Emergency Use Form

For Emergency Use of Investigational Drug, Biologic, or Device

Submit to TriHealth IRB at irb_hrpp@trihealth.com

Use this form to facilitate Emergency Use of an investigational product (investigational test article). If possible, notify the IRB Chairman (513-265-0936) or IRB Coordinator (847-306-0527) prior to Emergency Use. See the Emergency Use Checklist on page 2 of this form if you have questions about the types of situations that meet the criteria for the Emergency Use of an investigational product.

TO NOTE: It is understood that a need for an investigational drug or biologic may arise in an emergency situation that does not allow time for submission of an IND. FDA may authorize shipment of a test article in advance of IND submission. Requests to the FDA for authorization may be made by telephone or other rapid communication means. The Office of Crisis Management & Emergency Operations Center can be contacted at (866-300-4374) and (301-796-8240). Find additional contact information at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-investigational-drug-or-biologic.

1. BACKGROUND INFORMATION

a. Physician name:

b. Investigational product name:

c. Date of use of investigational product:

d. TriHealth site where investigational product was used:

e. Investigational product manufacturer:

f. Explain the rationale for the use of investigational product:

2. EMERGENCY USE CHECKLIST

All of the following criteria must be met to qualify for Emergency Use of an investigational product. Check the criteria that are applicable to your situation. Contact the IRB Chairman or IRB Coordinator if you have any questions about the criteria:

- ☐ **The investigational product is used to treat a single patient.**
- ☐ **The patient has a condition that is life-threatening or severely debilitating.**
- ☐ **No standard treatment is available.**
- ☐ **There is not sufficient time to obtain IRB review and approval.**
- ☐ **The emergency use will be reported to the IRB within 5 business days (when possible, the treating physician should consult with the IRB prior to use).**
- ☐ **Informed consent will be sought and documented from the patient or his/her legally authorized representative OR the criteria for waiver of informed consent are met (see section 3 below).**
- ☐ **The treatment will not be incorporated into a project that meets the definition of research requiring IRB review (it is not part of a systematic investigation specifically designed to contribute to generalizable knowledge).**

3. INFORMED CONSENT OR WAIVER OF INFORMED CONSENT CHECKLIST

INFORMED CONSENT:
Indicate if the investigator/ physician obtained informed consent from the subject or the subject's legally authorized representative prior to the use of the investigational product

- ☐ **Yes**
- ☐ **No (complete Waiver of Informed Consent Checklist below)**

WAIVER OF INFORMED CONSENT CHECKLIST:
The investigator AND a physician who is not participating in the use of the investigational product must document that all of the following criteria are met if informed consent was not (will not be) obtained. Check the criteria that are applicable to your situation.

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

4. REPORT TO IRB AFTER EMERGENCY USE

a. The following must be submitted / reported to the IRB within 5 business days of the use of the investigational product. Check the items that are included with your IRB submission:

- ☐ **This completed Emergency Use Form**
- ☐ **The informed Consent Document that was used OR documentation from an independent physician that the above criteria for waiver of informed consent were met (e-mail or letter from independent physician are acceptable for IRB submission).**

b. Explain any known results of the use of the investigational product:

c. Explain any serious adverse events and/or unanticipated problems associated with the use of the investigational product:

5. CERTIFICATION

I attest to the information contained in this form. I confirm that I will abide by the requirements of TriHealth and TriHealth IRB, as per Federal and State Regulations, and any manufacturer agreements. I have not been disbarred, suspended or restricted by any federal or state agency.

DATED Signature Investigator / Physician:

Submit Form to TriHealth IRB at irb_hrpp@trihealth.com