McLaren HEALTH CARE		**Policy Title:**	Annual Evaluation of the Human Research Protection Program
Effective Date:	November 1, 2022	**Policy Number:**	MHC_RP0202
Review Date:	July 14, 2023	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	March 22, 2024	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Official, HRPP		

1. Purpose

1.1. To establish a process for conducting the annual evaluation of the Human Research Protection Program (HRPP).

1.2. The objective of this evaluation is to measure and improve the program's quality, efficiency, and effectiveness.

1.3. The annual evaluation will assess the program's compliance with all applicable laws, regulations, ethical standards, accreditation standards and the promotion of health and welfare of human research subjects.

2. Scope

2.1. This policy applies to the HRPP and IRB staff.

3. Policy

3.1. The Annual McLaren HRPP evaluation review shall be conducted by the leaders of the Research Integrity department including the Institutional Official, VP of Clinical Excellence and Research, Research Integrity Manager, IRB Chair, and counsel as needed.

3.2. The evaluation plan includes the review of EQuIP activities, findings from internal directed for cause audits, random internal compliance reviews, review and assessment of comments and concerns submitted by the research community, sponsors and subjects, review and assessment of IRB and IRB members, a review of HRPP metrics as prescribed by AAHRPP, new requirements and research subject outreach plan.

4. Procedure

Evaluate the Resources and Performance of the HRPP

Resources for:

4.1. Appropriate office space, equipment, material, and technology.

4.2. Appropriate space to permit private conversations and to hold meetings.

4.3. Maintenance and secure storage of HRPP and IRB records

4.4. Auditing and other compliance activities and investigations of non-compliance

4.5. HRPP educational program – ensuring that the IRB, investigators, and staff receive training related to human research protections.

4.6. Access to legal counsel

4.7. Conflicts of interests

4.8. Quality improvement plan

4.9. Staffing commensurate with the size and complexity of the research program.

4.10. Adequate financial support

General Performance

4.11. Feedback from investigators, research staff, sponsors, and subjects

4.12. Results of regulatory audits

4.13. Results of continuous improvement activities

4.14. Compliance with policies and procedures

4.15. Compliance with regulatory requirements

Evaluate Institutional Review Board

4.16. Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed using the data below.

4.16.1. Report on the number of submissions reviewed in the fiscal year.

External IRB	HSR Determination	Exempt Initial Review	Expedited Initial Review	Full Board Initial Review	Expedited Modifications	Full Board Modifications	Expedited Continuing Reviews	Full Board Continuing Reviews	Unanticipated Problems	Noncompliance Determinations	Completed Studies	Total Studies Managed

4.16.2. Evaluate the turnaround times:

4.16.2.1. The median number of days from *complete submission to review* ' was the following:

NHSR Determination	X days
Exempt	X days
Expedited	X days
Convened	X days

'Review' means the time the IRB analyst completes pre-review and assigns application to IRB reviewer.

4.16.2.2. The median number of days from complete submission to IRB approval [2] for the following:

NHSR Determination[2]	X days
Exempt[2]	X days
Expedited	X days
Convened	X days

[2]When the IRB made the determination of human subject or not human subject research or when the research was determined to meet exempt category criteria.

4.16.3. Track results and examine significant trends.

4.17. Review data for metrics required by AAHRPP for the annual report.

4.18. Review the composition of IRBs to ensure compliance with regulatory guidance.

4.19. If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the IRB staff to modify the IRB structure.

Evaluate IRB Members and IRB Chair

4.20. The Research Integrity Manager will conduct an annual assessment of the IRB members including the chair to evaluate the knowledge, skills, and performance.

4.21. The Research Integrity Manager will consult the IRB chair when evaluating IRB members.

4.22. Each IRB member shall be provided with a copy of his or her evaluation.

4.23. If the IRB member evaluation is positive, an IRB member appreciation letter will be sent to the IRB member's supervisor (if employed or affiliated with MHC).

4.24. If concerns or opportunities are identified during the annual evaluation, the Research Integrity Manager with work with the IRB member to develop a plan to improve the individual's knowledge, skills, and performance.

4.25. The VP of Clinical Excellence and Research Integrity Manager will jointly evaluate the knowledge, skills and performance of IRB chairs and vice-chair(s).

4.26. A completed IRB chair evaluation will be provided to the Institutional Official.

4.27. The IRB chair and vice chair will be provided with a copy of his or her evaluation.

4.28. IRB Composition will be evaluated to assure compliance with regulatory and organizational requirements.

4.29. If the composition of an IRB does not meet regulatory and organizational requirements, work with the Institutional Official or designer to modify the IRB composition.

Review IRB Registration and FWA

4.30. Review the Federal Wide Assurance (FWA) to ensure that the information remains current and that an update is not required. Updates are required in the following circumstances:

4.30.1. Approaching 5-year renewal deadline
4.30.2. Change in institution name (update within 90 days)
4.30.3. Change in human protections administrator (update within 90 days)
4.30.4. Change in signatory official (update within 90 days)

4.31. Review the IRB registration(s) to ensure that the information remains current and that an update is not required. Updates are required in the following circumstances:

4.31.1. Approaching the 3-year renewal deadline
4.31.2. Change in contact person (update within 90 days)
4.31.3. Change in IRB Chairperson (update within 90 days)
4.31.4. Change in types of FDA-regulated products reviewed by IRB (update within 30 days)
4.31.5. Disbandment of an IRB (update within 30 days of cessation)

Evaluate HRPP Staff

4.32. Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff.

4.32.1. Provide a copy of the evaluation to the Institutional Official or designee.
4.32.2. Provide each HRPP staff with a copy of his or her evaluation.
4.32.3. If needed, work with each IRB staff person to develop a plan to improve the individual's knowledge, skills, and performance.

Evaluate HRPP / IRB Staff and IRB Member Education

New IRB Member Education

4.33. Review the new member orientation and training which includes:

4.33.1. IRB Member CITI Training and PRIM&R Ethical Research Oversight Course.

4.33.2. New IRB Member Training Manual

4.33.3. Training on the electronic IRB submission and review software

4.33.4. Training on Protocol Submission done by IRB Chair.

4.33.5. Mentoring on Protocol Submission Review which occurs in the IRB electronic system with the assigned primary reviewer (experienced member) along with the new IRB member.

4.33.6. New IRB member onboarding spreadsheet

IRB Member and HRPP / IRB Staff Education

4.34. Review IRB member and HRPP / IRB staff training which includes:

4.34.1. Continuing education activities provided at IRB meetings periodically either by the IRB Chair or the Compliance, QI and Education Specialist.

4.34.2. Review other continuing education webinar and conference offerings provided such as PRIM&R or AAHRPP Conference.

4.34.3. Review initial training developed specifically for each role which includes the orientation checklist and CITI training.

4.35. Training and education for HRPP and IRB staff is monitored by the Research Compliance, QI, and Education Specialist.

Research Subject and Community Outreach

4.36. Evaluate the research subject outreach plan and consider the following areas when evaluating the outreach plan:

4.36.1.1. Whether the existing scope and content of HRPP outreach materials continue to be adequate.

4.36.1.2. Whether modifications to existing outreach materials are necessary.

4.36.1.3. Whether or not the HRPP's existing materials are being regularly utilized by the IRB Office or by members of the research community in their own interaction with the communities in which they conduct research.

4.36.1.4. Whether there are new opportunities to provide outreach activities to the community.

4.36.1.5. Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.

4.37. Evaluate the quarterly Brown Bag session to the research community.

4.38. Assess appropriateness of articles written for the Research Matters Newsletter on relevant compliance and research activity issues

4.39. Review the data collected from community members who attend Brown Bag. All community members who attend the brown bag sessions are encouraged to submit evaluation forms.

Compliance Activities

4.40. Review the audit activities conducted by the Compliance, QI, and Education Specialist to assess IRB compliance with applicable federal, state, and local laws as well as institutional policies and procedures.

4.40.1. Activities may include but are not limited to the following:

4.40.1.1. Observation of IRB meetings or other related activities

4.40.1.2. Review of IRB files to assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures.

4.40.1.3. Review of the IRB database to assure all fields are completed accurately.

4.40.1.4. Other monitoring or auditing activities deemed appropriate by the IRB and HRPP

4.40.2. Review results of internal IRB compliance audits

4.40.2.1. If any deficiencies are noted, a corrective action plan is developed by the Compliance, QI and Education Specialist and IRB Chair and approved by the Institutional Official.

4.40.2.2. The IRB and IRB staff are responsible for implementing the corrective action plan, the results of which are evaluated by the Compliance, QI, and Education Specialist.

4.41. Review the audits of IRB protocols at least quarterly.

4.41.1. Results of the audits are shared with IRB members and Institutional Official and VP of Clinical Excellence and Research.

Emergency Preparedness

4.42. Review the MHC Emergency Preparedness Plan (MHC_RP0204 Emergency Preparedness Plan)

4.43. Include emergency preparedness events in annual report.

If deficiencies are identified in the emergency preparedness plan the VP of Clinical Excellence and Research and Institutional Official will be notified and action plans to correct the deficiencies will be implemented

5. References

5.1. 21 CFR 56.106, 21 CFR 56.107

5.2. 45 CFR 46.107, 45 CFR 46 Subpart E

Previous Revisions: 3/25/23, 7/14/23

Approvals:

Signature on File *3/22/2024*

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Institutional Official of Research