McLaren HEALTH CARE		**Policy Title:**	Humanitarian Use Device (HUD)
Effective Date:	July 20, 2012	**Policy Number:**	MHC_RP0120
Review Date:	December 18, 2015	**Section:**	Human Research Protections Program
Revised Date:	November 25, 2015	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is to set forth the requirements for IRB approval, monitoring, and continued reporting responsibilities, as well as procedures for physicians seeking to use a Humanitarian Use Device (HUD).

2. Scope

2.1. This policy and procedure apply to all HUD/HDE projects submitted to the McLaren Health Care Institutional Review Board (MHC IRB).

3. Definitions

3.1. Refer to Appendix I "*Definitions"*

4. Policy

4.1. The statute and the implementing regulation (21 CFR 814.124(a)) require IRB review and approve a HUD before it is administered or implemented in a patient.

4.1.1. It is the policy of the MHC IRB to review and approve the use of Humanitarian Use Devices (HUD).

4.1.2. Once approved, the clinical use of the HUD may be considered as any other approved device, with the caution that effectiveness has not been shown in clinical trials.

4.2. The IRB is responsible for the initial and the continuing review of the HUD.

4.2.1. For initial review of a HUD, the Principal Investigator must submit an application using eProtocol electronic submission system for the initial review and the IRB will perform a full board review.

4.2.2. For continuing review of HUD, the Principal Investigator must submit a continuing review application using eProtocol electronic submission system.

4.2.2.1. IRB may use expedited review procedure unless the IRB determines that full board review should be performed.

4.3. At the time of review, the IRB will determine if written consent from the participant for use of the HUD is necessary.

4.4. The HUD may not be administered to or implanted in a patient until the Principal Investigator has received the approval from the IRB.

4.4.1. There is an exception to this rule for an emergency situation in which the physician determines that approval cannot be obtained in time to prevent serious harm or death to the patient. Please refer to Policy *MHC_RP119 "Emergency Use of Investigational Drugs and Devices".*

5. Procedure

5.1. Applying for an Humanitarian Device Exemption (HDE):

5.1.1. To obtain approval for an HUD, an HDE application is submitted to FDA. The HDE application must contain sufficient information for the FDA to determine that:

5.1.1.1. The device does not pose an unreasonable or significant risk of illness or injury, and

5.1.1.2. The probable benefit to health outweighs the risk of injury or illness from its use taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

5.1.2. Is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose.

5.2. Criteria for HUD use:

5.2.1. Clinical (non-research) use:

5.2.1.1. The HUD may only be used after IRB approval has been obtained for the use of the device for the FDA approved indication.

5.2.1.2. HUD use is subject to continuing review and approval by the IRB; if applicable, the expedited procedure may be used at continuing review.

5.2.1.3. At the time of review, IRB will determine if written consent from the participant for use of the HUD is necessary.

5.2.1.4. To use a HUD for a new indication, a new designation of HUD status must be obtained (21 CFR 814.110).

5.2.2. Research use:

5.2.2.1. Prior IRB approval of a HUD is required before use.

5.2.2.2. When the HUD is being studied for a different indication(s), 21 CFR 812 applies including the requirements for a FDA approved IDE before starting the investigation of a Significant Risk Device.

5.2.2.3. For research under a HDE, the scope of the IRB approval is to confirm the planned use is consistent with the FDA-approved indication for the HDE.

5.2.2.4. Researchers who want to study a HUD for a new indication must submit an IDE application to FDA if the device is a significant risk device.

5.3. Initial Review:

5.3.1. Physicians wishing to use an HUD at McLaren Health Care (MHC) facilities must provide the MHC IRB an application for initial approval along with documentation verifying the device/product sponsor has been granted an FDA-approved Humanitarian Device Exemption (HDE) for use of this device.

5.3.2. New HUD use applications are submitted via eProtocol for regular review by the convened IRB.

5.3.3. The IRB will review the proposal at a convened meeting ensuring that appropriate expertise is available either within the membership in attendance or via the use of consultants

5.3.4. The IRB will review the risk to patients that are described in the product labeling and other materials, the proposed procedures to ensure the risks are minimized and will evaluate whether the risks are reasonable in relations to the potential benefits to patients at McLaren

5.3.5. The IRB will evaluate the proposed consent process (if applicable) and will determine if the materials are adequate and appropriate for the patient population

5.3.6. Policy *MHC_RP107 "Initial Review of Human Subject Research"* will be followed

5.4. Continuing Review

5.4.1. Physicians will need to submit the appropriate continuing review application form if the use of the HUD is expected to continue past the IRB approval expiration date.

5.4.2. Continuing Review applications are submitted via eProtocol

5.4.3. Policy *MHC_RP112 "Continuing Review of Human Subject Research"* will be followed

5.5. Changes to currently approved HUD

5.5.1. Changes in the approved HUD project, during the period for which IRB approval has already been given, may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to human subjects.

5.5.2. The physician must submit requests for changes to the IRB using eProtocol.

5.5.3. The physician must also submit the following items to the IRB on a timely basis:

5.5.3.1. Any amendments or supplements to the HDE;

5.5.3.2. Annual reports from the HDE holder;

5.5.3.3. Any reports of adverse effects or device failures submitted to the FDA as required under 21 CFR 803;

5.5.3.4. Any results of further animal, laboratory or clinical testing that may affect the risk-benefit ratio for use of the device;

5.5.3.5. Any final report from the IDE sponsor;

5.5.4. Policy *MHC_RP113 "Changes to Currently approved Research*" will be followed

5.6. HUD Closure Report:

5.6.1. A final report from the applicant must be submitted to the MHC IRB using eProtocol.

5.7. If the HUD is used in an emergency situation (off label) to save the life or protect the physical wellbeing of a patient, the procedures outlined in FDA regulations and local policy must be followed as specified in HRPP Policy *MHC_RP119 "Emergency Use of Investigational Drugs and Devices"* will be followed

6. Responsibilities:

6.1. Investigator:

6.1.1. Comply with the federal regulations, state and local laws, and all IRB determinations.

6.1.2. Submit an IRB application describing the proposed research involving a HUD to the IRB for review and approval prior to initiating the research

6.1.3. Submit any proposed changes to the IRB approved plan or patient materials and obtain approval for those changes prior to implementation, unless the change is necessary to avoid or mediate an apparent immediate risk to patient.

6.1.4. Submit continuing review material to the IRB sufficiently in advance of the expiration date to ensure IRB review and re-approval prior to expiration

6.1.5. If using a product for an indication not included in the approved labeling (e.g., off-label), be well informed about the product in order to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects.

6.1.6. Submit reports to the FDA, the IRB and the manufacturer/HD holder whenever a HUD may have caused or contributed to:

6.1.6.1. A death

6.1.6.2. Serious Injury which is life-threatening, results in permanent impairment of a bodily function or permanent damage to a body structure (21 CFR 803.3)

6.2. IRB Staff:

6.2.1. Review application for completeness

6.2.1.1. If application is not complete, the IRB Staff will contact the Principal Investigator with the explanation of what additional information/document(s) is/are needed

6.2.2. Assign IRB Chair or designee as a reviewer

6.2.3. If full board review is required, IRB Staff will assign the application to the next scheduled convened IRB meeting

6.3. IRB:

6.3.1. IRB Chair or designee and members are required to review and approve projects using the criteria at Federal Regulations 21 CFR 56

6.3.2. IRB Chair or designee and members should utilize additional criteria for approval if research subjects include vulnerable populations such as pregnant women, human fetuses, neonates, children or prisoners.

6.3.3. The IRB doesn't need to review and approve individual uses of a HUD. As long as the use of HUD is within FDA approved indication, the IRB may approve use of the device however it sees fit. That is, the IRB may approve use of the HUD without any further restrictions, use of the device under a protocol, or use of the device on a case-by-case basis

6.3.4. The IRB should be cognizant that the use of the device should not exceed the scope of the FDA approved indication

6.3.5. IRB will not approve use of the HUD for more than one year. The typical approval period is 364 days. However, the IRB may require review more often than annually as the IRB sees fit

6.3.6. If the HUD is the subject of a clinical investigation, (one in which safety and effectiveness data is being collected to support a PMA), the IRB must comply with all of the FDA regulations related to IRB review of research (21 CFR 56, 21 CFR 50)

7. References:

7.1. 21 CFR 803

7.2. 21 CFR 814

7.3. 21 CFR 812

7.4. MHC_RP107 "*Initial Review of Human Subject Research*"

7.5. MHC_RP112 "*Continuing Review of Human Subject Research*"

7.6. MHC_RP113 "*Changes to Currently approved Research*"

7.7. MHC_RP119 "*Emergency Use of Investigational Drugs and Devices*"

7.8. Appendix I "*Definitions*"

8. Previous Revisions: December 6, 2012

9. Supersedes Policy: *MHC_RP0123_"Humanitarian Use Device (HUD)"*

10. Approvals:

MHC Institutional Review Board initial approval: July 20, 2012

MHC Institutional Review Board acknowledgement: December 18, 2015

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