Treating Physician Certification: Emergency Use of an Unapproved Device Without Prior Independent Physician Assessment

**INSTRUCTIONS: Please provide the information requested and delete all text in red and blue before submitting. Do not edit or delete black text.**

**Today’s Date:**

**Unapproved Device name:**

**Date the unapproved device was used:**

**To: Institutional Review Board**

There is insufficient time to obtain an independent physician assessment prior to use of the unapproved device. I, the treating physician, certify that all of the following statements are true:

* The patient/participant was confronted by a life-threatening or severely debilitating situation necessitating the immediate use of the test article
* Time was not sufficient to obtain FDA approval for an IDE.
* No alternative method of approved or generally recognized therapy was available that provided an equal or greater likelihood of saving the life of the participant.
* There are anticipated benefits resulting from use of this unapproved device that outweigh the risks of using this device for the participant, and I have substantial reason to believe that the anticipated benefits will occur.

**Please provide the following information:**

**Signature of treating physician**

**Name of treating physician and credentials**

**Title**

**Department**

**Institutional affiliation**

**Email address**

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| **Signature of Independent Physician:** [obtain after use of device]  *I have reviewed the information provided and certifications made by the Principal Investigator above regarding the emergency use of the unapproved drug. I certify that the statements are true and that emergency use was appropriate.* | | |
|  |  |  |
| Name of Independent Physician |  |  |
|  |  |  |
| Signature of Physician |  | Date of Signature |
|  |  |  |