McLaren HEALTH CARE		**Policy Title:**	IRB Documentation and Research Record Retention
Effective Date:	July 20, 2012	**Policy Number:**	MHC_RP0114
Review Date:	April 14, 2016	**Section:**	Human Research Protections Program
Revised Date:	March 29, 2016	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is:

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 **non-Exempt** research records, including investigator files, for studies conducted at MHC and its subsidiary hospitals.

2.2. This policy applies to all **non-Exempt** research studies, whether or not 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 of time sufficient to comply with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.

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 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 including records for studies cancelled without participant enrollment must be retained for at least 7 years

4.4.3.1. After that time all records will be destroyed.

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 HRPP 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 HRPP 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 within the three-year period, reapplied for accreditation and the application results in Accreditation, in which case the records are 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. MHC IRB became an IRB of record and accepted oversight of all human subjected research for McLaren Health Care and it 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. Training records.

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

5.2.1.3.2. Training certificates for all Investigators and Research Staff are uploaded into eProtocol electronic submission system

5.2.1.3.3. Training certificates for IRB members are uploaded into eProtocol electronic submission system and also filed in the IRB member file and kept in the HRPP office.

5.2.1.4. IRB Study Files.

5.2.1.5. Documentation of exemptions.

5.2.1.6. Documentation of convened IRB meetings minutes.

5.2.1.7. Documentation of review by another institution's IRB when appropriate.

5.2.1.8. IRB Authorization Agreements and Letter(s) of Resolutions.

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. As of January 2012, the MHC employs an electronic protocol application system, "eProtocol".

5.3.2. The eProtocol system maintains electronic records of all documents submitted through the system for every protocol event. The eProtocol system contains a search function for locating and retrieving protocols by protocol number, protocol title, name of Principal Investigator, names of co-investigators, review type.

5.3.3. Electronic copies of all materials submitted to the IRB can be accessed through eProtocol on an event by event basis through the eProtocol which includes, but is not limited to:

5.3.3.1. Protocol Application(s). The protocol file includes one or more of the following application types:

5.3.3.1.1. Protocol Application for medical or nonmedical research (Regular, Expedited, and Exempt review) submitted for all new research projects;

5.3.3.1.2. Amendment Form, submitted for modifications to approved research;

5.3.3.1.3. Continuing Review Form, submitted for continuing review of research;

5.3.3.1.4. Final Report;

5.3.3.1.5. Protocol Violation/Exception Form;

5.3.3.1.6. Report Form.

5.3.3.2. Protocol and all other documents submitted as part of a new application, including:

5.3.3.2.1. Complete Protocol Application form

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

5.3.3.2.3. Recruitment materials / subject information (when applicable)

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

5.3.3.2.5. Investigator brochure (when one exists)

5.3.3.2.6. The complete protocol (when one exists)

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

5.3.3.3. If applicable, protocol and all other documents 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. When applicable, comments and responses exchanged via fax or email are also uploaded in eProtocol and included as attachments, or are stored in the hard copy file.

5.3.3.5. Copy of IRB-approved Consent Form.

5.3.3.6. DHHS-approved sample consent form document and protocol, when applicable.

5.3.3.7. IRB reviewer comments.

5.3.3.8. For expedited review, documentation of any determinations required by the regulations and protocol-specific findings supporting those determinations, including: waiver or alteration of the consent process,

research involving pregnant women, fetuses, and neonates, research involving prisoners, and research involving children.

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

5.3.3.10. Notification of suspension of research.

5.3.3.11. Correspondence pertaining to appeals.

5.3.3.12. Copies of approval letters and forms that describe what Principal Investigator must have before beginning the study.

5.3.3.13. IRB correspondence to and from research investigators.

5.3.3.14. All other IRB correspondence related to the research.

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

5.3.3.16. Reports of unanticipated problems involving risk to subjects or others and adverse events.

5.3.3.17. Copies of reports of injuries to participants.

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

5.3.3.19. Data and safety monitoring reports, if any.

5.3.3.20. Significant new findings.

5.3.3.21. The justification for using the expedited procedure for continuing review of research, if appropriate.

5.3.4. Event History function, thus all documents supporting each protocol event are accessible to reconstruct the entire history of a protocol.

5.3.5. Additionally, the MHC IRB office maintains a separate IRB paper file for each research protocol which includes but not limited to:

5.3.5.1. Protocol Application for medical or nonmedical research (Regular, Expedited and Exempt review) submitted for all new research projects;

5.3.5.2. Amendment Form, submitted for modifications to approved research;

5.3.5.3. Continuing Review Form, submitted for continuing review of research;

5.3.5.4. Final Report;

5.3.5.5. Protocol Violation/Exception Form;

5.3.5.6. Report Form;

5.3.5.7. Reviewer Checklists;

5.3.5.8. Copies of approval letters and forms that describe what Principal Investigator must have before beginning the study.

5.3.5.9. Copy of IRB-approved Consent Form.

5.3.5.10. E-mail correspondence between the IRB office and the Investigator and research staff.

5.3.6. Applications submitted on or after January 23, 2012 for each protocol file are organized to allow a reconstruction of a complete history of all IRB events related to the review and approval of the protocol that was submitted to MHC IRB.

5.3.7. MHC IRB will not go back to re-organize files that were approved by the original IRB(s).

5.4. The 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.

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

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

5.4.3.5. Names of consultants present.

5.4.3.6. Names of guests present, which includes 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. The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area.

5.4.3.8. Business Items discussed.

5.4.3.9. Continuing Education.

5.4.3.10. Actions taken, including separate deliberations, actions, and votes for each protocol undergoing initial review, continuing review, or review of modifications by the convened IRB.

5.4.3.11. Votes on these actions (Total Number Voting; Number voting for; Number voting opposing; Number abstaining; Number of those recused).

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

5.4.3.13. Summary of controverted issues and their resolution.

5.4.3.14. 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.

5.4.3.15. Risk level of initial and continuing approved protocols.

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

5.4.3.17. Review of Data and Safety Monitoring Board (DSMB) summary.

5.4.3.18. Review of Plans for Data and Safety Monitoring.

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

5.4.3.20. Protocol- specific documentation 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 of the required elements of informed consent, or when waiving the requirement to obtain an informed consent.

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

5.4.3.22. 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 on IRB forms.

5.4.3.23. Special protections warranted in for other groups of subjects who are likely to be vulnerable to coercion or undue influence, such as mentally disabled persons, or economically or educationally disadvantaged persons, regardless of source of support for the research.

5.4.3.24. The rationale for significant risk/non-significant risk device determinations.

5.4.3.25. Determinations of conflict of interest.

5.4.3.26. 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.

5.4.3.27. A list of research projects approved since the last meeting utilizing expedited review procedures. This will be listed as an Informational Item on the agenda.

5.4.3.28. An indication that, when an IRB member has a conflicting interest with the research under review, the IRB member was not present during the deliberations or voting on the proposal, and that the quorum was maintained.

5.4.3.29. 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 information about members:

5.5.1.1. Name

5.5.1.2. Earned degrees

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

5.5.1.3.1. For purposes of this roster, IRB members with research experience are designated as scientists (including the student member). 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 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. Affiliated or non-affiliated status. NOTE: Neither the member nor an immediate family member of the member may be affiliated with the MHC or any of the subsidiary hospitals.

5.5.1.6. Representative capacities of each IRB member; which IRB member is a prisoner representative (as required by Subpart C), and which IRB members are 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 (Chair, 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.

5.5.2. The HRPP office will keep IRB membership list current.

5.5.2.1. The Corporate Director of the HRPP will promptly report changes in IRB membership to the Office for Human Research Protections, Departments of Health and Human Services.

5.6. Access to IRB Records

5.6.1. Records of closed protocols are 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 eProtocol system resides on a secured server, with password-protected access.

5.6.2.1. Ordinarily, access to all IRB records is limited to the Corporate Director of the HRPP, 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 accreditation 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 them, as determined by the IO and Corporate Director of the HRPP.

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 HRPP and IRB Office; however, the IRB staff will provide copies of records for authorized personnel if requested.

5.6.6. All other access to IRB study files 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. The Investigator is 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. The Investigator must 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. Research records must be available for review by the IRB within a reasonable period of time upon request.

6.2.5. Study sponsors, federal agencies, or internal policy may require records to be maintained for an alternative period of time.

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

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

6.2.6. For research which is externally funded, all research records must be maintained for the period of time specified by the study sponsor and but no less than seven (7) years;

6.2.7. For research involving investigational drugs, biological products and other "test articles" under the regulation of the Food and Drug Administration (FDA), the record retention and accessibility requirements of the FDA must be met.

6.2.7.1. FDA requires sponsors and investigator's 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 they may have 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: November 19, 2012, November 16, 2015, February 12, 2016

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: December 4, 2015
April 14, 2016

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