**McLaren Health Care Institutional Review Board**

**APPLICATION FOR EMERGENCY USE OF TEST ARTICLE**

### INSTRUCTIONS: The MHC IRB recommends that the treating physician completes this form as detailed as possible and notifies the MHC IRB prior to emergency use of a test article in a life threatening situation. If it is not possible, the treating physician is required to inform the IRB within *5 working days* after the use of the test article to document in writing the emergency exemption from prospective IRB approval for use of an investigational drug or device with a human subject. See the Human Research Protection Program Policies and Procedures for detailed instructions “*MHC\_RP0119\_Emergency Use of Investigational Drugs and Devices”.*

### Completed form should be signed by the physician requesting the emergency use and submitted either by scanning to *hrpp@mclaren.org* or faxing to (248) 276-9732.

**Once submitted, the IRB Chair or designee will review the form and acknowledgment letter will be sent to the physician. *For questions, please contact MHC IRB office at:*** ***hrpp@mclaren.org*** ***or (248) 484-4950.***

**\* Test Article - Includes any drug, biological product or medical device for human use or any other article subject to federal regulation.**

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| AN EMERGENCY WAIVER FOR USE OF A TEST ARTICLE MUST MEET THE FOLLOWING CRITERIA: |
| 1. **The patient has a life-threatening or severely debilitating disease or condition; and**
2. **There are no standard or generally recognized alternative treatment options with an equal or greater likelihood of treating the patient’s condition; and**
3. **The patient’s condition requires immediate intervention before review at a convened meeting of the IRB is possible to avoid major irreversible morbidity or death.**
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| **IMPORTANT NOTE:** **Per FDA regulations, permission for Emergency Use may only be granted one (1) time per institution for one (1) patient under the three (3) conditions listed above.If any of the above three (3) conditions do not apply, or if there is a desire to use the test article again on the same or different patient, an IRB Application must be submitted for review and approval by a convened IRB.** |

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| **Select all that apply.** |

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| **Section A: EMERGENCY USE INFORMATION FOR INITIAL REQUEST *(required)*** |
| 1. NAME OF DRUG/BIOLOGIC/DEVICE:      2. IND/IDE #:       *IF NO IND/IDE EXISTS, CONTACT THE FDA FOR AN EMERGENCY USE IND/IDE. PROVIDE A COPY OF THE FDA LETTER GRANTING THE EMERGENCY USE IND WITH THIS REPORT.*3. MANUFACTURER:      4. DOSAGE:     5. INDICATION FOR EMERGENCY USE:       |
| 6. DESCRIBE THE PATIENT'S CONDITION AND EXPLAIN WHY THE EMERGENCY USE OF THE TEST ARTICLE IS REQUIRED (PROVIDE THE MHC IRB WITH THE PATIENT”S INITIALS): 7. DATE TEST ARTICLE WILL BE ADMINISTERED/UTILIZED:      8. WILL INFORMED CONSENT BE OBTAINED FROM THE PATIENT OR THE PATIENT’S LEGALLY AUTHORIZED REPRESENTATIVE? [ ] YES [ ]  NO  **If no**, **please complete Section B below**.9. PROVIDE A BRIEF DESCRIPTION OF THE INFORMED CONSENT PROCESS (INCLUDE A COPY OF THE CONSENT DOCUMENT THAT WILL BE PROVIDED THE PATIENT):10.PROVIDE AN EVALUATION OF THE LIKELIHOOD FOR A SIMILAR NEED FOR EMERGENCY USE OF THIS TEST ARTICLE. **NOTE THAT IF FUTURE USE IS LIKELY, A NEW IRB APPLICATION MUST BE SUBMITTED**:  |
| ***By signing below, the treating physician:**** *Certifies that this patient is in a life-threatening situation for which no acceptable treatment is available;*
* *Certifies that there is insufficient time to obtain approval of the full board IRB for use of the test article;*
* *Acknowledges that the patient may not be considered a research subject and any data generated may not be claimed as research. The outcome of this emergency use may not be included in any report of research activity, except possibly for case reports, and;*
* *Acknowledges that any subsequent use of the test article in the same or different patient requires submission of an IRB application to the IRB for full board review.*

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| **SECTION B: IF UNABLE TO OBTAIN INFORMED CONSENT PRIOR TO EMERGENCY TREATMENT, PLEASE COMPLETE THIS SECTION****(If informed consent will be obtained, skip this section)** |
| In some emergency use circumstances, it may not be feasible to obtain informed consent prior to the administration or use of the test article. An exception to the informed consent requirements is acceptable if the treating physician and a physician who is not otherwise involved in the patient’s treatment must certify in writing that the following four (4) conditions exist:  |
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| 1. The patient is confronted with a life-threatening situation necessitating an immediate use of the

test article; and 1. The patient is unable to provide effective consent; and
2. There is insufficient time in which to obtain consent from the patient's legally authorized representative; and
3. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of treating the patient's condition.
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| **REQUEST FOR WAIVER OF INFORMED CONSENT:** |
| *By signing below, I certify that this emergency use meets all four (4) of the conditions listed above.* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_NAME OF TREATING PHYSICIAN (print) SIGNATURE OF TREATING PHYSICIAN DATE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_NAME OF PHYSICIAN NOT INVOLVED SIGNATURE OF PHYSICIAN NOT INVOLVED DATEIN PATIENT”S TREATMENT (print) IN PATIENT”S TREATMENT |