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| 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**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |