine Review
4.4.2. Directed For-Cause Audit
4.4.3. Document Development
4.4.4. Talks and Presentation
4.4.5. Assistance with Organization of Records and Documentation Practices
4.4.6. Study Start-Up for New Investigators
4.4.7. Assist with audits from external agencies (FDA, Sponsor, etc.) by:
4.4.7.1. Reviewing study records in preparation for the FDA inspection.
4.4.7.2. Developing a CAPA Plan.
4.4.7.3. Being present during the interview with the FDA (note: Investigators are required to notify MHC IRB of pending FDA inspection only, but have to request assistance with preparation and attendance).
4.4.8. Study Binder Set-Up.
4.4.9. Evaluate findings on the QA/QI Self-Assessment Checklist including assisting with developing a CAPA plan.
4.4.10. Navigating through eProtocol.

4.5. All evaluation findings are confidential and will not be disclosed to entities outside of the Institution, unless necessary to disclose these findings as required by state or federal regulations.

4.6. All evaluations will be conducted for Quality Improvement purposes and should not be viewed as punitive.

5. Procedure

5.1. The investigator or designee will complete the Service Request Form.
5.2. The QI and Education Specialist will:

5.2.1. Evaluate the feasibility of the request within the scope of the EQuIP.
5.2.2. Email a copy of the request to the Corporate Director of HRPP.
5.2.3. Notify the requestor within 5 business days an execution plan with details and projected completion date.
5.2.4. Recommend or collaborate with appropriate individuals or departments (i.e. Privacy officer, IRB), if applicable, to create the requested service.
5.2.5. Complete a QA/QI review or audit according to established policies:
5.2.5.1. MHC_RP0302_QA/QI Routine Reviews
5.2.5.2. MHC_RP0303_Directed For-Cause Audit
5.2.5.3. Any findings will be discussed with the Investigators to promote ethical conduct of human research protection, constant quality improvement, and open communication between the Investigators and the HRPP.
5.2.5.4. Once the request has been completed, a closeout letter will be electronically mailed to requestor and Corporate Director of HRPP.

6. Responsibilities

6.1. Quality Improvement and Education Specialist will receive and execute the request.

6.2. .Principal Investigator (PI) will make the request and provide staff or resources (time and location), if applicable, to complete plan.
6.2.1. It is the responsibility of all Investigators to strive to conduct ethical human subject research.
6.2.2. Research sites should understand the intent of the Quality Improvement Evaluations and provide adequate working conditions for the Quality Improvement Coordinator to evaluate their protocol.
6.2.3. The investigator is responsible for notifying the MHC IRB of a pending FDA inspection. However, the PI must request for the EQuIP office to assist with preparation and/or being in attendance during audit process.

6.3. Corporate Director of HRPP will approve or disapprove request.

7. References:

7.1. MHC_RP0302_QA/QI Routine Reviews
7.2. MHC_RP0303_Directed for Cause Audits

8. Previous Revisions: None

9. Supersedes Policy: None

Approvals:

Michael McKenna, MD Executive Vice President/ Chief Medical Officer Institutional Official of Research	Date