### **REPORT FOR EMERGENCY USE OF**

### **Emergency Use Status**

### [ ]  The emergency use has already occurred and I am reporting this for the first time to the IRB.

[ ] The emergency use has not occurred, and I need acknowledgment from the IRB Chair that the use of the test article constitutes an emergency use before the sponsor will ship the drug or device.

### [ ]  This is a follow-up report to the IRB for an emergency use that was prospectively reported to the IRB on       (insert date).

### **Emergency Use Requirements (all answers must be “yes”)**

|  |  |
| --- | --- |
| * + - 1. A test article was/will be used on a human subject
 | [ ]  *Yes* [ ]  *No*  |
| 1. The patient was/is in a life-threatening or severely debilitating situation
 | [ ]  *Yes* [ ]  *No*  |
| 1. There was/is no alternative method of approved or generally recognized therapy available that provides an equal or greater likelihood of saving the participant’s life.
 | [ ]  *Yes* [ ]  *No*  |
| There was/is not sufficient time to obtain IRB approval prior to the use of the investigational test article.  | [ ]  *Yes* [ ]  *No*  |

1. **Test Article Information**

|  |
| --- |
| * + - 1. Type of test article: [ ]  Drug [ ]  Device [ ]  Biologic
 |
| * + - 1. Name of test article:
 |
| * + - 1. IDE# or IND # (Required for drug or biologic):
 |
| * + - 1. Course of treatment and dose (if applicable):
 |
| * + - 1. Location of treatment (i.e., NMH, RIC):
 |

1. **Prior or Future Use of the Test Article:** FDA allows for one emergency use of a test article without prospective IRB review. Any subsequent use of the investigational product at the institution must have prospective IRB review and approval. FDA acknowledges, however, that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue.

|  |  |
| --- | --- |
| * + - 1. Has this test article previously been used at this institution under the emergency use provision without prospective IRB review?
 | [ ]  *Yes* [ ]  *No*  |
| If “yes”, provide justification for treating a second individual at this institution without prospective IRB approval.      |
| * + - 1. Do you intend to use this test article in an off-label/emergency use manner in the future?
 | [ ]  *Yes* [ ]  *No*  |
| If “yes”, specify when a new protocol submission will be submitted to the IRB for review for future use of the test article.       |

1. **Patient Information**

|  |
| --- |
| * 1. Patient Initials
 |
| * 1. Conditions requiring use of the test article
 |
| * 1. Any prior course of treatment
 |
| * 1. Patient protection measures
 |

1. **Follow-up information after the use of the test article:**

|  |
| --- |
| * + - 1. Date the test article was administered:
 |
| * + - 1. Description of the patient’s status:
 |
| * + - 1. Was written consent obtained from the patient or the patient’s legally authorized representative?[ ]  Yes [ ]  No ,

If “No”: Explain why written informed consent could not be obtained from the patient or the patient’s legally authorized representative.      Complete Section G, Independent Physician’s Assessment |

1. **Independent Physician’s Assessment - Complete section 1 or 2 (whichever applies) when written informed consent CANNOT be obtained from the patient receiving the test article.**

|  |
| --- |
| * + - 1. **When the assessment is provided prior to the use of the test article**
 |
| * + - * 1. I am not participating in the care of the patient
 | [ ]  Yes [ ]  No  |
| * + - * 1. The four conditions below must be met in order to allow an emergency waiver of informed consent:
* The subject is confronted by a life-threatening situation necessitating the use of the test article; and,
* Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject; and
* Time is not sufficient to obtain consent from the subject's legal representative; and
* No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

Explain how these conditions are met:       |

|  |
| --- |
| * + 1. **When the assessment is provided after the use of the test article**
 |
| * + - * 1. I am not participating in the care of the patient
 | [ ]  Yes [ ]  No  |
| * + - * 1. The treating physician may only use a test article without written informed consent and an independent physician assessment when he/she has determined that

immediate use of the test article was required to preserve the subject's life,* Informed consent could not be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject; and
* Time was not sufficient to obtain consent from the subject's legal representative; and
* No alternative method of approved or generally recognized therapy was available that provided an equal or greater likelihood of saving the subject's life, and

Provide an evaluation assessing if the above conditions were met:       |

**I certify that the above information is accurate.**

Print Name:

Signature of the Physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department:

1. **investigator’s assurance**

 I agree to adhere to the treatment course as described in this form. I agree not to extend the use of this test article beyond the patient and treatment involved in this request and to report to IRB any unexpected side effects at any time they occur. If there is the possibility that the test article may need to be used again in this manner, a formal IRB application will be submitted for IRB review and approval before the next use.

Print Name:

Signature of the Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department:

e-mail:

Phone/Pager:

**If IRB Chair/Designee Concurrence is required by the sponsor in order to ship the drug/device, please complete the following and provide to the IRB.**

|  |  |
| --- | --- |
| Emergency Use of a Test ArticleWith Informed Consent | Emergency Use of a Test ArticleWithout Informed Consent |
| I verify that all of the following statements are true:[ ]  The participant was/is confronted by a life-threatening or severely debilitating situation.[ ]  No standard acceptable treatment was/is available.[ ]  There was/is not sufficient time to obtain IRB approval in advance of the use of the test article. | I verify that all of the following statements are true:[ ]  The participant was/is confronted by a life-threatening situation necessitating the use of the test article.[ ]  Informed consent could/can not be obtainedfrom the participant because of aninability to communicate with, or obtain legally effective consent from, the participant.[ ]  Time was/is not sufficient to obtain consent from the participant’s legal representative.[ ]  No alternative method of approved or  generally recognized therapy that provided an equal or greater likelihood of saving thelife of the participant was/is available.[ ]  Independent Physician Assessment was completed |

**The IRB is aware of the proposed emergency use and considers the use to meet the requirements of 21 CFR 56.104(c).**

Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the IRB Chair or Designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_