McLaren HEALTH CARE		Policy Title:	Full Board Review of Human Subject Research
Effective Date:	July 20, 2012	**Policy Number:**	MHC_RP0108
Review Date:	November 1, 2021	**Section:**	Research Integrity
Revised Date:	March 22, 2024	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Official, HRPP		

1.0 **Purpose**

1.1 The purpose of this policy is to define the procedures for the McLaren Health Care (MHC) Institutional Review Board (IRB) at a convened IRB that applies to initial review, continuing review as well as amendments to research protocols that are not exempt, that do not qualify for expedited review procedures, or that may qualify for expedited review.

2.0 **Scope**

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

3.0 **Definitions**

3.1 Refer to Appendix I "Definitions"

4.0 **Policy**

4.1 The MHC IRB must review all non-exempt human subject research and clinical investigations at a convened meeting where 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, is present accept when the research is eligible for review using expedited review procedures.

4.2 Full Board review is required for:

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

4.2.2 Modifications to Full-board protocols that are not minor change(s).

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

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 initially reviewed by the fully convened board 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.

5.0 **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 IRB electronic application system.

5.1.1.1 Agenda list for the upcoming meeting, typically contains:

5.1.1.1.1 A statement on confidentiality of meetings.
5.1.1.1.2 Conflict of interest statements.
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 were reviewed and recommended for approval via expedited review procedures prior to the publication of the agenda, and do not need to be presented at a convened meeting.
5.1.1.1.8 Other items such as findings on reports which do not require presentation at the convened meeting.
5.1.1.1.9 Minutes from the previous corresponding meeting.
5.1.1.1.10 Any other supporting documentation related to the upcoming meeting.

5.1.2 Once the agenda is published through the IRB electronic system and all members can access to view the protocol materials to be presented.

5.1.3 Members participating remotely have electronic access to the same meeting material as members who attend in-person.

5.1.4 The IRB meeting is scheduled for 2 hours and can review approximately 5-10 studies. Actual meeting time will vary depending 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 Pre-Review

5.2.1 An application must be completed and submitted using the IRB electronic application system.

5.2.2 IRB staff advise PI and research staff in preparation and completion of the application process.

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

5.2.4 IRB staff conduct a pre-review of the application and supporting documents to identify non-scientific issues.

5.2.5 IRB staff submit concerns to the study team for incomplete submissions, clarifications, or minor changes to allow for review by the fully convened IRB.

5.2.6 IRB staff evaluates the protocol to determine whether a consultant is needed and notifies the IRB chair or the Corporate Manager of Research Integrity (See this policy Appendix B - Guidelines on "Use of Consultants")

5.2.7 IRB staff verifies current training for researchers and research staff listed on the application. IRB staff will notify the principal investigator (PI) of any individuals without current training.

5.2.8 IRB staff verifies whether the application was submitted by the PI or by someone else. If the application was submitted by someone other than the PI, a copy of the assurance page signed and dated by the PI is required.

5.2.9 The investigator will be informed either via IRB electronic application system or e-mail of missing materials.

5.2.10 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 process, 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 **Full Board Assignment**

5.4.1 IRB staff will schedule full board review applications for the next available convened IRB meeting.

5.5 **Assignment and Material Distribution**

5.5.1 After it has been determined that the protocol submission is complete, the IRB staff. will assign protocols for review *to primary reviewer and one or more secondary reviewers* (if needed) to the research. (See this policy Appendix A - Assignment of Reviewers).

5.5.2 Primary and Secondary Reviewers are responsible for the following:

5.5.2.1 Having thorough knowledge of all the details of the proposed research.

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

5.5.2.2 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.”

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

5.5.2.2 Exercising the authority to 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.

5.5.2.3 Exercising the authority to vote on the final determinations of those recommendations.

5.5.3 A primary reviewer will be used for full board review. Note: while a primary reviewer will be used, a majority of members present at the convened IRB meeting must vote for approval of the research study for the research to be approved.

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

5.5.5 If reviewers are absent from the meeting, a new reviewer may be assigned, provided the new reviewer has studied the materials prior to the meeting. Additionally, an absent reviewer can submit written comments for presentation at the convened meeting, as long as there is another reviewer present at the convened meeting.

NOTE: all the IRB members receive, and are expected to review all studies, not just those which they were assigned for review.

5.5.6 If a reviewer is absent, they may submit comments in IRB, the electronic application system indicating a recommendation for approval. However, such a recommendation will not be counted as a vote.

5.5.7 Reviewers typically have 7 days to review the research study.

5.5.8 IRB staff members consult with the IRB Chair or Corporate Manager of Research Integrity as necessary when making reviewer assignments.

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

5.5.10 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.

5.6 **Pre-Meeting Distribution of Documents**

5.6.1 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 to allow sufficient time for the review process. Materials will include the IRB agenda, meeting minutes, applicable business and education material, and protocol review materials.

5.6.2 Comments may be sent to the investigators from any members of the IRB via the IRB electronic application system at any time prior to the meeting.

Material Received by the IRB

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

5.6.4 If a reviewer requires additional information to complete the review, they may either contact the investigator directly, or post their comments in (Electronic IRB software system).

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

Initial Review

5.6.6 The following materials are required for initial review of all types of research:

5.6.6.1 Completed IRB Application

5.6.6.2 The complete protocol (when one exists)

5.6.6.3 Recruitment (if applicable, HIPAA request for waiver for recruitment and Screening materials)

5.6.6.4 All subject information

5.6.6.5 Proposed Informed Consent / Parental Permission / Assent Form(s) (when applicable) Document(s) (if applicable) of request for waiver of consent.

5.6.6.6 Investigator Drug Brochure or Information for Use (when one exist) or explanation for exemption from IND or IDE regulation and documentation of pharmacy oversight of investigational drug, if applicable

5.6.6.7 Product labeling, if applicable for drugs

5.6.6.8 Evidence of scientific or scholarly review if completed by another entity if you wish IRB to defer to this review.

Social-Behavioral Research Components

5.6.6.9 Investigator-authored Psychological or Educational Measures

5.6.6.10 Investigator-authored Surveys, Questionnaires

Biomedical Research Components

5.6.6.11 Investigator's Drug Brochure or Package Insert

5.6.6.12 Device Brochure and/or another device information

Sponsored Research

5.6.6.13 Detailed Sponsor's Protocol

5.6.6.14 Relevant Grant Applications or Contracts

5.6.6.15 For HHS-supported multi-center trials: HHS-approved Consent Forms and Protocol

Other

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

5.6.6.17 Any additional documentation the Investigator deems pertinent.

Review of Substantive Revisions Required by IRB

5.6.6.18 Response from investigator addressing substantive revisions required by the IRB.

5.6.6.19 Revised protocol in "track changes" format, or other document describing where in the protocol the change has been applied, as applicable.

5.6.6.20 Revised consent/authorization form(s) in both "track changes" and clean copy format, as applicable

5.6.6.21 Any other documentation requested by the IRB at its prior review.

Continuing Review

5.6.7 Completed Continuing Review Application

5.6.8 A summary of the protocol and any amendments, and access to the full protocol, including all modifications to date

5.6.9 Any relevant multi-center reports

5.6.10 Status report on the progress of the research, including:
- 5.6.10.1 the number of participants screened for the research project.
- 5.6.10.2 the number of participants found ineligible for the research.
- 5.6.10.3 the number of participants enrolled (accrued)
- 5.6.10.4 a summary of anticipated adverse events that have occurred at a frequency or magnitude greater than anticipated.
- 5.6.10.5 a description of any unanticipated problems involving risks to participants or others and of any serious, unanticipated adverse events which have not previously been provided to the IRB.
- 5.6.10.6 a summary of any withdrawal of participants from or complaints about the research
- 5.6.10.7 a summary of any lost-to-follow-up participants from the research
- 5.6.10.8 a summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research.
- 5.6.10.9 a copy of the current informed consent document(s)
- 5.6.10.10 a summary of protocol deviations

5.6.11 Current and any proposed recruitment and screening materials

5.6.12 Current and any proposed Informed consent document(s)

5.6.13 Any related post approval reports - reports from data and safety monitoring committees, outside agencies or bodies (for example, any Food and Drug Administration (FDA) or cooperative group audit or monitoring visit) if applicable.

5.6.14 Any additional pertinent documentation requested by the IRB.

5.6.15 Modifications

5.6.16 The following materials are required for amendments to approved/exempted research:
- 5.6.16.1 Completed Amendment application.
- 5.6.16.2 Detailed description of proposed changes
- 5.6.16.3 Revised protocol if applicable, in “track changes”
- 5.6.16.4 Relevant modified study documents

5.6.16.5 Recruitment Materials, Screening Materials, and Consent Documents, as applicable

5.6.16.6 Revised consent/authorization form(s) in “track changes” format, if applicable.

5.6.16.7 Any additional pertinent documentation requested by IRB.

Adverse Events, Reports of Unanticipated Problems Involving Risks to Participants or Others, Protocol Deviations and Non-compliance

5.6.17 Completed adverse event, unanticipated problems involving risks to participants or others, protocol deviations or noncompliance report form(s)

5.6.18 Proposed corrective action plan, if applicable

5.6.19 Revised consent form and revised protocol (if applicable), with rationale for change

5.6.20 Any additional pertinent documentation requested by IRB.

5.6.21 All IRB members will have an opportunity to ask questions and post their comments (if any) prior to 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.

5.7.2 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.

5.7.3 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.

5.7.4 All members are able to participate actively and equally in all discussions.

5.7.5 When the IRB reviews research involving participants vulnerable to coercion or undue influence, one or more individuals (e.g., IRB members or consultant) who are knowledgeable about or experienced in working with such participants are present (see MHC_RP0116 Vulnerable Subjects in Research.

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

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

5.7.8 The IRB chair will be responsible for ensuring that the meetings remain appropriately convened.

5.7.9 If the quorum fails during a meeting, such as due to lack of most 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.

5.7.10 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.

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

5.7.12 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.

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

- 5.7.13.1 Total number voting
- 5.7.13.2 Number for
- 5.7.13.3 Number opposed
- 5.7.13.4 Number abstaining

5.7.13.5 Names of those abstaining
5.7.13.6 Names of those recusing

5.7.14 Votes are indicated by voice vote or show of hands.
5.7.14.1 Votes for members attending via teleconference are polled by names.

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

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

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

5.7.18 Ad hoc consultants may not vote with the IRB.

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

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

5.7.21 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.

5.7.22 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 Research Integrity website for the benefit of all investigators, research coordinators and other research staff when submitting protocol materials. Additionally, this information is available in the Research Integrity office.

5.8.4 Special meetings are a full board determination must be made prior to the next regularly scheduled IRB meeting, a special IRB meeting

may be convened, for which one or more members of the IRB may participate by teleconference, videoconference, or electronically and shall be counted toward meeting quorum. This process requires that all attendees receive all pertinent information and can actively and equally participate in the discussion of all protocols, and that meeting minutes state this for the record. may be called at any time by the IRB chair or the Corporate Research Integrity Manager.

5.9 **Meeting Procedures**

5.9.1 IRB staff will take attendance at the meeting and record voting members present and absent using the quorum worksheet.

5.9.2 IRB staff will 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.

5.9.3 IRB staff will navigate the IRB electronic application system during the discussions.

5.9.4 IRB Chair will lead the discussion of each protocol, continuing review, or amendment listed on the meeting agenda.

5.9.5 The IRB chair, or vice-chair if the IRB chair is absent, will call the meeting to order, once it has been determined that a quorum is in place.

5.9.6 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.

5.9.7 IRB members leaving the meeting room or tele/audio conference due to a conflicting interest will be contacted and informed to rejoin by phone.

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

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

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

5.9.8.3 Final minutes will be signed by the IRB chair or vice-chair (when applicable) and the Corporate Manager of Research Integrity.

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

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

5.9.10 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 the "criteria for approval" checklist.

5.9.11 All members including IRB chair present at a convened meeting have full voting rights, except in the case of a conflict of interest or if primary member's alternate member is present, only the primary member can vote.

5.9.12 For the research to be approved, it must receive the approval of most of those voting members present at the meeting.

5.9.13 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.

5.9.14 Protocol materials are available online, via the web-based "IRB electronic application system" system:

5.9.14.1 The protocol materials are provided via projection system or webinar format during the meeting.

5.9.15 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 PI may be invited to the IRB meeting to answer questions about their proposed or ongoing research.

5.10.2 The PI may not be present for the discussion or vote on their research.

5.10.3 Ex-officio guests are individuals who, by virtue of their position and their role in the HRPP, occasionally attend IRB meetings.
5.10.3.1 Ex-officio guests include the institutional official.
5.10.3.2 Ex-officio guests may fully participate in the IRB discussion and deliberations but may not vote.

5.10.4 Other guests may be permitted to attend IRB meetings at the discretion of the IRB chair and the Corporate Manager of Research Integrity.

5.10.5 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 IRB electronic application system.

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 or prescriptive. May not be used for substantive changes or requirements or requests for more information that are necessary for the IRB to be able to determine whether the criteria for approval are satisfied.

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.

The approval date:

5.11.1.2.2 Once the stipulations have been verified by the IRB Chair or designee the date of IRB approval is the date of the convened IRB meeting.

5.11.1.2.3 When a research study is approved subject to stipulations, the date of expiration is one year

from the date of the convened meeting (minus one day). It is not calculated from the date that the IRB chair or designee verifies the requested changes and grants final approval. The approval period expires at 11:59 p.m. on the expiration date set forth in the IRB approval letter.

5.11.1.2.4 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.

5.11.1.2.5 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 for the IRB to decide.

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 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.

5.11.1.4.3 A new application must address all previous concerns outlined by the IRB for the previously disapproved protocol.

5.11.1.5 **Suspension of IRB Approval**: An action of the IRB or Organizational Official to withdraw IRB approval of some temporarily or permanently 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 IRB electronic application system when the PI requests to retract a submission.

5.11.1.8.1 Withdrawn studies will be removed from the IRB electronic application 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 Post Meeting Record Keeping and Notification

5.12.1 The IRB minutes will include a summary of the IRB's discussion and resolution of substantive issues as well as any specific determinations made with regard to risk level, review period, consent waivers or inclusion of participants requiring additional protections. Minutes must also include a tally of the votes by category (for, against, and abstaining) as well as the names of individuals who recused themselves from the discussion and vote due to a potential conflict of interest.

5.12.2 The IRB's decisions regarding protocols will be documented and sent to the principal investigator and any indicated correspondent(s) within 2 business days.

5.12.2.1 Correspondence related to approved studies will indicate:
- 5.12.2.1.1 the approval period and the investigator's responsibilities during the approval (e.g., adverse event reporting, amendment requests, etc.)
- 5.12.2.1.2 documents or request approved or acknowledged.
- 5.12.2.1.3 a reminder to use only the approved consent/assent form, and
- 5.12.2.1.4 a reminder that the IRB must approve any changes to the protocol prior to initiation of the changes.

5.12.2.2 Correspondence **on protocols that have not been approved** will provide a detailed description of the IRB's concerns and reasons for not approving the protocol.

- 5.12.2.2.1 Correspondence on protocols that are **Approved with Contingencies**: will provide a detailed description of the IRB's stipulations pending full approval of the IRB.

5.12.2.3 **Before issuing the IRB approval letter**, IRB staff confirm that:
- 5.12.2.3.1 All the applicable Ancillary Committees approvals are in place. If applicable approvals are not in place, IRB staff notify the investigator in writing, requesting the appropriate information.

- 5.12.2.3.2 All study personnel have completed the required human subject protection training. If the PI and study personnel have not completed training, IRB staff notify the PI. All study personnel must complete required training before the IRB can issue approval.

- 5.12.2.3.3 Before issuing approval, IRB staff verify that any pending IND or IDE has been approved by the FDA or has passed the 30-calendar day FDA clearance period. If the IND or IDE submission is pending acknowledgment of receipt by the FDA, or the 30-calendar day clearance period has not passed, the IRB stipulates in the IRB approval letter that research must not commence until IND or IDE is in place. The PI provides IRB with FDA correspondence confirming that the IND or IDE is

in place, or the 30-calendar day period has passed, prior to initiating the research.

5.12.3 Minutes and protocol correspondence are always available to the Institutional Official. Summaries of IRB activities will be made available to the Institutional Official and VP of Clinical Excellence and Research upon demand. A copy of finalized signed minutes from each convened meeting are forwarded to Institutional Official and individuals determined by IO and VP of Clinical Excellence and Research.

6.0 **References:**

6.1 45 CFR 46
6.2 21 CFR 56
6.3 " Criteria for approval" Worksheet
6.4 MHC_RP0109 "Criteria for IRB Approval of Research"
6.5 MHC_RP0126 "Conflict of Interest: IRB Members"
6.6 Appendix I "Definitions"

7.0 **Previous Revisions:** 8/8/12, 3/28/13, 9/18/13, 11/20/15, 8/6/20, 12/14/21, 1/12/23

8.0 **Supersedes Policy:** MHC_RP0114 Full Board Review of Human Subject Research

9.0 **Approvals:**

MHC Institutional Review Board initial approval: 7/20/12

MHC Institutional Review Board acknowledgment: 9/20/13, 11/20/15

Signature on File *3/22/2024*

_____ _____

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

Appendix A Assignment of Reviewers

Reviewer Selection Research requiring convened MHC IRB review is assigned to primary and secondary reviewers based on conditions described below.

A. Number of Reviewers

1. IRB staff assign one primary and one or more secondary reviewer (if needed) for all submissions scheduled for convened review, including initial, continuing review, amendment, and event report submissions. IRB staff may add reviewers for additional expertise, as necessary.

2. Both the primary and secondary reviewer(s) are expected to perform an in-depth review of the research. The primary reviewer leads the IRB's discussion of the protocol, providing a summary of the research and potential concerns, if any. The secondary reviewer(s) provides additional comments or information before full Board discussion. Materials that are distributed to assigned reviewers and all other IRB members are listed in HRPP policy MHC_RP0109 Full Board of Human Subject Research

B. Reviewer Expertise

1. When making reviewer assignments, the IRB staff member considers the following:
    - Reviewer's scientific and/or scholarly expertise
    - Reviewer experience status "experienced vs. non experienced"
    - Reviewer's status as scientist or nonscientist
    - Reviewer workload
    - Potential conflicts of interest (as defined in HRPP policy HRPP policy [MHC_RP0126 COI for IRB Members
    - The need for special representation (e.g., vulnerable populations).

2. IRB staff consult with the IRB Chair as necessary when making reviewer assignments. The Chair may reassign the review of research as he/she determines to be appropriate.

3. When the research involves a vulnerable category of participants (e.g., children), a reviewer knowledgeable about and experienced in working with these participants will be selected.

Appendix B Use of Consultants

1. When necessary, the IRB chair or the Corporate Manager of Research Integrity may solicit individuals from any of the McLaren subsidiary hospitals or the community with competence in special areas to assist in the review of issues or protocols, which require appropriate **scientific, scholarly, or other (e.g., experience with a population)** expertise beyond or in addition to that available on the IRB.

2. The need for an outside reviewer is determined in advance of the meeting by the IRB chair or the Corporate Manager of Research Integrity by reviewing the protocols scheduled to be reviewed at the convened meeting.

3. If necessary, the IRB will defer to another meeting or obtain 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.

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

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

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

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

8. The Corporate Manager of Research Integrity reviews the conflicting interest policy for IRB members with consultants and consultants must verbally confirm to the Manager that they do not have a conflict of interest prior to review.

9. 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.

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

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

12. 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 PI and research protocol).

    a. The member who sought the ad hoc consultation is responsible for sharing the information with the IRB.