Emergency Use Notification to WSU IRB

Do not include any HIPAA identifiers of the patient in this notification.

Date: _____

To: Wright State Institution Review Board; University Hall, Wright State University

This is to inform you of the emergency use (outside the approved indication) of (name of drug or device) _____ on _____/_____/_____.

I concur that this use met the criteria of Emergency Use as defined by the FDA under 21CFR56.102(d). See definition below: □ YES □ NO

Emergency use is defined as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.

A life-threatening condition that needs immediate treatment.

Description: ____________________________________________________________

No generally acceptable alternative treatment for the condition exists.

Explanation: __________________________________________________________

Because of the immediate need to use the drug/device, there is no time to use existing procedures for IRB approval.

Explanation: __________________________________________________________

Humanitarian Use Device

This emergency use involved a Humanitarian Use Device

□ NO □ YES

IF YES: complete the following section:

IRB-HSR # of the protocol for the HUD: _______

The HUD device is currently indicated by the FDA to treat __________________________________________.
This off-label use was to treat the patient for:
___________________________________

Consent
Was consent obtained from the patient?
☐ YES
☐ NO

IF YES- attach a copy of the signed consent form.
IF NO- complete the following section:

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

Signatures:

By signing below I confirm the patient met all criteria listed above.

____________________________ ___________________________ __________
Signature of Study Team Member   Name Printed   Date

____________________________ ___________________________ __________
Signature of 2nd Physician   Name Printed   Date
Not Affiliated with Study

Additional information:  

Signature

____________________________ ___________________________ __________
PI Name Printed   PI Signature   Date