McLaren HEALTH CARE		**Policy Title:**	Study Suspension, Termination and Investigator Hold
Effective Date:	January 16, 2012	**Policy Number:**	MHC_RP0111
Review Date:	November 20, 2015	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	November 04, 2015	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. **Purpose**

1.1. The purpose of the policy is to establish guidelines for administrative hold, suspending, closing or termination of McLaren Healthcare (MHC) Institutional Review Board (IRB) approval of human subjects' research.

2. **Scope**

2.1. This Policy applies to all Principal Investigators, Research Staff, MHC IRB Members, IRB Chair or designees, MHC IRB Staff.

2.2. Non-exempt human subject research and clinical investigations reviewed by the McLaren Health Care Institutional Review Board (MHC IRB) at a convened meeting are subject to this policy.

3. **Definitions**

3.1. Refer to Appendix I "*Definitions*"

4. **Policy**

4.1. The MHC IRB has the authority to suspend, close, or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval includes a statement of the reasons for the IRB's action and is reported promptly to the investigator, appropriate institutional officials, department or agency head, and regulatory agencies 45 CFR 46.113, 21 CFR 56.108(b)(3) and 21 CFR 56.113.

4.1.1. Investigators may appeal an IRB decision. A principal investigator may appeal the decision by writing a letter to the IRB requesting reconsideration. At the discretion of the chair, the investigator may make such an appeal in person and/or in writing to the IRB.

4.2. IRB approval may be suspended or terminated if research is not being conducted in accordance with IRB or regulatory requirements or has been associated with unexpected problems or serious harm to subjects.

4.3. Research for which the Principal Investigator (PI) does not provide an IRB Continuing Review submission or if the MHC IRB does not grant approval prior to the study expiration date, the MHC IRB will notify the PI of the expiration of approval and that all research activities must stop.

4.3.1. If the study approval has lapsed more than 14-days and the PI has not provided the required continuing review information, the study will be administratively closed by the MHC IRB.

4.4. Suspension or termination may be in response to a noncompliance investigation or unanticipated problem. Investigators will be notified in writing of a termination or suspension of research.

4.5. Investigators will be notified in writing of a termination or suspension of research.

4.6. An investigator may request an investigator hold on a protocol when the investigator wished to temporarily or permanently stop some or all approved research activities. A hold is initiated by an Investigator. Investigator holds are not suspensions or terminations.

4.7. Suspension or termination of protocols approved by the IRB can also be issued by Organization officials acting outside of and unrelated to the HRPP (i.e., not necessarily related to protecting the rights and welfare of study participants). Such Organization actions can be made by the Organization President, Executive Leadership Team of each Subsidiary hospital or Program Directors. Such Organization actions may be made for any reason in furtherance of the Institution's interest provided, however, that the aggrieved PI is entitled to all rights and procedures afforded to him/her under the Grievance Policy.

4.7.1. The PI must report any suspension or termination of the conduct of research by organization officials to the IRB. The IRB will then determine if suspension or termination of IRB approval is warranted.

4.8. IRB actions will occur in compliance with 45 CFR 46.113, 21 CFR 56.108(b)(3) and 21 CFR 56.113.

5. Procedure

5.1. When study approval is suspended or terminated by the convened IRB or an authorized individual, in addition to stopping all research activities, the convened IRB or individual ordering the suspension or termination will require notification to any subjects currently participating that the study has been suspended or terminated. The convened IRB or individual ordering the suspension or termination will consider whether procedures for withdrawal of enrolled subjects are necessary to protect their rights and welfare of subjects, such as: transferring participants to another investigator; making arrangements for care or follow-up outside the research; allowing continuation of some research activities under the supervision of an

independent monitor; or requiring or permitting follow-up of participants for safety reasons.

5.2. If follow-up of subjects for safety reasons is permitted/required by the convened IRB or individual ordering the suspension or termination, the convened IRB or individual ordering the suspension or termination will require that the subjects should be so informed and that any adverse events/outcomes be reported to the IRB and the sponsor.

5.3. Investigator MUST continue to provide reports on adverse events and unanticipated problems to both the IRB and sponsor just as if there had never been a suspension (i.e., all events that need to be reported during a study need to continue to be reported during the suspension period).

5.4. Immediate Actions for Imminent Protection of Human Subjects: The MHC IRB has given the authority and responsibility to the IRB chair, vice-chair or IO to suspend temporarily or terminate research studies for the imminent protection of human subjects. The IRB chair, vice-chair or IO may reach this decision with consultation from others (e.g., members of the MHC IRB) if needed. If the IRB chair, vice-chair or IO exercises this authority, he/she will communicate with the MHC IRB immediately to inform the members of the action and the MHC IRB will determine the proper course of action from that point forward. The IRB chair may call an emergency IRB meeting to discuss appropriate actions or the vice-chair or IO may request an emergency IRB meeting. The decision to terminate or suspend a research study may also be reached at the time of the regularly scheduled convened IRB meeting.

5.5. Protection of Currently Enrolled Participants: Before a termination or suspension is put into effect, the convened IRB or IRB designee considers whether any additional procedures need to be followed to protect the rights and welfare of current participants. Such procedures might include:

5.5.1. Transferring participants to another investigator.

5.5.2. Making for clinical care outside the research.

5.5.3. Allowing continuation of some research activities under the supervision of an independent monitor.

5.5.4. Requiring or permitting follow-up of participants for safety reasons.

5.5.5. Requiring adverse events or outcomes to be reported to the IRB and the sponsor.

5.5.6. Notification of current participants.

5.5.7. Notification of former participants.

5.5.8. The IRB may decide additional procedures are needed to protect the rights and welfare of current subjects.

5.5.9. The decision to suspend or terminate and the reason for the decisions are documented in the IRB meeting minutes.

5.6. Investigator Hold

5.6.1. Investigators must notify the IRB in writing that:

5.6.1.1. They are voluntarily placing a study on hold.

5.6.1.2. A description of the research activities that will be stopped.

5.6.1.3. Proposed actions to be taken to protect current participants.

5.6.1.4. Actions that will be taken prior to IRB approval of proposed changes in order to eliminate apparent immediate harm.

5.6.2. Upon receipt of written notification of the investigator the IRB Analyst places the research on the agenda for review.

5.6.3. The IRB Chair and/or Corporate Director of the HRPP, in consultation with the investigators, determine whether any additional procedures need to be followed to protect the rights and welfare of current participants as described in "Protection of currently enrolled participants" below.

5.6.4. The IRB Chair and/or Corporate Director of the HRPP, in consultation with the investigators, determine how and when currently enrolled participants will be notified of the hold.

5.6.5. Investigators may request a modification of the hold by submitting a request for a modification to previously approved research.

6. Responsibilities

6.1. Principal Investigators are responsible for:

6.1.1. Abiding by all IRB determinations and decisions;

6.1.2. Notifying the IRB of the following:

6.1.2.1. Suspensions, terminations, or other limits on their participation in IRB approved human subjects research imposed by study sponsors or regulatory agencies;

6.1.2.2. Adverse event or unanticipated problem involving risks to human subjects or others.

6.1.2.3. Any problem with the conduct of the IRB approved human subject research which may impact the rights or welfare of study subjects or impact the IRB's determinations.

6.1.3. Notifying the study sponsor(s) when IRB approval is suspended or terminated;

6.1.3.1. For Food and Drug Administration (FDA) regulated research involving an investigational drug or device, an investigator shall report to the sponsor, within 5 business days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation. (21 CFR 812.150(a)(2)).

6.1.4. Notifying currently enrolled participants when IRB approval is suspended, terminated, or expired. The MHC IRB must approve the communications to research subjects from the PI.

6.2. Sponsors or Sponsor-Investigators are responsible for:

6.2.1. Notifying FDA and all reviewing IRB's and participating investigators of any withdrawal of approval of an investigation or a part of an investigation by a reviewing IRB for FDA-regulated research involving an investigational device within 5 working days after receipt of the withdrawal of approval. 21 CFR 812.150(b)(2)

6.2.2. Notifying all reviewing IRB's and participating investigators of any withdrawal of FDA approval of the investigation within 5 business days after receipt of notice of withdrawal of approval. 21 CFR 812.150(b)(3)

6.3. IRB Chair or designee is responsible for:

6.3.1. Determining if immediate actions are needed to protect the rights and welfare of study subjects prior to the item(s) being reviewed by the next available fully convened IRB.

6.3.1.1. The IRB Chair or designee may determine that immediate suspension of the research or of specific research procedure is necessary to protect study subjects or others from harm;

6.3.1.2. The IRB Chair or designee will report this action to the fully convened IRB at the next available meeting after the suspension;

6.3.1.3. The IRB will be provided all information which was available to the Chair or designee that lead to the suspension of IRB approval and any subsequent information that has been brought to light.

6.3.2. Before an investigator hold, suspension, or termination is put into effect, the convened IRB, or if time does not permit, an IRB Chair/Vice-Chair, must determine whether any additional procedures are needed to protect the rights and welfare of current subjects.

6.4. IRB is responsible for:

6.4.1. Suspending or terminating currently approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. This includes suspending or terminating research when the following to be significant:

6.4.1.1. There is apparent or perceived imbalance of risk to benefit ratio based on events that have occurred since IRB approval was granted;

6.4.1.2. There is serious or continuing non-compliance that places participants or others at unnecessary risk;

6.4.1.3. There is suspension of privileges for the PI at the site at which the research is conducted;

6.4.1.4. There is an FDA clinical hold placed on an investigational drug, device, or biologic being utilized in the research;

6.4.1.5. The study has received an FDA Warning letter because of objectionable activity;

6.4.1.6. There is lack of appropriate oversight by the Principal Investigator or others responsible for the safety and well-being of participants;

6.4.1.7. There are allegations of non-compliance that, if substantiated, would place participants or others at risk of harm;

6.4.1.8. Notifying immediately the Principal Investigator, the co-investigator, the Principal Investigator's Chairperson, the Institutional Official, as applicable, of suspensions or terminations;

6.4.1.9. Notifying Office for Human Research Protection (OHRP), and if applicable, FDA or other federal agencies, within 30 days of IRB suspensions or terminations.

6.4.2. Suspending a PIs ability to submit new human research studies for IRB consideration;

6.4.3. Considering whether procedures for withdrawal of enrolled participants take into account their rights and welfare;

6.4.4. Responsible for reporting the investigator holds, suspensions, closures and/or terminations within 30 days to the IO.

7. References

7.1. 21 CFR 56.108(b)(3)

7.2. 21 CFR 56.113

7.3. 21 CFR 812.150(a)(b)(2)(3)

7.4. 45 CFR 46.113

7.5. Appendix I "Definitions

8. Previous Revisions: December 12, 2012

9. Supersedes Policy: *MHC_RP0116 Study Suspension, Termination and Investigator Hold*

10. Approvals:

MHC Institutional Review Board initial approval: February 17, 2012

MHC Institutional Review Board acknowledgment: February 17, 2012
November 20, 2015

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