Independent Physician Certification: Emergency or Compassionate Use of an Unapproved Device

**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:**

**Investigational Device name:**

**Date the investigational device was used:**

**To: Institutional Review Board**

I, a physician not involved in the treatment of the patient, certify that all of the following statements are true:

* The patient/participant was confronted by a serious disease or condition that the device is intended to treat or diagnose.
* 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 independent physician**

**Name of independent physician and credentials**

**Title**

**Department**

**Institutional affiliation**

**Email address**