McLaren HEALTH CARE		**Policy Title:**	Reporting to Regulatory Agencies and Institutional Officials
Effective Date:	January 16, 2012	**Policy Number:**	MHC_RP0124
Review Date:	December 18, 2015	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	December 2, 2015	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is to define the procedures the McLaren Health Care Institutional Review Board (MHC IRB) follow when reporting:

1.1.1. Any unanticipated problem involving risks to subjects or others (UPIRSO);

1.1.2. Any serious or continuing noncompliance with Department of Health and Human Services (DHHS) or FDA regulations or the requirements or determinations of the MHC IRB; or

1.1.3. Any suspension or termination of MHC IRB-approved human-subjects research.

2. Scope

2.1. This policy applies to all Principal Investigator (PI), research staff, MHC IRB members, IRB Chair or Designees, IRB staff, and administrators.

2.2. Any individual who is involved in conducting a human subject research study that is under the jurisdiction of the McLaren Human Research Protections Program (MHC HRPP).

3. Definitions

3.1. Refer to Appendix I “Definitions”

4. Policy

4.1. Federal Regulations require prompt reporting to the appropriate institutional official and as applicable, the federal agency head, or the FDA of:

4.1.1. Any unanticipated problems involving risks to subjects or others;

4.1.2. Any serious or continuing noncompliance or the requirements or determinations of the MHC IRB; or

4.1.3. Any suspension or termination of IRB approval.

4.2. Consistent with federal regulations, the MHC IRB is responsible for reporting on behalf of all MHC subsidiary hospitals:

4.2.1. Any unanticipated problems involving risks to subjects or others;

4.2.2. Any serious or continuing noncompliance with Department of Health and Human Services (DHHS) or FDA regulations or the requirements or determinations of the MHC IRB; or

4.2.3. Any suspension or termination of MHC IRB-approved non-exempt human subjects research to the applicable institutional officials and as required or appropriate, to the applicable regulatory agencies.

4.3. Institutional Official can suspend/terminate the researchers and/or research at any McLaren subsidiary hospitals.

4.4. The Federalwide Assurances (FWAs) is designated to apply all subparts of the Common Rule to DHHS funded supported or conducted human-subjects research only.

4.4.1. In general, the same criteria and process for the conduct and oversight of human-subjects research, for determinations about reportable events and for actions taken in response to such events will apply to all human-subjects research in which MHC subsidiary hospitals are engaged, regardless of funding source.

4.5. If an event involves human-subjects research that is not DHHS funded or supported, the MHC IRB is not required to report the event to the Office for Human Research Protections (OHRP) or other relevant federal department or agency head (reporting to the Food and Drug Administration (FDA) may still be required, if the research is subject to FDA regulations).

4.5.1. The IRB may voluntarily report any such event to OHRP or other agencies in its discretion. All other reporting requirements described below apply regardless of funding source.

4.6. MHC IRB will comply with the requirement stated above and the following procedures describe how these reports are handled.

5. Procedure

5.1. IRB staff will initiate these procedures as soon as the IRB takes any of the following actions:

5.1.1. Determines that an event may be considered an unanticipated problem involving risks to subjects or others.

5.1.2. Determines that non-compliance was serious or continuing.

5.1.3. Suspends or terminates approval of research.

5.2. The Corporate Director of the HRPP or designee is responsible for preparing reports or letters which includes the following information:

5.2.1. The nature of the event (Unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research).

5.2.2. Name of the institution conducting the research.

5.2.3. Number of the research project assigned by the MHC IRB, title of the research project and, when applicable, grant proposal in which the problem occurred.

5.2.4. Name of the principal investigator on the protocol.

5.2.5. A detailed description of the problem including the findings of the organization and the reasons for the IRB's decision.

5.2.6. Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.).

5.2.7. Plans, if any, to send a follow-up or final report by the earlier of:

5.2.7.1. A specific date.

5.2.7.2. When an investigation has been completed or a corrective action plan has been implemented.

5.3. The Institutional Official, Corporate Director of the HRPP or IRB Chair is responsible for review and approval of the final report(s).

5.4. The Institutional Official is the signatory for all correspondence from the facility.

5.5. The Corporate Director of the HRPP or designee sends a copy of the final report(s) to:

5.5.1. The MHC IRB by including the letter in the next agenda packet as an information item.

5.5.2. The Institutional Official.

5.5.3. The following federal agencies:

5.5.3.1. OHRP, if the study is subject to DHHS regulations or subject to a DHHS FWA [Note: As reflected in Section 4.3 above, reporting to OHRP is not required unless the study is federally supported or conducted].

5.5.3.2. FDA, if the study is subject to FDA regulations.

5.5.3.3. If the study is conducted or funded by any Federal Agency other than DHHS that is subject to "The Common Rule", the report is sent to OHRP or the head of the agency as required by the agency.

5.5.3.4. Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.

5.5.4. Principal investigator and the Academic Advisor (applicable).

5.5.5. Sponsor, if the study is sponsored.

5.5.6. The Privacy Officer of an applicable hospital, if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity.

5.5.7. Others as deemed appropriate by the Institutional Official.

5.6. The Corporate Director of the HRPP or designee will ensure that all steps of this policy completed generally within 30 days of the date when:

5.6.1. The MHC IRB determines that an incident is an unanticipated problem involving risks to subjects or others;

5.6.2. The MHC IRB determines that an incident is serious or continuing noncompliance with Department of Health and Human Services (DHHS) or FDA regulations or the requirements or determinations of the PHRC; or

5.6.3. The MHC IRB or Institutional Official suspends or terminates MHC IRB-approved research.

6. References:

6.1. 45 CFR 46

6.2. 45 CFR 56

6.3. HRPP MHC_RP111 "Study Suspension, Termination and Investigator Hold"

6.4. HRPP MHC_RP121 *"Reporting Adverse Events and Unanticipated Problems Involving Risks to subjects or Others (UPIRSO)"*

6.5. HRPP MHC_RP123 *"Non-Compliance in Human Subject Research"*

6.6. Appendix I "*Definitions"*

7. Previous Revisions: November 29, 2012

8. Supersedes Policy: *MHC_RP0120 Reporting to Regulatory Agencies and Institutional Officials*

9. Approvals:

MHC Institutional Review Board initial approval: February 17, 2012

MHC Institutional Review Board acknowledgement: December 18, 2015

_____ _____

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