**IRB Member Emergency Use Checklist**

Emergency Use is a pathway intended to address these *emergency* situations to allow clinicians access to investigational drugs, biologics or devices when no alternatives exist or have been exhausted.

As stipulated in the federal regulations/guidance, a physician who intends to treat a patient with an unapproved test article in an emergent situation should conclude that:

1. The patient has a life-threatening condition that needs immediate treatment.
2. No generally acceptable alternative treatment for the condition exists; and
3. Because of the immediate need to use the test article (drug, device or biologic), there is no time to use existing procedures to get prospective IRB approval for the use.

|  |  |  |
| --- | --- | --- |
| Date of Event:Click or tap to enter a date. | Date of Notification: Click or tap to enter a date. | eBridge #:Click or tap here to enter text.  |
| Investigator: Click or tap here to enter text. | Name of Investigational Product: Click or tap here to enter text. | Reviewer: Click or tap here to enter text. |

1. Provide a summary of the patient and the emergency use event.

Click or tap here to enter text.

1. The treating physician has indicated the patient is experiencing a life-threatening situation necessitating the use of a test article. [ ]  Yes [ ]  No
2. The treating physician has indicated that there is no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient. [ ]  Yes [ ]  No
3. The treating physician has obtained an independent physician’s assessment of the event confirming the following elements. [ ]  [ ]  [ ]  Yes [ ]  No
* The patient is confronted by a life-threatening situation necessitating the use of the test article.
* Informed consent cannot be obtained from the because of an inability to communicate with or obtain legally effective consent from the patient (if applicable).
* Time is not sufficient to obtain consent from the patient's legal representative.
* There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient
1. Informed Consent has been obtained from the patient.[ ]

[ ]  Yes [ ]  No If no, go to question #6

1. The physician obtained consent from the patient's legal authorized representative (LAR).

[ ]  Yes [ ]  No [ ]  N/A

If no, has the physician informed the patient and/or LAR at the earliest opportunity of the use of the test article [ ]  Yes [ ]  No

**Consent Form (if applicable):**

If consent is being obtained, does the consent form include a statement that the test article (drug, biologic or device) has not been proven safe or effective for this indication by the FDA [ ]  Yes [ ]  No

|  |
| --- |
| **Comments/Notes** |
| Click or tap here to enter text. |
| **Recommendation**  |
| [ ]  Acknowledge, and the use meets the criteria as outlined in FDA regulations 21 CFR 56.102(d),56.104(c), 312.36, and 50.24 | [ ]  Acknowledge, but the use does not meet the criteria as outlined in FDA regulations 21 CFR 56.102(d),56.104(c), 312.36, and 50.24 and forward to Full Committee for review  |

Reviewer Name:Click or tap here to enter text. Date: Click or tap to enter a date.