McLaren HEALTH CARE		Policy Title:	Investigator Requested Services
Effective Date:	October 8, 2015	Policy Number:	MHC_RP0305
Review Date:	August 20, 2020	Section:	Research Integrity
Revised Date:	January 20, 2023	Oversight Level:	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Official, HRPP		

1. Purpose

1.1. This policy outlines the McLaren Health Care (MHC) Education and Quality Improvement Program (EQuIP) services that can be provided to research investigators and research staff.

1.2. The purpose of the EQuIP services:

1.2.1. To promote quality improvement among 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. Refer to Appendix I *"Definitions"*

4. Policy

4.1. The McLaren Health Care 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.

4.2. As part of the McLaren's AAHRPP Quality Improvement and Quality Assurance Program, 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 the IRB electronic application system.

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 Manager of Research Integrity.

5.2.3. Notify the requestor within 5 business days of 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. All 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 the requestor and Corporate Manager of Research Integrity.

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's 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 QI and Education Specialist 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 EQuIP to assist with preparation and/or being in attendance during audit process.

6.3. Corporate Manager of Research Integrity 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: 11/28/21

9. Supersedes Policy: None

10. Approvals:

Signature on File *1/31/23*

Justin Klamerus, MD, MMM Date
Executive Vice President/ Chief Medical Officer
Institutional Official of Research