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 ArticleWith Informed Consent | Emergency Use of a Test ArticleWithout 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 obtainedfrom the participant because of aninability 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