McLaren HEALTH CARE		Policy Title:	Emergency Use of a Test Article
Effective Date:	November 3, 2017	**Policy Number:**	MHC_RP0119
Review Date:	August 14, 2020	**Section:**	Research Integrity
Revised Date:	January 14, 2023	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Official, HRPP		

1. Purpose

1.1. To describe the procedure for emergency use of a Food and Drug Administration (FDA) regulated investigational drug, biologic, or device in a single subject.

1.2. To define the applicability of the Food and Drug Administration (FDA) emergency exemption from prospective IRB approval for use of an investigational drug or unapproved medical device with a human subject.

1.3. To ensure that the emergency use of the investigational drug or unapproved medical device meets the federal criteria for such use and that the IRB is appropriately notified of the use.

2. Scope

2.1. This policy applies only to single time emergency use of an FDA regulated test article when there is not sufficient time to obtain IRB concurrence or approval and with or without informed consent. This policy does not apply when using an approved drug/biologic/device for off-label purpose when the goal is medical treatment or "compassionate use" (expanded access) for drugs or devices (see MHC-R0127 Expanded Access of Investigational Drugs and Devices).

3. Definitions

3.1. Refer to Appendix I *"Definitions"*

4. Policy

4.1. The MHC IRB requires notification prior to the single time emergency use of a test article whenever possible. This notification should not be considered an IRB approval.

4.2. In HHS and other sponsored research, the physician may treat the patient using a test article without prior IRB approval (if the situation meets the FDA requirements). 45 CFR 46.116(f), states, "nothing in this policy [45 CFR 46] is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law".

4.3. Under FDA regulations, the emergency use of a test article, other than a medical device, is a clinical investigation, the patient is a participant, and the FDA may require data from an emergency use to be reported in a marketing application.

4.4. Whenever emergency care is initiated without prior IRB review and approval, the Office for Human Research Protection (OHRP) holds that the patient may not be a research subject, and such emergency care may not be claimed as research, nor may the outcome of such care be included in any report of a research activity subject to DHHS regulations.

4.5. If there is insufficient time to obtain IRB approval of the test article prior to use, as preferred, the investigator must report the emergency use to the MHC IRB within 5 working days and present information that confirms appropriate use of the test article. The IRB chair or a designee will review the report to verify that circumstances of the emergency use conformed to FDA regulations.

4.6. If use is for a life-threatening or serious disease but time is sufficient to obtain IRB Chair concurrence or IRB approval, follow procedures in the MHC-R0127 Expanded Access of Investigational Drugs and Devices. IRB Chair concurrence or IRB approval must be obtained whenever possible.

5. Procedure

Emergency IND or Emergency Protocol for Drugs and Biologics

5.1. The emergency use of an unapproved investigational drug or biologic for the treatment of a patient with an immediately life-threatening or serious disease or condition when no satisfactory alternative therapy options are available requires an Investigational New Drug Exemption (IND) from the FDA. If enrollment of the intended patient/participant in a clinical trial is not possible (e.g., the patient does not meet eligibility criteria or there is not an ongoing clinical trial of the investigational product) or is not feasible (e.g., distance to a trial precludes participation), there are two mechanisms available for emergency access to the drug or biologic, an Emergency Protocol (IND held by existing IND Sponsor) or an Emergency IND (IND held by physician). Instructions for Emergency Protocols and Emergency INDs are available on FDA's Expanded Access Categories for Drugs website. In either case, the emergency use must be reported to the IRB within 5 working days.

Emergency Use for Medical Devices

5.2. FDA procedures for the emergency use of investigational medical devices differ from those for drugs. The criteria for emergency use of a medical device include:

5.2.1. The patient has a life-threatening condition that needs immediate treatment.
5.2.2. No generally acceptable alternative treatment for the condition exists; and
5.2.3. Because of the immediate need to use the device, there is no time to use other expanded access mechanisms to obtain FDA approval for the use.

5.3. In addition to the above, FDA expects the physician to assess the potential for benefit from the use of the unapproved device, and to have substantial reason to believe that benefits will exist. The physician should follow as many patient protection procedures as possible including obtaining:

5.3.1. Informed consent from the patient or a legal representative;
5.3.2. Clearance from McLaren Health facility;
5.3.3. Concurrence of the IRB chairperson or their designee;
5.3.4. An independent assessment from an uninvolved physician; and
5.3.5. Authorization from the device manufacturer.

5.4. The emergency use must be reported to the FDA within 5 days by either the IDE sponsor, if one exists, or by the physician when no IDE exists. Instructions regarding reporting and the address to send the report to are available on this FDA website: https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices.

5.5. If concurrence of the IRB chairperson or their designee was not obtained in advance of the emergency use, the emergency use must be reported to the IRB within 5 working days. If concurrence was obtained, consult with the IRB office regarding any documentation requirements post use.

IRB Notification of Emergency Use of Test Article

5.6. Whenever possible, the investigator proposing emergency use of test article should contact the MHC IRB for guidance.

5.7. Exemption from Prospective IRB Approval: If the immediate use of the test article is, in the healthcare provider's opinion, required to preserve the life of the patient or prevent major irreversible morbidity (e.g., blindness, loss of hearing, loss of limb, paralysis, stroke) the PI must determine that all the following criteria has been met for the physician to treat their patient with a test article without prospective IRB approval:

5.7.1. Patient has a life-threatening or severely debilitating condition;
5.7.2. No standard or generally recognized alternative treatment is available; and
5.7.3. There is not sufficient time to obtain IRB review approval.

5.8. The PI submits to the MHC IRB a documented report, within five (5) working days following the emergency use of the article as described below.

5.8.1. Submit "**Application for Emergency Use of Test Article**" in the electronic IRB system.

5.8.2. Upload with "Application for Emergency Use of Test Article" all documentation necessary to support the necessity of emergency use.

5.8.3. When subsequent use of the test article at McLaren Health can be anticipated, every effort should be made to either become an investigator or develop a protocol for future use of the article and submit to the IRB for approval. FDA regulations require that any subsequent use of the test article at an institution has prospective IRB review and approval. However, FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual under the emergency use provision if the only obstacle is IRB approval or IRB Chair concurrence has not been obtained.

Emergency Use Waiver from Requirement for Informed Consent

5.8.4. The investigator is required to obtain informed consent of the patient or the patient's legally authorized representative (LAR) unless both the investigator and a physician, who is not otherwise participating in the clinical investigation, certify in writing all the following specific conditions [21 CFR 50.23(a)] are met:

5.8.4.1. The patient is confronted by a life-threatening or severely debilitating condition necessitating the use of the test article.

5.8.4.2. Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the patient.

5.8.4.3. Time is not sufficient to obtain consent from the patient's LAR.

5.8.4.4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patient's life.

5.8.5. If it is the investigator's opinion that immediate use of the test article is required to preserve the patient's life, and there is not sufficient time to obtain an independent physician's determination that the four conditions above apply, the investigator should make the determination.

5.8.5.1. The determination must be reviewed and evaluated, in writing, by a physician who is not participating in the clinical investigation [21 CFR 50.23(b)] within 5 working days after the use of the article.

5.8.5.2. The investigator must notify the IRB within 5 working days after the use of the test article [21 CFR 50.23(c)].

5.9. The IRB staff will review all submitted documentation for completeness.

5.9.1. If the application is deemed as incomplete, the investigator will be contacted with an explanation of what additional information/documentation is required.

5.9.2. Applications deemed as complete will be forwarded to an IRB reviewer for evaluation along with a copy of this policy.

5.10. Upon receipt of the complete application and supporting documentation, the IRB reviewer will evaluate whether the emergency use was consistent with FDA's regulations and MHC IRB policy.

5.11. The IRB reviewer may request additional information or review by an independent physician when determining whether the criteria for emergency exemption is met.

5.12. The IRB reviewer is responsible for informing the investigator of his/her concurrence or disagreement with the emergency exemption.

5.13. When the IRB reviewer disagrees with the emergency exemption, the emergency use will be scheduled for full board review at the next available convened meeting of the MHC IRB.

5.14. If the investigator plans to use the test article later, a separate initial application must be submitted to the IRB via the iRIS system for review and approval prior to such use.

6. Responsibilities

6.1. Investigator and/or Physician:

6.1.1. A physician may treat a patient with an unapproved medical device or drug in an emergency if he/she concludes and documents that the FDA criteria for emergency use are met.

6.1.2. When possible, the investigator should notify the IRB prior to any emergency use.

6.1.2.1. Notification may include justification for use, the consent document, and, for emergency use of drugs, documentation of FDA authorization.

6.1.2.2. Within 5 working days of the emergency use, the investigator must submit the "Application for Emergency Use of Test Article" in the electronic IRB system and any supporting documentation.

6.1.3. The physician should implement as many of the following additional patient protections as possible:

6.1.3.1. Seek concurrence of the IRB chair or designee for the use of the test article prior to its use.

6.1.3.2. Assessment from a physician who is not participating in the study in which the test article is being used.

6.1.3.3. Obtain informed consent of the patient or the patient's legally authorized representative unless both the investigator and a physician, who is not otherwise participating in the clinical investigation, certify that the requirements for an emergency exception from the requirement for informed consent are satisfied.

6.2. IRB Chair or designees:

6.2.1. Review the emergency use report and determine that:

6.2.1.1. The use of a test article was consistent with the federal criteria for emergency use in accordance with FDA regulations.

6.2.1.2. Consent was obtained in accordance with FDA regulation at 21 CFR §50 (or the circumstance meet the exception to the requirement for consent in 21 CFR §50.23 (a)-(c)).

6.2.2. In the event the IRB Chair, or designee, concludes that the emergency use does not appear to comply with the FDA regulations and guidance, the IRB chair or designee will inform the investigator and refer the emergency use to the convened board for evaluation of potential noncompliance.

7. References

7.1. 21 CFR 50

7.2. 21 CFR 56 102

7.3. 21 CFR 56 104

7.4. FDA Guidance "Emergency Use of an Investigational Drug or Biologic"

7.5. AAHRPP I.7.C

7.6. Application for Emergency Use of Test Article

8. Previous Revisions: December 02, 2012, March 10, 2013, December 14, 2021

9. Supersedes Policy: MHC_RP0128_" Emergency Use of Investigational Drugs and Devices".

10. Approvals:

MHC Institutional Review Board acknowledgment: 7/20/12, 12/4/15

Signature on File *1/31/23*

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