McLaren HEALTH CARE		**Policy Title:**	Full Board Review of Human Subject Research
Effective Date:	July 20, 2012	**Policy Number:**	MHC_RP0108
Review Date:	November 20, 2015	**Section:**	Human Research Protections Program
Revised Date:	November 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 (MHC) Institutional Review Board (IRB) follow when conducting initial and continuing review of human subjects research and clinical investigations and review of proposed changes in approved research at a convened meeting

2. Scope

2.1. Except when an expedited review procedure is used, the IRB will conduct review of all non-exempt research at convened meetings at which a quorum of the members is present.

3. Definitions

3.1. Refer to Appendix I "Definitions"

4. Policy

4.1. Except when an expedited procedure is used, the MHC IRB must review all non-exempt human subject research and clinical investigations at a convened meeting at which more than half the members, including at least one physician-scientist member and one nonscientific member, are present unless the research is eligible for review using the expedited review procedure

4.2. Full Board review is required for:

4.2.1. All Initial Review applications submitted to the MHC IRB that are not eligible for expedited review procedure

4.2.2. Revision(s) to a project that is/are non-minor changes(s)

4.2.3. Continuing reviews of projects that are not eligible for expedited review procedure

4.2.4. Disapproval of a new project, regardless of review level

4.2.5. Issues in which resolution cannot be made between the IRB reviewer and the investigator

NOTE: Research that underwent full review during the initial review will typically not be eligible for expedited review at the time of continuing review unless the research meets the criteria under expedited category 8 or 9. Please refer to Policy *MHC_RP0106 "Expedited Review of Human Subject Research"*

4.3. When reviewing non-exempt human subject research and clinical investigations, the IRB Chair and IRB members are subject to the Policy *MHC_RP0126 "Conflict of Interest for IRB Members.*

5. Procedure

5.1. Meeting Agenda and Limitations

5.1.1. Approximately 7 days prior to the IRB convened meeting, all members receive the following through eProtocol electronic submission system:

5.1.1.1. Agenda list for the upcoming meeting, which typically contains:

5.1.1.1.1. A statement on confidentiality of meetings,

5.1.1.1.2. Conflict of interest statement(s),

5.1.1.1.3. Introduction of new members

5.1.1.1.4. Minutes from the previous meeting,

5.1.1.1.5. education and information items (including reports to be discussed)

5.1.1.1.6. Protocols which will be presented at the meeting,

5.1.1.1.7. Protocols (new, minor modifications, or continuing reviews) which, since the previous convened meeting for this IRB, have been reviewed by the expedited process and recommended for approval, and do not need to be presented at a convened meeting,

5.1.1.1.8. Other items (such as findings on Reports which have not required presentation at the convened meeting).

5.1.1.2. Minutes from the previous corresponding meeting

5.1.1.3. Any other related supporting documents related to the upcoming meeting

5.1.2. Once an agenda is published through eProtocol, all members are granted view access to the presented protocol materials

5.1.3. The IRB meeting is scheduled for 2 hours and is capable of reviewing approximately 5-10 studies. The variation is dependent on the complexity of the research, whether it's a continuation or modification of previously approved research, and the available expertise in attendance at the IRB meeting.

5.2. Preliminary Review

5.2.1. An application must be completed and submitted using eProtocol IRB online system.

5.2.2. IRB staff checks for completeness and accuracy (e.g., appropriate documents attached)

5.2.3. IRB staff evaluates the protocol to determine whether a consultant is needed and notifies the IRB Chair or the Corporate Director of the HRPP

5.2.3.1. Policy on "Use of Consultants" is followed

5.2.4. IRB staff verifies current training for researchers listed on the application. IRB staff will notify the PI of any individuals without current training; those individuals must have current training before the approval letter can be issued.

5.2.5. IRB Staff verifies whether an application was submitted by the PI or by someone else. If the application was submitted by someone other than the PI, a signed assurance page will be requested.

5.2.6. The investigator will be informed either via eProtocol or e-mail of missing materials.

5.2.7. In the case of a PI who is submitting a protocol for the first time or an investigator who may not be well-versed in the protocol submission procedures, individualized IRB consultations can be arranged.

5.3. Change in Review Level:

5.3.1. Investigators indicate on the e-application whether they believe the research study qualifies for the expedited review, but the IRB Staff, Chair, or members may change the level of review if the selection is not appropriate.

5.4. Assignment and Material Distribution

5.4.1. After it has been determined that the protocol submission is complete, the IRB Staff, with the assistance of the "*Experienced / Non-Experienced IRB Member Worksheet*" will assign protocols for review paying close attention to the scientific content of the protocol, the potential reviewer's area of expertise and representation for vulnerable populations involved in the research.

5.4.2. A primary review procedure is used for full review research. Note: while a primary review procedure is used, in order for the research to be approved, a majority of members present at the convened IRB must vote for approval of the research study.

5.4.3. IRB Staff will assign the primary reviewer and one or more "secondary" reviewer(s) (if needed) to the research project based on experience, the potential reviewer's area of expertise and representation for vulnerable populations involved in the research

5.4.3.1. The Primary and Secondary Reviewers are responsible for:

5.4.3.1.1. Having a thorough knowledge of all of the details of the proposed research

5.4.3.1.2. Performing an in-depth review of the proposed research

5.4.3.1.3. Leading the discussion of the proposed research at the convened meeting, presenting both positive and negative aspects of the research, and leading the IRB through the regulatory criteria for approval according to Policy *MHC_RP0109_ "Criteria for IRB Approval of Research*."

5.4.3.1.4. Making suggestions for changes to the proposed research, where applicable.

5.4.4. IRB Staff will also assign a presenter to lead the discussion of the proposed research at the convened meeting.

5.4.4.1. Presenter usually serves as a Primary Reviewer

5.4.5. A secondary reviewer may be assigned to review the full submission materials or may be asked to review specified sections of the submission (i.e. the consent/assent, permission forms, HIPAA)

5.4.6. If reviewer(s) are absent from the meeting, a new reviewer may be assigned, providing the new reviewer has reviewed the materials prior to the meeting. Additionally, an absent reviewer can submit their written comments for presentation at the convened meeting, as long as there is another reviewer present at the convened meeting. NOTE: all of the IRB members receive and are expected to review all studies, not just the ones they are assigned for reviewing.

5.4.6.1. If an absent reviewer submits comments, those can indicate a recommendation regarding approval, but such recommendation will not be counted as a vote.

5.4.7. The reviewer(s) have typically 7 days in which to review the research study.

5.4.8. When the IRB is presented with a protocol which may be outside of the knowledge base or representative capacity of all of the IRB members, an outside consultant will be sought.

5.4.9. The IRB defers to another meeting or obtains consultants if there is not at least one person on the IRB with appropriate scientific or scholarly expertise or other expertise or knowledge to conduct an in depth review of the protocol.

5.5. Pre-Meeting Distribution of Documents

5.5.1. All materials required for the convened IRB review of research study will typically be available online to IRB members at least 7 days prior to the meeting date.

5.5.2. Comments may be sent to the Investigators from any members of the IRB at any time prior to the meeting

5.5.3. All IRB members receive their review materials which will include IRB agenda, meeting minutes, applicable business and continuing education material and protocol review materials at least 7 days prior to the meeting date to allow sufficient time for the review process.

5.6. Material Received by the IRB

5.6.1. At least one primary reviewer must receive and review all of the documents prior to the convened board meeting.

5.6.1.1. If a reviewer requires additional information to complete the review they may either contact the investigator directly, contact the IRB Office to make the request of the investigator or post their comments in eProtocol (electronic submission system).

5.6.1.2. Each assigned reviewer receives and reviews the following documentation, as applicable, for all assigned protocols:

5.6.1.2.1. Complete Protocol Application form

5.6.1.2.2. Proposed Consent / Parental Permission / Assent Form(s) (when applicable)

5.6.1.2.3. Recruitment materials / subject information (when applicable)

5.6.1.2.4. Data collection instruments (including all surveys and questionnaires)

5.6.1.2.5. Investigator Brochure (when one exists)

5.6.1.2.6. The complete protocol (when one exists)

5.6.1.3. Once an agenda is published, all IRB members will receive the same material as primary/secondary reviewers

5.6.1.4. All IRB members will have an opportunity to ask questions and post their comments (if any) prior and/or during the meeting

5.7. Quorum and Voting at IRB Meetings

5.7.1. A quorum consists of a simple majority (more than half) of the voting membership, including at least one member whose primary concern is in a non-scientific area.

5.7.1.1. IRB members are considered present and participating at a duly convened IRB meeting when either physically present or participating through electronic means (e.g., teleconferencing or video conferencing) that permits them to listen to and speak during IRB deliberations and voting.

5.7.1.2. MHC IRB Members have the option to either attend in person, via teleconference, or video conference.

5.7.1.3. Members present via teleconference or video conference shall be noted as such in the meeting minutes. The standard for members participating by teleconference or video conferencing is the same for those attending in person, giving all members the opportunity to participate fully in IRB deliberations.

5.7.1.4. All Members are able to participate actively and equally in all discussions.

5.7.2. If research involves an FDA-regulated article, a licensed physician must be included in the quorum.

5.7.3. The IRB Chair, with the assistance of the IRB staff, will confirm that an appropriate quorum is present before calling the meeting to order.

5.7.4. The IRB Chair will be responsible to ensure that the meetings remain appropriately convened.

5.7.5. If the quorum fails during a meeting, such as due to lack of a majority of IRB members being present or an absence of a nonscientist member, the IRB cannot take any further actions or vote until the quorum is restored.

5.7.6. The IRB Staff will document the time of late arrivals and early departure for all IRB members and notify the IRB Chair if a quorum is not present.

5.7.7. A quorum worksheet is completed by the IRB Staff to determine and document whether the IRB meeting is appropriately convened and maintained.

5.7.8. It is generally expected that at least one unaffiliated member and at least one member who represents the general perspective of participants (the same individual can serve in both capacities) will be present at all IRB meetings.

NOTE: Although the IRB may, on occasion, meet without this representation, individuals serving in this capacity must be present for at least 80% of the IRB meetings.

5.7.9. IRB minutes shall include documentation of quorum and votes for each IRB action and determination by recording votes as follows:

5.7.9.1. Total number voting

5.7.9.2. Number for

5.7.9.3. Number opposed

5.7.9.4. Number abstaining

5.7.9.5. Names of those abstaining

5.7.9.6. Names of those recusing.

5.7.10. Votes are indicated by voice vote or show of hands

5.7.10.1. Votes for members attending via teleconference are polled by names

5.7.11. Members leaving the meeting room due to a conflicting interest, or for any other reason, will not be recorded as part of the quorum for a particular protocol.

5.7.12. An individual who is not listed on the official IRB membership roster may not vote with the IRB.

5.7.13. A non-voting ex-officio member of, or representative to, the MCH IRB may not vote with the IRB.

5.7.14. Ad hoc consultants may not vote with the IRB.

5.7.15. A nonscientist must always be present for any vote to be taken.

5.7.16. When a member and their alternate both attend a meeting, either person (but not both) may vote on each protocol.

5.7.16.1. Generally if one of these individuals was the primary reviewer of a given protocol for that review cycle, that person votes on the protocol at the convened meeting.

5.7.17. Voting by proxy is not permitted.

5.8. IRB Meeting Schedule

5.8.1. The IRB meets on a regular basis throughout the year (usually twice per month).

5.8.2. The schedule for the IRB may vary due to holidays or lack of quorum.

5.8.3. The schedule for IRB meetings can be found on the HRPP website for the benefit of all investigators, research coordinators and other research staff when submitting protocol materials. Additionally, this information is available in the HRPP Office.

5.8.3.1. Special meeting may be called at anytime by the IRB Chair or the Corporate Director of the HRPP.

5.9. Meeting Procedures

5.9.1. The IRB Chair, or Vice-Chair in the event that the IRB Chair is absent, will call the meeting to order, once it has been determined that a quorum is in place.

5.9.2. The Chair or Vice-Chair will remind IRB members to recuse themselves from the discussion and vote by leaving the room where there is a conflict.

5.9.3. The IRB will review and discuss the IRB minutes from the prior meeting and determine if there are any revisions/corrections to be made.

5.9.3.1. If there are no changes to be made, the minutes will be accepted as presented and considered final.

5.9.3.2. If it is determined that revisions/corrections are necessary, the minutes will be amended and presented at the following IRB meeting.

5.9.3.3. Final minutes will be signed by the IRB Chair or Vice-Chair (when applicable) and the Corporate Director of the HRPP.

5.9.3.4. It is the responsibility of the IRB Staff to record the proceedings of the session. In addition, the assigned IRB Staff is responsible for taking minutes at each IRB meeting.

5.9.4. The IRB reviews all submissions for initial and continuing review, as well as requests for modifications assigned to a convened meeting.

5.9.5. The Primary Reviewer or an assigned presenter will provide an overview of the research and lead the IRB through the completion of the regulatory criteria for approval using ”Criteria for approval” checklist

5.9.6. All members present at a convened meeting have full voting rights, except in the case of a conflict of interest.

5.9.6.1. In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

5.9.7. Protocol materials are available online, via the web-based “eProtocol” system:

5.9.7.1. The protocol materials are provided via projection system during the meeting.

5.9.8. Criteria for approval is also available to all members in the form of a laminated handout

5.10. Guests

5.10.1. At the discretion of the IRB, the Principal Investigator may be invited to the IRB meeting to answer questions about their proposed or ongoing research.

5.10.1.1. The Principal Investigator may not be present for the discussion or vote on their research.

5.10.2. Ex-officio guests are individuals who, by virtue of their position and their role in the HRPP, occasionally attend IRB meetings.

5.10.2.1. Ex-officio guests include the Institutional Official.

5.10.2.2. Ex-officio guests may fully participate in the IRB discussion and deliberations, but may not vote.

5.10.3. Other guests may be permitted to attend IRB meetings at the discretion of the IRB Chair and the Corporate Director of the HRPP Office.

5.10.4. Guests, other than ex-officio guests, may not speak unless requested by the IRB and must sign a confidentiality agreement.

5.11. Possible IRB Determinations:

5.11.1. The IRB, IRB Chair or designee makes the following determinations and PIs are notified via eProtocol;

5.11.1.1. Approved Without Stipulations: The study is approved as submitted. The PI is not required to change any aspect of the protocol or informed consent document. The approval date is the date of the IRB meeting. The approval is valid for one year unless the IRB Committee, IRB Chair or designee designates a shorter period due to the risk in the study.

5.11.1.2. Approved with Contingencies: Occurs when the stipulations are minor in nature (e.g., require simple concurrence from the PI and do not require substantive judgment by the IRB Committee).

5.11.1.2.1. The IRB may vote to authorize the IRB Chair or designee to approve the response submitted by the PI unless the investigator does not provide the minor revisions requested.

5.11.1.2.2. Should the IRB Chair or designee feel that the response is not adequate or requires review by the fully convened IRB, the study would be added to the next available agenda for the committee that originally reviewed the application.

5.11.1.2.3. The PI may not make additional changes until full IRB approval is granted.

5.11.1.3. Moved: Occurs when IRB Chair, member or designee has determined that further information regarding the protocol is needed in order for the IRB to make a determination.

5.11.1.3.1. Moved studies will be transferred to the next convened IRB meeting

5.11.1.4. Not Approved: The IRB has determined that the research cannot be conducted at MHC and its subsidiary hospitals or by employees or agents of MHC and its subsidiary hospitals or otherwise under the auspices of MHC.

5.11.1.4.1. Once a study has been disapproved, it can be submitted as a new application to the IRB for re-consideration.

5.11.1.4.2. A new submission of previously disapproved protocols must be reviewed by the fully convened IRB.

5.11.1.5. A new application must address all previous concerns outlined by the IRB for the previously disapproved protocol. Suspension of IRB Approval: An action of the IRB or Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures.

5.11.1.5.1. Suspended studies remain open and are subject to continuing review.

5.11.1.6. Tabled: the study might be tabled when the quorum was lost during the convened IRB meeting,

5.11.1.7. Termination: A directive of the convened IRB to permanently cease all activities in a previously IRB-approved research protocol.

5.11.1.7.1. Terminated protocols are considered closed and no longer require continuing review.

5.11.1.7.2. Terminations of protocols approved under expedited review must be made by the convened IRB.

5.11.1.8. Withdrawn: Occurs when the IRB Analyst removes a study from eProtocol when the PI requests to retract a submission

5.11.1.8.1. Withdrawn studies will be removed from the eProtocol system at the request of the PI, IRB Analyst, and/or by the IRB Chair or designee.
5.11.1.8.2. No further action will be taken unless the PI resubmits the protocol

5.12. Use of Consultants:

5.12.1. When necessary, the IRB Chair or the Corporate Director of the HRPP may solicit individuals from any of the McLaren's subsidiary hospitals or the community with competence in special areas to assist in the review of issues or protocols, which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB.

5.12.1.1. The need for an outside reviewer is determined in advance of the meeting by the IRB Chair or the Corporate Director of the HRPP by reviewing the protocols scheduled to be reviewed at the convened meeting.

5.12.1.2. The IRB staff will ensure that all relevant materials are provided to the outside reviewer prior to the convened meeting.

5.12.2. Written statements of consultants will be kept in IRB records.

5.12.2.1. Key information provided by consultants at meetings will be documented in the minutes.

5.12.2.2. Written reviews provided by the outside reviewer will be filed with the protocol.

5.12.3. The Corporate Director of the HRPP Office reviews the conflicting interest policy for IRB members with consultants and consultants must verbally confirm to the Corporate Director of the HRPP Office that they do not have a conflict of interest prior to review.

5.12.3.1. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation.

5.12.4. The IRB Chair will present the consultant's findings to the full board for consideration either in person or in writing.

5.12.4.1. If in attendance, these individuals will provide consultation but may not participate in or observe the vote.

5.12.5. Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher's confidentiality (unless the question raised is generic enough to protect the identity of the particular PI and research protocol).

6. Responsibilities:

6.1. **IRB** is responsible for the following:

6.1.1. Conducting the review of human subjects' research and the conduct of the IRB meeting in accordance with federal regulations, state and local laws, and institutional policies. Refer to policy MHC_RP109 "*Criteria for IRB Approval of Research and Possible IRB Actions".*

6.1.2. Reviewing the draft IRB meeting minutes for accuracy and providing any necessary editorial or content comments;

6.1.3. Voting on the IRB meeting minutes at the next convened meeting.

6.2. **Primary and Secondary Reviewers** are responsible for the following:

6.2.1. Have the authority and should make recommendations to the fully convened, IRB. These recommendations can be accepted as presented, modified, or rejected by a motion and passed by a majority;

6.2.2. Have the authority to vote on the final determinations of those recommendations.

6.3. IRB Chair is responsible for the following:

6.3.1. Signing off on meeting minutes that have been approved by a fully convened IRB;

6.3.2. The IRB Chair is a voting member of the IRB.

6.3.3. Lead the discussion of each protocol, continuing review, or amendment listed on the meeting agenda.

6.3.4. Upon presentation of the study by the reviewers, the Chair requests the motion, for each submission, by the reviewer(s), if applicable and opens the discussion;

6.4. IRB Staff is responsible for the following:

Before the meeting:

6.4.1. Advise PI and research staff in preparation and completion of the application process;

6.4.2. Conduct a pre-review of the application and supporting documents to identify non-scientific issues;

6.4.3. Ensure all applicable documents have been provided;

6.4.4. Submit concerns to the study team for incomplete submissions, clarifications or minor changes to allow for review by the fully convened IRB;

6.4.5. Schedule full board review applications to the next available convened IRB meeting;

6.4.6. Assign full board review applications to a primary and secondary reviewer(s) (when applicable);

6.4.7. Ensure IRB has adequate representation during the evaluation of the proposed human subjects research;

During the meeting:

6.4.8. Take attendance at the meeting and record voting members present and absent using the quorum worksheet.

6.4.9. Record late arrivals, early departures, and individuals recused or out of the room for one reason or another during the discussion and vote on each protocol

6.4.10. Record the minutes

6.4.11. Navigate the eProtocol system during the discussions

7. References:

7.1. 45 CFR 46

7.2. 21 CFR 56

7.3. "Criteria for approval" Worksheet

7.4. MHC_RP0109 "*Criteria for IRB Approval of Research*"

7.5. MHC_RP0126 "*Conflict of Interest: IRB Members*"

7.6. Appendix I "*Definitions*"

8. Previous Revisions: August 8, 2012, March 28, 2013, September 18, 2013

9. Supersedes Policy: *MHC_RP_0114 Full Board Review of Human Subject Research*

10. Approvals:

MHC Institutional Review Board initial approval:	July 20, 2012
MHC Institutional Review Board acknowledgment:	September 20, 2013 November 20, 2015

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