McLaren HEALTH CARE		Policy Title:	Reporting to Regulatory Agencies and Institutional Officials and AAHRPP
Effective Date:	January 16. 2012	**Policy Number:**	MHC_RP0124
Review Date:	August 17, 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. To describe policies and procedures for ensuring prompt HRPP/IRB reporting of events to institutional official(s), sponsor(s), and the appropriate federal regulatory agency as required in federal regulations and AAHRPP.

2. Scope

2.1. This policy applies to all principal investigators (PI), research staff, MHC IRB members, IRB chair or designees, IRB staff, and administrators involved in conducting a human subject research study that is under the jurisdiction of the McLaren Human Research Protections Program (MHC HRPP).

3. Definitions

3.1. Refer to Appendix I *"Definitions"*

4. Policy

4.1. Federal regulations require prompt reporting to the appropriate institutional official and as applicable, the federal agency head, or the FDA of:

4.1.1. Any unanticipated problems involving risks to subjects or others.

4.1.2. Any serious or continuing noncompliance or the requirements or determinations of the IRB of Record; or

4.1.3. Any suspension or termination of IRB approval.

4.2. Consistent with federal regulations, the MHC IRB is responsible for reporting on behalf of all MHC subsidiary hospitals:

4.2.1. Any unanticipated problems involving risks to subjects or others.

4.2.2. Any serious or continuing noncompliance with Department of Health and Human Services (DHHS), FDA regulations or the requirements or determinations of the MHC IRB; or

4.2.3. Any suspension or termination of MHC IRB-approved non-exempt human subject research to the applicable institutional officials and as required or appropriate, the applicable regulatory agencies.

4.3. The Institutional Official can suspend/terminate the researchers and/or research at any McLaren subsidiary hospital.

4.4. The Federalwide Assurance (FWAs) is designated to apply all subparts of the Common Rule to DHHS funded supported or conducted human-subjects research only.

4.4.1. In general, the same criteria and process for the conduct and oversight of human-subjects research, for determinations about reportable events and for actions taken in response to such events will apply to all human-subjects research in which MHC subsidiary hospitals are engaged, regardless of funding source.

4.5. If an event involves human-subjects research that is not DHHS funded or supported, the MHC IRB is not required to report the event to the Office for Human Research Protections (OHRP) or other relevant federal department or agency head.

4.5.1. Reporting to the Food and Drug Administration (FDA) may still be required if the research is subject to FDA regulations.

4.6. When the human-subjects research is DHHS funded or supported, the MHC IRB is required to report unanticipated problems involving risks to participants or others (UPIRSO) to the Office for Human Research Protections (OHRP).

4.7. MHC IRB will comply with the requirements stated above and the following procedures describe how these reports will be handled.

4.8. When MHC research is under the oversight of an IRB other than the MHC IRB, reports to federal oversight agencies may be made by either the IRB of record or MHC, with responsibility typically addressed in the IRB reliance agreement. The Corporate Manager of Research Integrity or designee will ensure that MHC's reporting obligations, internal and external, are fulfilled.

4.9. MHC is required to report certain information relevant to MHCs HRPP to AAHRPP. Reporting requirements and the timeframes for reporting (e.g., within 48 hours, within 30 days, or annually) are described in AAHRPPs Accreditation Procedures. The Corporate Manager of Research Integrity or designee will ensure the MHC's reporting obligations to AAHRPP are fulfilled.

5. Procedure

5.1. IRB staff will initiate the procedures as soon as the IRB:

5.1.1. Determines that an event may be considered an unanticipated problem involving risks to subjects or others.

5.1.2. Determines that non-compliance was serious or continuing.

5.1.3. Suspends or terminates approval of research.

5.2. The Corporate Manager of Research Integrity or designee is responsible for preparing reports or letters including the following information:

5.2.1. The nature of the event (Unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension, or termination of approval of research).

5.2.2. Name of the institution conducting the research.

5.2.3. Number of the research project assigned by the MHC IRB, title of the research project and, when applicable, grant proposal in which the problem occurred.

5.2.4. Name of the principal investigator on the protocol.

5.2.5. A detailed description of the problem including the findings of the organization and the reasons for the IRB's decision.

5.2.6. Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.).

5.2.7. Plans, if any, to send a follow-up or final report by the earlier of:

5.2.7.1. A specific date.

5.2.7.2. When an investigation has been completed or a corrective action plan has been implemented.

5.3. The Institutional Official, Corporate Manager of Research Integrity, or IRB chair is responsible for review and approval of the final report(s).

5.4. The Institutional Official is the signatory for all correspondence from the facility.

5.5. The Corporate Manager of Research Integrity or designee will send a copy of the final report(s) to:

5.5.1. The MHC IRB by including the letter in the next agenda packet as an information item.

5.5.2. The Institutional Official.

5.5.3. The following federal agencies:

5.5.3.1. OHRP, if the study is subject to DHHS regulations or subject to a DHHS FWA [Note: As reflected in Section 4.3 above, reporting to OHRP is not required unless the research is supported or conducted by DHHS or another Common Rule department or agency].

5.5.3.2. FDA, if the study is subject to FDA regulations.

5.5.3.3. Other Federal departments or agencies when applicable and required.

5.5.3.4. Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.

5.5.4. Principal investigator and the academic advisor (applicable).

5.5.5. Sponsor (if applicable).

5.5.6. The privacy officer of the applicable hospital, if the event involved unauthorized use, loss, or disclosure of individually identifiable patient information from that covered entity.

5.5.7. Others as deemed appropriate by the Institutional Official.

5.6. The Corporate Manager of Research Integrity or designee will ensure that all steps of this policy are generally completed within 30 days of the date when:

5.6.1. The MHC IRB determines that an incident is an unanticipated problem involving risks to subjects or others.

5.6.2. The MHC IRB determines that an incident is serious or continuing noncompliance with Department of Health and Human Services (DHHS) or FDA regulations or the requirements or determinations of the PHRC; or

5.6.3. The MHC IRB or Institutional Official suspends or terminates MHC IRB-approved research.

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)

5.7. Research Compliance, QI and Education Specialist, researchers, and/or the IRB are responsible for informing the Corporate Manager of Research Integrity of any of the AAHRPP reportable events listed below. Corporate Manager of Research

Integrity or designee will report to its accrediting body (AAHRPP) as soon as possible but within 48 hours:

5.7.1. Any negative actions by a government oversight office, including but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.

5.7.2. Any litigation, arbitration, or settlements initiated related to human research protections.

5.7.3. Any press covering (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding UNM's human research protections program.

6. References

6.1. 45 CFR 46

6.2. 45 CFR 56

6.3. MHC_RP111_Study Suspension, Termination and Investigator Hold

6.4. MHC_RP121_Reportable Events and Unanticipated Problems Involving Risks to subjects or Others (UPIRSO)

6.5. MHC_RP123 _Non-Compliance in Human Subject Research

6.6. Appendix I_ Definitions

7. Previous Revisions: 11/29/12, 12/14/21, 1/16/23

8. Supersedes Policy: *MHC_RP0120 Reporting to Regulatory Agencies and Institutional Officials*

9. Approvals:

MHC Institutional Review Board initial approval: 2/17/12

MHC Institutional Review Board acknowledgement: 12/18/15

Signature on File *3/22/2024*

Justin Klamerus, MD, MMM Date
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Institutional Official of Research