Wright State IRB Emergency Use Determination Form

Directions:

This form should be completed and sent to the IRB Chair/Office prior to the emergency use of the test article to receive the written concurrence (email or formal letter) of the IRB Chair/Designee prior to use.

If you cannot obtain concurrence from the IRB Chair/Designee prior to the emergency use, you still must complete and sign this form before engaging in the emergency use. This includes obtaining certification from a non-treating physician.

Then, within 5 working days, you must submit this completed form and the Emergency Use Follow-Up Report Form with all required attachments to the **Wright State** IRB office at irb@wright.edu. If you received prior concurrence from the IRB Chair/Designee, you must also submit both completed forms to the IRB Office.

General Information:

Treating Physician Name:

Department:

Phone:

Email:

Type of test article (Drug/Device/Biologic):

Name of test article:

Name of Manufacturer (include copy of written authorization from manufacturer/ sponsor or FDA):

IDE# or IND # (if applicable):

Location of treatment (i.e., Wright State Campus, Miami Valley, Dayton VAMC):

Emergency Use Criteria (Please check all to confirm applicability, if all not applicable, please contact IRB Office for guidance):

☐ The patient has a life-threatening or serious disease or condition that needs immediate treatment.

☐ No generally acceptable alternative treatment for the condition exists.

☐ There is insufficient time to obtain IRB approval from the IRB at a convened meeting.

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Emergency Use Status (Choose One Option Below):

☐ The emergency use has not occurred, and I am seeking concurrence from the IRB Chair that the use of the test article constitutes an emergency use.

☐ The emergency use has already occurred without IRB concurrence and I am reporting this for the first time to the IRB within the 5-day requirement and have included a completed Follow-Up Report Form as required.

Informed Consent (Choose One Option Below):

☐ Prior to emergency use, check here to indicate that a copy of the written informed consent document is included for IRB Chair/Designee or Independent Physician review and that it contains all the required elements as defined by the Wright State *Informed Consent Policy*.

Informed consent will be obtained from (check one): ☐ Patient ☐ Legally Authorized Representative

☐ Prior to emergency use, check here to indicate that you are requesting a waiver of informed consent from the IRB Chair/Designee because all the following are true:

- The subject is/was confronted by a life-threatening situation necessitating the use of the test article and no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.
- Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject; and
- Time is/was not sufficient to obtain consent from the subject's legal representative.

☐ If unable to obtain IRB concurrence before emergency use, check here to indicate that informed consent could not be obtained from the patient or legally authorized representative and you received signed concurrence from an Independent Physician that the waiver met the requirements (see below):

Name of Ind. Physician (Print Clearly): _____

I certify that I am not involved in the care of this patient and all the following are true with regards to this case:

- The subject is/was confronted by a life-threatening situation necessitating the use of the test article and no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

- Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject; and
- Time is/was not sufficient to obtain consent from the subject's legal representative.

Signature Ind. Physician: _____

Date of Determination: _____

Department: _____ Email: _____

☐Determination Made Prior to Use ☐Determination Made After Use

Patient Information (Please complete all of the following) Patient

Initials:

Age:

Explain the nature of the life-threatening or severely debilitating situation and why the use of the test article is/was necessary: (If response larger than space provided, please attach separate document.)

Describe any prior course of patient treatment or any possible alternative treatments: (If response longer than space provided, please attach separate document.)

Describe planned course of treatment and planned monitoring of condition after use: (If response longer than space provided, please attach separate document.

Describe whether a future emergency use of this test article will be needed at local site: (Note that if a future use is likely, a new IRB application must be submitted for such use. If response longer than space provided, please attach separate document.)

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Treating Physician Certification

All the above information is true to my knowledge. I agree to adhere to the requirements of the *Emergency Use* Policy and the treatment course as described in this form. I agree not to extend the use of this test article beyond the patient and treatment described in this request and to provide the Wright State IRB with the required Follow-Up Report Form. If there is the possibility that the test article may need to be used again at local site, a formal IRB application will be submitted for IRB review and approval before the next use.

Print Name: _____

Signature of the Treating Physician: _____

Date: _____

Concurrence by the IRB Chair/Designee Prior to Emergency Use (Check One):

☐ I concur that the proposed use the FDA requirements for Emergency Use of a Test Article With Informed Consent

☐ I concur that the proposed use meets meets the FDA requirements for Emergency Use of a Test Article Without Informed Consent

Print Name: _____

Signature of the IRB Chair/Designee: _____

Date of Initial Concurrence: _____

If unable to contact and obtain confirmation from the IRB chair <u>prior to emergency use</u> of a test article, a physician who is not participating in the clinical treatment of the patient must complete this section:

By signing below, the non-treating physician:

- Certifies that this patient is in a life-threatening situation for which no acceptable treatment is available;
- Certifies that there is insufficient time to obtain approval of the full board IRB for use of the test article.
- Acknowledges that the patient may not be considered a research subject and any data generated may not be claimed as research. The outcome of this emergency use may not be included in any report of research activity.

Print Name: _____

Signature of the Non-Treating Physician: _____

Date: _____