Wright State IRB Emergency Use Follow-Up Report

Directions: Complete and submit this form **to the IRB Office** within 5 working days of the emergency use of the test article along with a copy of the Emergency Use Determination Form and any required attachments.

Date(s) of Emergency Use of Test Article:

Please describe patient outcomes after use including any adverse events that occurred after the emergency use of this test article: (If response longer than space provided, please attach separate document.)

Please describe the plan to meet any sponsor/FDA reporting that is required after emergency use of this test article: (If response longer than space provided, please attach separate document.)

Please describe the consent process that occurred and confirm that the consent form use was placed in the patient's medical record. If a copy of the unsigned consent form (should contain no patient identifiers) that was used was not previously submitted, please include a copy with this submission. (If response longer than space provided, please attach separate document.)

Signature of the Treating Physician: _____

Date of Follow-Up Submission: _____

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Convened Wright State IRB Review and Concurrence with Emergency Use

The Wright State IRB reviewed this case at a convened meeting on _____ and verified that:

- The patient was confronted by a life-threatening situation necessitating the use of the test article.
- No alternative method of approved or generally recognized therapy was available that provided an equal or greater likelihood of saving the patient's life, and
- Time was not sufficient to obtain prospective approval from the convened IRB.

To be signed by the IRB chair or designee after an assessment by the IRB at a convened meeting indicating approval of the appropriateness of the emergency waiver and the consent process employed.

Signature of the IRB Chair/Designee: _____

Date: _____