McLaren HEALTH CARE		**Policy Title:**	Human Research Protection Program Emergency Preparedness Plan
Effective Date:	January 19, 2023	**Policy Number:**	MHC_RP0204
Review Date:		**Section:**	Research Integrity
Revised Date:	March 25, 2023	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Official, HRPP		

1. Purpose

1.1. To outline the processes required to maintain operations of the Human Research Protection Program (HRPP) to protect the rights and welfare of research participants in the event of an emergency or disaster situation. This policy also addresses maintaining the operations of the Research Integrity department . Disaster situations include, but are not limited to extreme weather events, natural disasters, man-made disasters, and infectious disease outbreaks.

2. Scope

2.1. Research-specific disaster and emergency response planning is limited to those areas of operation not otherwise covered by overall McLaren Health Care disaster planning, as well as protection of human research participants.

3. Definitions

3.1. Refer to Appendix I “Definitions”

4. Policy

4.1. It is essential that the Human Research Protection Program be able to function in its protective capacity throughout any disaster or emergency, while aligning with institution or system planning.

4.2. Research Integrity department leadership will coordinate with designated system leadership or institution-specific leadership disaster and emergency response planning.

4.3. The Research Integrity leadership r, VP of Clinical Excellence and Research, Institutional Official and/or designee are responsible for developing, maintaining, and carrying out the HRPP emergency preparedness, continuity and recovery plan.

4.4. Researchers are responsible for carrying out selected HRPP emergency plan procedures.

4.5. Research Integrity will ensure sustainability of MHC IRB functions and continued protection of research participants.

4.6. The organization shall proactively identify external IRBs on which it can rely temporarily during an emergency.

4.7. Depending on the nature of the event, Research Integrity leadership will collaborate with institutional leadership to determine the types of research that might continue and the types that the organization may need to temporarily postpone.

4.8. Notifications of contingency plan implementation to the research community will be made via the Research Integrity website and email through the electronic application submission system.

4.9. Education of emergency preparedness related to HRPP will occur periodically via educational session offerings.

4.10. Emergency response plans will be evaluated annually and after each enactment of the policy to ensure effectiveness. Changes will be made, as needed.

5. Procedure

5.1. In the event of an anticipated or actual emergency, the Institutional Official or designee, the VP of Clinical Excellence & Research, the MHC IRB chair and Research Integrity leadership will assess the nature of the event, level of risk and the appropriate response. This assessment and response will include any Federal, State, or local government directives.

5.1.1. The process starts when an emergency/disaster situation impacting the HRPP has occurred, or in preparation for scenarios where a potential emergency is imminent (e.g., natural disaster, man-made disaster, infectious disease pandemic, etc.) and HRPP operations and/or the ability of investigators to conduct Human Research is, or is likely to be, adversely impacted.

5.1.2. The process ends when the impact to the HRPP and the conduct of Human Research is assessed, and appropriate guidance is provided to Research Integrity personnel and the broader Research community.

Research Integrity Department, HRPP and IRB Responsibilities

5.2. Assess whether the situation might impact Research Integrity department operations.

5.2.1. Notify staff and implement necessary emergency action(s).

5.2.2. Determine if work may need to occur remotely or at an alternative off-site MHC office location.

5.2.3. Work with staff to determine capacity of workload to prioritize protocol processing and continuing review applications.

5.2.3.1. If applicable, notify the research community of limited capacity to process and review submissions.

5.2.3.2. If necessary to continue random reviews of research conduct, the Research Compliance office will notify researchers of remote monitoring in place of on-site visit.

5.3. Assess whether the situation might impact MHC IRB operations.

5.3.1.1. If currently approved human research has or will expire prior to MHC IRB review:

5.3.1.1.1. It may be necessary to implement procedures outlined in *MHC_RP01111, Study suspension, Termination and Investigator Hold,* to protect participants from harm.

5.3.2. Research Integrity leadership or designee will communicate to all IRB members activation of and how the HRPP emergency preparedness plan may affect completing their responsibilities:

5.3.2.1.1. Additional considerations in the reviewer's worksheet may be incorporated into IRB reviews, where appropriate, to maximize regulatory flexibility while continuing to ensure research subject safety during the emergency/disaster.

5.3.2.1.2. Need for flexibility in attending convened IRB meetings to achieve quorum and regulatory meeting requirements.

5.3.3. To maintain meeting continuity, it may be necessary to implement alternative review procedures including virtual platform or teleconference.

5.3.3.1. If a virtual meeting or teleconference is also not feasible under the circumstances of the emergency, determine the need to reschedule applicable meetings.

5.3.3.2. In instances where the convened IRB is unable to meet and IRB approval for a study may lapse, the IRB Chair can determine whether subjects can continue to participate in research activities if it is in the best interest of previously enrolled subjects.

5.3.4. In consultation with IRB chair and VP of Clinical Excellence and Research, Research Integrity leadership or designee will determine whether additional

communications to the research community are necessary to inform investigators of any additional measures the IRB will take to maximize regulatory flexibility during the emergency/disaster and notify the community as appropriate. Examples include but are not limited to:

5.3.4.1. Use of waivers of documentation of consent for minimal risk research.

5.3.4.2. In lieu of protocol site visits, alternate methods for safely assessing patient may be identified (e.g., phone contact, virtual visit, alternate location).

5.3.4.3. In certain circumstances, it may become necessary to rely on an accredited external IRB with which MHC has a reliance agreement in place.

Investigator Responsibilities

5.4. Research Integrity leadership or designee will communicate to researchers the activation of the HRPP Emergency Preparedness Plan that may impact the conduct of research studies.

5.5. IRB chair or designee will assess the potential impact on research participants with a focus on protection from harm. These assessments will be conducted with the applicable investigators, as appropriate:

5.5.1. Some research participants may need to continue their investigational interventions or receive an alternative intervention to assure their safety and well-being, such as such as the use of remote study visits, conference calls, or video conferencing.

5.5.2. Some research studies may need to halt in-person interactions or change locations of interactions to assure participant safety and well-being.

5.5.3. Some research studies may need to halt recruitment and enrollment throughout the emergency period.

5.6. Researchers will work with IT, research pharmacy and applicable laboratories to ensure the research data, medications, and/or specimens collected for the studies are stored and backed up appropriately to protect them depending on nature of disaster.

Research Informatics and IT

5.7. Assess the potential impact on information systems.

5.7.1. The Research Integrity staff will work with IT resources and/or electronic system vendors to ensure continuity of operations if electronic systems are inaccessible or not operational for extended periods of time during an emergency/disaster.

5.7.2. The Research Integrity leadership will collaborate with the IRB electronic system administrator and the vendor of the IRB's electronic system to ensure that records are maintained on a secure server that is accessible in the event of an emergency.

5.8. Consider use of "downtime" procedures if systems are not able to be accessed. Upon recovery from the emergency, resumption of normal operations will proceed at the fastest rate possible, but complete recovery will be dependent upon the extent of procedural changes that were made for the emergency.

5.9. Updates to the research community will continue via the Research Integrity website and email through the electronic application submission system.

Education and Evaluation

5.10. Periodic Review of the Emergency Plan Educational Materials – The Research Integrity leadership is responsible for ensuring the educational materials are reviewed and updated as necessary, based on the outcome of the periodic evaluation of the emergency preparedness plan.

5.11. Periodic Evaluation of the Emergency Plan - The Research Integrity leadership and VP of Clinical Excellence and Research are responsible for evaluating the emergency preparedness plan and making changes, when appropriate. This evaluation shall occur at least annually with the annual HRPP evaluation (*MHC_RP0202 Annual Evaluation of the Human Research Protections Program*).

5.12. Recovery Period

5.12.1. Following the resolution of the event, PI and study teams should review:

5.12.1.1. All current, active patients and determine if there were deviations to treatment or follow-up requirements.

5.12.1.2. Identify any serious adverse events that require reporting that may have occurred during the emergency period when some services may have been suspended.

5.12.1.3. Identify any protocol modifications that may be required to address on-going issues following the emergency identified either locally or by the study sponsor and submit to the IRB for review and determination.

5.12.2. Following the resolution of the event, the VP Clinical Excellence and Research, Research Integrity leadership and the IRB Chair will review:

5.12.2.1. Ongoing statuses of studies that may have been suspended.

5.12.2.2. All actions/determinations made during the event to assure there is appropriate documentation of each review.

5.12.2.3. Contact study teams to assist with on-going requirements that may be in place as the organization resumes services and activities.

5.12.2.4. Conduct a situation de-brief within thirty days of resolution of the event to assess program performance and effectiveness of the emergency management plan, making adjustments to the plan as needed, including development of QA/QI initiative.

5.12.2.5. Present post-emergency evaluation to the Research Advisory Board.

5.13. The HRPP Emergency Preparedness Plan for the research community will be available on the Research Integrity website and email through electronic IRB software system if available.

5.14. Education of emergency preparedness related to HRPP will occur periodically via educational session offerings.

6. References

6.1. AAHRPP Element I.1.H
6.2. AAHRPP Element 1.5.B
6.3. Effects of Disasters on Human Research Protections Programs Guidance May 14, 2018

7. Appendix

7.1. Appendix I “Definitions”

Previous Revisions: none

Supersedes Policy: N/A

Approvals:

Signature on File *4/7/2023*

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Institutional Official of Research