Independent Physician Certification: Emergency Use of a Test Article Without Informed Consent

**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:**

**Test article name:**

**IND or IDE number (if available):**

**Date the test article was administered:**

**Principal Investigator/Treating Physician:**

**To: Institutional Review Board**

I have reviewed the information provided, and certifications made, by the Principal Investigator (Treating Physician) regarding the emergency use of the test article referenced above and certify that all of the following statements are true:

* The participant was confronted by a life-threatening or severely debilitating situation necessitating the use of the test article
* Informed consent could not be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant
* Time was not sufficient to obtain consent from the participant’s legal representative.
* 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.

**Please provide the following information:**

**Signature of independent physician**

**Name of independent physician and credentials**

**Title**

**Department**

**Institutional affiliation**

**Email address**