Protocol Director:

Protocol:

Name of Test Article:

*include IND/IDE Number, if applicable*

Date of Use of Test Article:

Date of Submission by PD:

*(Must be within 5 working days of the Emergency Use of the Test Article)*

**Verification of IRB Chair or Designated Member of the IRB**

*Complete the information in one or both columns, as appropriate:*

|  |  |
| --- | --- |
| Emergency Use of a Test Article  With Informed Consent | Emergency Use of a Test Article  Without Informed Consent |
| I verify that all of the following statements are true:  The participant was confronted by a life-  threatening or severely debilitating situation.  No standard acceptable treatment was  available.  There was not sufficient time to obtain  IRB approval in advance of the use of  the test article. | I verify that all of the following statements are true:  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.  No alternative method of approved or  generally recognized therapy that provided  an equal or greater likelihood of saving the  life of the participant was available.  Independent Physician Certification  Provided *(Section D of Form APP-11m)* |

Name of IRB Chair or Designated IRB Member

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Signature of IRB Chair or Designated IRB Member Date