|  |
| --- |
| University of California, Irvine – Institutional Review Board**REVIEWER’S SUPPLEMENTAL CHECKLIST - Emergency Use of a Test Article** |
| **Protocol HS #:**  | **Lead Researcher:**  |
| **Title:**  |
| **Person Requesting Determination: Telephone #:** |
| **Department:**  |
| **Exempt Category - Emergency Use of a Test Article (All of the following must be true)** |
|

|  |
| --- |
| **CHECK ONE:** |

|  |
| --- |
| **CHECK ONE:** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **CHECK ONE OF THREE CHOICES:**

|  |
| --- |
| * The participant is confronted by a life-threatening situation necessitating the use of the test article.
* Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant.
* Time is not sufficient to obtain consent from the participant’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 participant.
 |

|  |  |  |
| --- | --- | --- |
| * Immediate use of the test article is (was), in the investigator's opinion, required to preserve the life of the participant
* Time is (was) not sufficient to obtain the independent determination a physician who is (was) not otherwise participating in the clinical investigation
* *Before the use of the test article* the investigator will certify (has certified) in writing all of the following:

|  |
| --- |
| * The participant is confronted by a life-threatening situation necessitating the use of the test article
* Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant
* Time is not sufficient to obtain consent from the participant’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 participant
 |

* *After the use of the test article* a physician who is not otherwise participating in the clinical investigation will certify (has certified) in writing within 5 working days after the use of the article all of the following:

|  |
| --- |
| * The participant was confronted by a life-threatening 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.
* There was available no alternative method of approved or generally recognized therapy that provided an equal or greater likelihood of saving the life of the participant
 |

* The above documentation required will be (was) submitted to the IRB within 5 working days after the use of the test article
 |

 |

 |
| I verify that the Emergency Use of the Test Article was appropriate based on FDA regulations [21 CFR 56.104(c)] and where applicable, the exceptions to the requirement to obtain informed consent for emergency use of a test article in accordance with FDA regulations were met [21 CFR 50.23(b)].**Reviewer’s Signature**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |