McLaren HEALTH CARE		Policy Title:	IRB Documentation and Research Record Retention
Effective Date:	July 20, 2012	**Policy Number:**	MHC_RP0114
Review Date:	August 12, 2020	**Section:**	Research Integrity
Revised Date:	March 22, 2024	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Official, HRPP		

1. Purpose

1.1.1. To provide guidance on preparation and maintenance of IRB documentation of activities of McLaren Health Care Institutional Review Board (MHC IRB) associated with its oversight of research per 45 CFR 46.115, 21 CFR 56.115 "An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities".

1.1.2. To establish guidelines for the identification, retention, and disposal of regulatory files and research records held by the MHC Investigators in accordance with federal regulations, state and local laws, and institutional policies.

2. Scope

2.1. This policy applies to all **Human Subjects Research** records, including investigator files for studies conducted at MHC and its subsidiary hospitals, regardless of whether participants were enrolled.

3. Definitions

3.1. Refer to Appendix I *"Definitions"*

4. Policy

4.1. IRB Records:

4.1.1. The IRB maintains a complete set of materials relevant to the review of the research protocol or plan for a period sufficient to comply with legal and regulatory requirements, sponsor requirements, organizational policies, and procedures.

4.1.2. Although exempt studies would be exempt from the record-keeping requirements of the Common Rule, they are not exempt from the record-keeping requirements of HIPAA, funders, journals, etc.

4.2. IRB Minutes:

4.2.1. The IRB documents discussions and decisions on research studies and activities in accordance with legal and regulatory requirements, sponsor requirements (if any), and organizational policies and procedures.

4.3. All records must be accessible for inspection and copying by authorized representatives of the FDA, OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

4.4. IRB and Research Record Retention:

4.4.1. In accordance with the Common Rule and FDA regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)), IRB records are retained for at least three years after the completion of the research, either electronically or as a hard copy.

4.4.2. In accordance with federal HIPAA privacy regulations, IRB records pertaining to records containing protected health information (PHI) are retained for at least six years after the completion of the research.

4.4.3. It is MHC's policy to retain records for the greatest amount of mandated time. Thus, all research records, including investigator study files and records for studies cancelled without participant enrollment must be retained for at least 7 years.

4.4.3.1. All records will be destroyed after 7 years.

4.4.3.2. Sponsored grants and contracts may require additional periods for record retention.

4.4.4. Other documents, such as IRB agendas and IRB minutes for the current IRB year are maintained in the Research Integrity office. Periodically, these documents are sent to an external vendor for long-term storage.

4.4.5. General correspondence from investigators and other documents not specific to a particular research protocol are maintained indefinitely in the Research Integrity office.

4.5. Accreditation of Human Research Protection Programs (AAHRPP) Records Retention:

4.5.1. Applications, reports, and other documents from site visits resulting in accreditation will be kept for 10 years from the date of accreditation.

4.5.2. Applications, reports, and other documents from site visits not resulting in accreditation are kept for three years from the date of the decision to withhold accreditation unless the organization has reapplied for accreditation and the

application results in accreditation. Records will then be kept for 10 years from the date of accreditation.

4.6. Research Conflict of Interest (COI) Committee Records Retention:

4.6.1. All committee meetings and communication will be retained for at least 7 years.

4.6.2. All decisions regarding review of financial disclosures and determinations of FCOI and management plans will also be retained for at least 7 years.

5. Procedure

5.1. As of January 2012 MHC IRB, became the IRB for, and accepted oversight of all human subject research for McLaren Health Care and its subsidiary hospitals as of January of 2012.

5.1.1. All IRB files from previous IRBs were transferred to MHC IRB.

5.2. IRB Records:

5.2.1. IRB records include, but are not limited to:

5.2.1.1. Written operating procedures.

5.2.1.2. IRB membership rosters.

5.2.1.3. Resumes, CVs, Bio sketches or similar documentation for each IRB member.

5.2.1.4. Training records.

5.2.1.4.1. The IRB staff maintains accurate records listing research investigators, IRB members, and IRB staff that have fulfilled the facility's human subject training requirements.

5.2.1.4.2. Training certificates for all investigators, research staff, and IRB members are uploaded into the iRIS system.

5.2.1.4.3. Additionally, training certificates for IRB members are filed in their respective IRB member file and kept in the Research Integrity office.

5.2.1.5. IRB study files.

5.2.1.6. Documentation of exemptions.

5.2.1.7. Documentation of convened IRB meetings minutes.

5.2.1.8. IRB authorization agreements and letter(s) of resolution.

5.2.1.9. Federal wide assurances.

5.2.1.10. Protocol violations or exceptions submitted to the IRB.

5.2.1.11. Quality assurance reviews.

5.3. IRB Study Files:

5.3.1. Applications submitted on or after January 23, 2012, are maintained via the iRIS submission system, by MHC. Each protocol file is organized to allow a reconstruction of a complete history of all IRB events related to the review and approval of the protocol submitted to MHC IRB.

5.3.2. Electronic records of all documentation related to every protocol event submitted is maintained in the iRIS system. The system also contains a search function for locating and retrieving protocols.

5.3.3. Electronic copies of all materials submitted to the IRB can be accessed on an event-by-event basis. This may include, but is not limited to:

5.3.3.1. Protocol application forms. The protocol file includes one or more of the following application types.

5.3.3.1.1. Initial protocol application for medical or nonmedical research (full board, expedited, and exempt review) - submitted for all new research projects.

5.3.3.1.2. Modification Form - submitted for changes to approved research.

5.3.3.1.3. Continuing Review Form - submitted for continuing review of research.

5.3.3.1.4. Final Report Form – submitted upon completion of research project, including data analysis.

5.3.3.1.5. Protocol Violation/Exception Form.

5.3.3.1.6. Unanticipated problem report form.

5.3.3.2. Protocol and all supporting documentation submitted as part of a new application, including:

5.3.3.2.1. Proposed consent / parental permission / assent forms (when applicable)

5.3.3.2.2. Recruitment materials / subject information (when applicable)

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

5.3.3.2.4. Investigator brochure (if applicable)

5.3.3.2.5. The complete protocol (when one exists)

5.3.3.2.6. Scientific evaluations, when provided by an entity other than the IRB.

5.3.3.3. All documentation submitted as part of a request for continuing review/termination of research application.

5.3.3.4. IRB comments and investigator responses that occurred during IRB review are included with each application. This may include correspondence done via iRIS or exchanged via fax or email. Fax and email correspondence will be included as attachments.

5.3.3.5. IRB-approved consent forms.

5.3.3.6. DHHS-approved sample consent forms and protocol documents, when applicable.

5.3.3.7. For expedited review:

5.3.3.7.1. Records must include the rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.

5.3.3.7.2. IRB records for initial and continuing review of research by the expedited procedure include:

5.3.3.7.2.1. The justification for using the expedited procedure.

5.3.3.7.3. The rationale for conducting continuing review of research that otherwise would not require continuing review.

5.3.3.7.4. The rationale for a determination that research appearing on the list of eligible expedited review categories is greater than minimal risk.

5.3.3.7.5. Actions taken by the reviewer.

5.3.3.7.6. Any findings required by laws, regulations, codes, and guidance to be documented.

5.3.3.8. Notification to the PI of expiration of IRB approval and instructions for submitting relevant continuing review materials.

5.3.3.9. Notification of suspension of research.

5.3.3.10. Correspondence pertaining to appeals.

5.3.3.11. Copies of approval letters and forms that describe what must be in place before research activity for the study may begin.

5.3.3.12. IRB correspondence to and from research investigators.

5.3.3.13. All other IRB correspondence related to the research.

5.3.3.14. For devices, documentation of IRB determination of significant risk/non-significant risk and a report of prior investigations.

5.3.3.15. Reports related to unanticipated problems involving risk to subjects or others, and adverse events.

5.3.3.16. Copies of reports of injuries to participants.

5.3.3.17. Progress reports submitted by investigators.

5.3.3.18. Documentation of non-compliance.

5.3.3.19. Documentation of audits, investigations, reports of external site visits.

5.3.3.20. Data and safety monitoring reports.

5.3.3.21. Significant new findings regarding the research.

5.3.3.22. Justification for using the expedited procedure for continuing review of research, when applicable.

5.3.4. Event History – provides access to all documents supporting each protocol event to reconstruct the entire history of a protocol.

5.3.5. MHC IRB will not revise or reorganize files that were approved by the original IRB(s).

5.4. IRB Minutes:

5.4.1. Proceedings are written and available for review by the next regularly scheduled IRB meeting date.

5.4.2. Once reviewed and acknowledged by members at a subsequent IRB meeting, the minutes must not be altered by anyone including a higher institutional authority.

5.4.3. Minutes of IRB meetings must contain sufficient detail to show:

5.4.3.1. Attendance.

5.4.3.2. Names of members present. Including **each attending member's or alternate's representative capacity (e.g., scientist, non-scientist, unaffiliated, member who represent the general perspective of research participants).**

5.4.3.3. Names of members or alternate members who are participating via videoconference or teleconference.

5.4.3.4. Names of alternates attending in lieu of specified (named) absent members. NOTE: Alternates may only substitute absent members as designated on the official IRB membership roster.

5.4.3.5. Names of consultants' present. Including a brief description of the consultant's expertise and documentation that the consultant did not vote.

5.4.3.6. Names of guests present, including investigators, when present.

Note: *The minutes will indicate, by name, those members who enter or leave the meeting. The vote on each action will reflect those members present for the vote on that item. Members who recuse themselves because of conflict of interest are listed by name and the reason documented.*

5.4.3.7. Names of IRB support IRB/HRPP support staff.

5.4.3.8. The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area.

5.4.3.9. Business items discussed with sufficient information to identify the research activities being reviewed.

5.4.3.10. Continuing education.

5.4.3.11. Deliberations, actions taken, and votes for each protocol undergoing initial review, continuing review, or review of modifications by the convened IRB.

5.4.3.12. Detail of member votes on each action: total number of members voting; number voting for; number voting opposing; number abstaining; number of those recused. When a member recuses or abstains from the vote, the minutes will reflect their name and justification for doing so.

5.4.3.13. Basis or justification for these actions including required changes in research.

5.4.3.14. Basis for disapproving research.

5.4.3.15. Summary of controverted issues and their resolution.

5.4.3.16. Approval period for initial and continuing approved protocols, including identification of research that warrants review more often than annually and the basis for that determination.

5.4.3.17. Rationale for conducting continuing review on research that otherwise would not require continuing review.

5.4.3.18. Risk level of initial and continuing approved protocols.

5.4.3.19. Review of interim reports (e.g., unanticipated problems or safety reports; amendments; report of violation; serious or continuing non-compliance; suspensions/terminations, etc.

5.4.3.20. Review of data and safety monitoring board (DSMB) summary.

5.4.3.21. Review of plans for data and safety monitoring.

5.4.3.22. Justification for deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.

5.4.3.23. The ICF was reviewed and determined to meet applicable regulatory requirements.

5.4.3.24. Protocol- specific documentation indicating that the research meets the required criteria [45 CFR 46.116(d)] when approving a consent procedure that does not include or that alters some or all the required elements of informed consent, or when waiving the requirement to obtain an informed consent.

5.4.3.25. Protocol-specific documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived.

5.4.3.26. When approving research that involves populations covered by Subparts B, C, or D of 45 CFR 46, the minutes will document the IRB's justifications and findings regarding the determinations stated in the subparts or the IRB's agreement with the findings and justifications as presented by the investigator.

5.4.3.27. Special protections warranted for other subject populations that are likely to be vulnerable to coercion or undue influence, such as mentally disabled, or economically or educationally disadvantaged persons or persons unable to or with diminished capacity to consent regardless of source of support for the research.

5.4.3.28. Rationale for significant risk/non-significant risk device determinations.

5.4.3.29. Determinations of conflict of interest.

5.4.3.30. Any other determinations required by applicable law, regulations, code, or guidance.

5.4.3.31. Identification of any research for which there is need for verification from sources other than the investigator that no material changes are made in the research.

5.4.3.32. A list of research projects approved since the last meeting via expedited review procedures, listed as informational items.

5.4.3.33. When an IRB member has a conflicting interest with the research under review, the minutes will indicate that the IRB member was not present during the deliberations or voting on the proposal, and that quorum was maintained.

5.4.3.34. Key information provided by consultants will be documented in the minutes or in a report provided by the consultant.

5.4.4. The minutes of convened IRB meetings are considered confidential, and access to them is secured.

5.5. IRB Membership Roster:

5.5.1. A membership list of IRB members must be maintained and must contain the following member information:

5.5.1.1. Name

5.5.1.2. Earned Degrees

5.5.1.3. Status as scientist (physician-scientist, another scientist, non-scientist, or social behavioral scientist).

5.5.1.3.1. The roster will designate IRB members with research experience as scientists (including students). Research experience includes training in research (e.g., doctoral degrees with a research-based thesis) and previous or current conduct of research. Students being trained in research fields will also be designated as scientists.

5.5.1.4. Indications of experience, such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations.

5.5.1.5. Unaffiliated status - Neither the member nor an immediate family member of the member is affiliated with the MHC or any of the subsidiary hospitals.

5.5.1.6. Representative capacities of each IRB member: prisoner representative (as required by Subpart C), knowledgeable about or experienced in working with children, pregnant women, cognitively impaired individuals, and other vulnerable populations locally involved in research.

5.5.1.7. Role on the IRB (Chairman, Vice-Chair, etc.).

5.5.1.8. Voting status.

5.5.1.9. For alternate members, the primary member or class of members for whom the member could substitute.

5.5.1.10. The Research Integrity office will keep the IRB membership list current.

5.5.1.11. The Director of Corporate Research Administration will promptly report changes in IRB membership to the DHHS Office for Human Research Protections.

5.6. Access to IRB Records

5.6.1. Hard copy records of closed protocols will be sent to an external vendor for long-term storage. Access to those materials can be obtained in 48 hours or less, if necessary.

5.6.2. The iRIS system resides on a secured server, with password-protected access.

5.6.2.1. Ordinarily, access to all IRB records is limited to the Director of Corporate Research Administration, IRB Chair, IRB members, IRB staff, authorized institutional officials and officials of federal and state regulatory agencies (OHRP, FDA).

5.6.2.2. Research investigators are provided reasonable access to files related to their research.

5.6.2.3. Appropriate accrediting bodies are provided access and may recommend additional procedures for maintaining security of IRB records.

5.6.3. All other access to IRB records is limited to those who have legitimate need for access, as determined by the IO and Director of Corporate Research Administration.

5.6.4. Records are accessible for inspection and copying by authorized representatives of federal regulatory agencies during regular business hours.

5.6.5. Records may not be removed from the Research Integrity office; however, the IRB staff will provide copies of records for authorized personnel if requested.

5.6.6. Access to IRB study files outside of those which is listed above is prohibited.

6. Responsibilities:

6.1. IRB Staff

6.1.1. Will maintain a full set of materials for all research that is reviewed and approved by the MHC IRB.

6.1.2. Will maintain records for a minimum of seven (7) years after IRB closure of the study.

6.2. Investigator:

6.2.1. Responsible for the collection, management, storage, and retention of research records.

6.2.2. The investigator should adopt an organized system of data collection and record retention and ensure compliance by all his/her direct reports regarding such data.

6.2.3. Maintain all research records (e.g., signed informed consent documents, source documents, case report forms, laboratory results, and regulatory binder documents) to allow for a complete accounting of study activity for a minimum of seven (7) years after the study is closed by the MHC IRB.

6.2.4. Must make research records available for review by the IRB within a reasonable period upon request.

6.2.5. If required by study sponsors, federal agencies, or internal policy the PI must maintain records for an alternative period.

6.2.5.1. Investigators must be familiar with these requirements and maintain all research records for the period which meets the requirements of all parties.

6.2.5.2. This period cannot be less than the *seven (7)* years as required by MHC Policy.

6.2.6. All research records for externally funded research must be maintained for the period specified by the study sponsor and no less than seven (7) years.

6.2.7. Must ensure record retention and accessibility requirements of the FDA are met for research involving investigational drugs, biological products, and other test articles under the regulation of the Food and Drug Administration (FDA).

6.2.7.1. The FDA requires sponsors and investigators to retain records and reports for 2 years after a marketing application is approved for the drug; or if an application is not approved for the drug, until 2 years after shipment and

delivery of the drug for investigational use is discontinued and the FDA so notified. [21 CFR 312.62(c)].

6.2.8. For research involving investigational devices, the FDA requires the sponsor and/or investigator to maintain records "for a period of 2 years after the latter of the following two dates:

6.2.8.1. The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a remarket approval application or a notice of completion of a product development protocol. [21 CFR 812.140 (d)]; and

6.2.9. The PI should be aware of any additional specific contractual obligations associated with record retention and accessibility.

6.2.9.1. The PI should review their contract, grant, or other sponsor agreement for these requirements.

7. References:

7.1. 45 CFR 46.115

7.2. 21 CFR 56.115

7.3. 21 CFR 812.140 (d)

7.4. 21 CFR 312.62 (c)

7.5. Appendix I "Definitions"

8. Previous Revisions: 11/19/12, 11/16/15, 2/12/16, 11/25/21, 1/12/23

9. Supersedes Policy: MHC_RP0105 IRB Documentation and Records

10. Approvals:

MHC Institutional Review Board initial approval: July 20, 2012

MHC Institutional Review Board acknowledgment: 12/4/15, 4/14/16

Signature on File *3/22/2024*

Justin Klamerus, MD, MMM Date
Executive Vice President/Chief Clinical Officer
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