McLaren HEALTH CARE		**Policy Title:**	Protocol Violations and Exceptions
Effective Date:	July 20, 2012	**Policy Number:**	MHC_RP0122
Review Date:	April 14, 2016	**Section:**	Human Research Protections Program
Revised Date:	March 30, 2016	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is to describe the procedures associated with study related deviations or violations from the protocol and how they should be handled by Principal Investigators (PIs) and the McLaren Health Care Institutional Review Board (MHC IRB).

1.2. The purpose of this policy is to describe the procedures associated with the Protocol Exceptions and how they should be handled by Principal Investigators (PIs) and the MHC IRB.

2. Scope

2.1. These policies and procedures apply to all IRB members and staff.

3. Definitions

3.1. Refer to Appendix I "Definitions".

4. Policy

4.1. When a change in either a therapeutic or non-therapeutic research protocol occurs that is unplanned and was not necessary to eliminate a hazard to subjects the Institutional Review Board (IRB) must be notified, when applicable.

4.2. Protocol Violations must be reported to the IRB within 10 working days of the study team's knowledge of the occurrence.

4.2.1. Protocol Violations are those that:

4.2.1.1. Affect the rights, safety, or welfare of study subjects;

4.2.1.2. Change the risk/benefit ratio;

4.2.1.3. Affect the scientific design of the study, OR;

4.2.1.4. Violate an ethical principle.

4.3. Protocol Exception is a one-time enrollment of an individual who does not meet current IRB approved criteria for inclusion in the research study as outlined in the protocol.

4.3.1. Protocol Exceptions require prior approval from the MHC IRB and the study sponsor, if applicable, prior to the enrollment of the subject.

4.4. Protocol Deviations (an occurrence that does not meet the definition of Exception or Violation) are to be recorded by the investigator and submitted to the MHC IRB at the time of the continuing review.

4.5. All members of the research team are responsible for the appropriate reporting to the IRB and other applicable parties of protocol violations from the study protocol. The PI, however, is ultimately responsible for ensuring the prompt reporting of protocol violations.

4.5.1. The PI is also responsible for ensuring all reported protocol violations are reviewed to determine whether the report represents a change in the risks and/or benefits to study subjects, and whether any changes in the informed consent document(s), the protocol or other study-related documents are required.

4.5.2. Failure to report protocol violation in a timely manner may be considered serious and/or continuing noncompliance as outlined in Policy MHC_RP123 *"Non-Compliance in Human Subject Research".*

4.6. Although this policy outlines the MHC IRB reporting requirements for protocol violations and exceptions from the protocol, it is the responsibility of the PI to understand and meet all reporting requirements of the sponsor and other applicable agencies, including Office for Human Research Protection (OHRP), Food and Drug Administration (FDA), National Institutes of Health (NIH), and others as applicable and required by federal regulation.

5. Procedure

5.1. PI must complete a Protocol Violation/Exception Form using eProtocol electronic submission system.

5.2. Protocol Violation/Exception form must be completed for those events that qualify as a protocol violation or exception.

5.3. IRB Staff will review the Protocol Violation/Exception form for completeness.

5.4. IRB Staff will forward the report to the IRB Chair or designee for review.

5.4.1. If the report represents a HIPAA concern, the IRB Staff will assign the report to a Committee member with a Privacy/Compliance expertise.

5.4.2. If the violation involves significant risks to subjects or others, it will be reviewed by the fully convened IRB.

5.4.3. If the violation does not represent a change to the risk/benefit profile of the research study, it can be processed by expedited procedures and reported to the fully convened IRB as information.

5.5. IRB Chair may choose to place any protocol violations or exceptions on the agenda of the next convened IRB meeting for discussion.

5.6. The investigator may be asked to appear at that meeting to answer any questions or clarify issues for the MHC IRB.

6. Responsibilities:

6.1. Principal Investigator:

6.1.1. It is the responsibility of the investigator to submit protocol violations or protocol exceptions to the IRB within ten (10) business days of the study team's knowledge of the event whenever the violation results in or has a potential to increase risk(s) to subjects or decrease benefit or, has the potential to recur.

6.1.2. Failure to report all violations and/or exceptions within ten (10) business days may be considered non-compliance and therefore, investigators should report any suspected violations and/or exceptions.

6.2. IRB Staff:

6.2.1. Upon receipt of the Protocol Violation/Exception Form from a Principal Investigator, the MHC IRB staff checks the form for completeness. If any applicable sections of the form are incomplete or have been answered unsatisfactorily, the IRB staff will contact the investigator or the designated contact person to obtain additional information.

6.2.2. Assist the PI and research staff with responding to IRB concerns and/or requests for additional information.

6.2.3. Assigns the submission of the events to the agenda for review and discussion by the fully convened IRB, as applicable.

6.2.4. Documents the discussion in the IRB meeting minutes.

6.2.5. All protocol violations and exceptions occurring in a study that has been approved by the MHC IRB are reviewed by the IRB Chair or designee who determines if the event(s) involves significant risks to the subject(s).

6.2.6. IRB Chair or designee receives and reviews the report of the event(s) considered to be a protocol violation/exception.

6.2.7. Based on the information received from the investigator, the IRB Chair or designee may suspend research to ensure protection of the rights and welfare of participants.

6.2.7.1. Suspension directives made by the IRB Chair or designee must be reported to a meeting of the convened IRB.

6.2.8. The IRB or the IRB Chair or designee have authority to require submission of more detailed contextual information by the PI, the sponsor, the study coordinating center.

6.2.9. If the report does not represent a change to the risk/benefit profile of the research study, it can be processed by expedited procedures and reported to the fully convened IRB as information.

6.2.10. If the report involves significant risks to subjects or others, it will be reviewed by the fully convened IRB.

7. References:

7.1. 45 CFR 46

7.2. 21 CFR 56

7.3. MHC_RP123 *"Non-Compliance in Human Subject Research"*

7.4. Appendix I *"Definitions"*

8. Previous Revisions: November 24, 2015

9. Supersedes Policy: None

10. Approvals:

MHC Institutional Review Board initial approval:	July 20, 2012
MHC Institutional Review Board acknowledgements:	December 4, 2015 April 14, 2016

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