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| **or-logo-stacked** | **Institutional Review Board**  **Human Research Protections**  **Notification Form: Emergency Use of an Investigational Drug or Biologic Product**  *Version March 2019* |

#### **INSTRUCTIONS: PLEASE REVIEW THE FOLLOWING INFORMATION BEFORE COMPLETING THIS FORM.**

**FOR ADDITIONAL INFORMATION VISIT:** [**https://research.uci.edu/compliance/human-research-protections/researchers/expanded-access-and-right-to-try.html**](https://research.uci.edu/compliance/human-research-protections/researchers/expanded-access-and-right-to-try.html)

#### Emergency Exemption from Prospective IRB Approval:

**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 [21 CFR 56.102(d)].**

**The emergency use provision in the FDA regulations [21 CFR 56.104(c)] is an exemption from prior review and approval by the IRB. The exemption, which may not be used unless all of the conditions described in 21 CFR 56.102(d) exist, allows for one emergency use of a test article without prospective IRB review.** FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. *FDA acknowledges, however, that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue.*

**Life-threatening**, for the purposes of section 56.102(d), includes the scope of both life-threatening and severely debilitating, as defined below.

* **Life-threatening** means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.
* **Severely debilitating** means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

#### Process at UCI:

### The IRB requests that the Investigator *notify the IRB prior to the emergency use.* Notification occurs by completion of this form. There are two parts to this form.

### To initiate a notification, **Part I** must be completed. IRB Chair confirmation of notification will be obtained. Notification will be used to confirm that the circumstances meet the regulatory or legal requirements for the emergency use of a test article. Notification will also be used by the IRB to initiate tracking to ensure that the Investigator files a report within the five working days after the use of the test article as required by 21 CFR 56.104(c).

### Accordingly, **Part II** must be submitted within five working days after the use of the test article. The complete report will then be reviewed by the IRB at a convened meeting. IRB review is not merely confirmation of the emergency use but is an assessment of the circumstances, the appropriateness of the emergency waiver, and the consent process employed. Following the meeting, the physician will be provided confirmation of IRB review and any noted concerns or requests for additional information. This confirmation should be maintained with the physician's records for audit purposes.

Exemption from Informed Consent Requirement:

Although the emergency use is exempt from IRB review, it is not exempt from the FDA regulatory requirements to obtain and document consent. For an emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following [21 CFR 50.23(a)]:

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.

If, in the investigator's opinion, immediate use of the test article is required to preserve the subject's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the clinical investigator should make the determination and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The investigator must notify the IRB within 5 working days after the use of the test article [21 CFR 50.23(c)].

**Part I: EMERGENCY USE OF AN INVESTIGATIONAL DRUG OR BIOLOGIC PRODUCT**

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| **This form should be signed by the physician requesting the emergency use, prior to use.** **Complete and submit Part I of this form via fax to (949) 824-1465 or email to HRP staff at** [**IRB@research.uci.edu**](mailto:IRB@research.uci.edu)**.** | | | | |
| **Section I: EMERGENCY USE INFORMATION FOR INITIAL NOTIFICATION** | | | | |
| A. NAME OF THE INVESTIGATIONAL DRUG OR BIOLOGIC (TEST ARTICLE): | | | | |
| B. IND/IDE #:       *IF NO IND/IDE EXISTS, CONTACT THE FDA FOR AN EMERGENCY USE IND/IDE. PROVIDE A COPY OF THE FDA LETTER GRANTING THE EMERGENCY USE IND WITH THIS REPORT.* | | | | |
| C. MANUFACTURER: |  | D.DOSAGE: |  | |
| E. INDICATION FOR EMERGENCY USE: | | | | |
| F. DESCRIBE THE PATIENT'S CONDITION AND EXPLAIN WHY THE EMERGENCY USE OF THE TEST ARTICLE IS REQUIRED: | | | | |
| G. DATE TEST ARTICLE WILL BE ADMINISTERED/UTILIZED: | | | | |
| H: WILL INFORMED CONSENT OBTAINED FROM THE PATIENT OR THE PATIENT’S LEGALLY AUTHORIZED REPRESENTATIVE? YES  NO  **If no**, complete Part I, Section II below. | | | | |
| **By signing below, the Investigator:**   * Certifies that this patient is in a life-threatening situation for which no standard 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, except possibly for case reports, and; * Acknowledges that any subsequent use of the test article in the same or different patient requires submission of an IRB application to the IRB for full board review. | | | | |
| NAME OF INVESTIGATOR[[1]](#footnote-1) (print) SIGNATURE OF INVESTIGATOR DATE | | | | |
| **Section II: IRB CHAIR CONFIRMATION** | | | |
| **By signing below, the IRB Chair confirms / understands that:**   * that this patient is in a life-threatening situation for which no standard acceptable treatment is available; * that there is insufficient time to obtain approval of the full board IRB for use of the test article * The physician is required to notify the IRB of all emergency uses within five days of the use and to notify the IRB in writing of all exceptions to the requirement for consent within five days of the exception.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NAME OF IRB CHAIR, VICE CHAIR OR MEDICAL PHYSICIAN DESIGNEE (print) SIGNATURE DATE | | | |
| **Section III: REQUEST FOR WAIVER OF INFORMED CONSENT**  ***(If informed consent will be obtained, skip this section)*** | | | |
| In some emergency use circumstances, it may not be feasible to obtain informed consent prior to the administration or use of the test article. An exception to the informed consent requirements is acceptable if the Investigator and a physician who is not otherwise involved in the patient’s treatment must certify in writing that the following four (4) conditions exist: | | | |
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| 1. The patient is confronted with a life-threatening situation necessitating the use of the   test article; and   1. Informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from the patient; and 2. Time is not sufficient to obtain consent from the patient's legal representative; and 3. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject. | | | |
| **REQUEST FOR WAIVER OF INFORMED CONSENT:** | | | |
| *By signing below, I certify that this emergency use meets all four (4) of the conditions listed above.* | | | |
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| *NAME OF INVESTIGATOR*[[2]](#footnote-2) *(print) SIGNATURE OF INVESTIGATOR DATE* | | | |
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| *NAME OF NON-TREATING PHYSICIAN[[3]](#footnote-3) (PRINT) SIGNATURE OF NON-TREATING PHYSICIAN DATE* | | | |

**Part II: EMERGENCY USE – FOLLOW UP**

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| **Section A: FOLLOW-UP REPORT *(required)*** |
| **Within *five working days* after the use of an investigational drug or biologic a signed version of this part of the form, summarizing the consent process (if applicable), the date and results of the emergency use must be submitted to the IRB.** The report will be reviewed by the IRB at a convened meeting.  IRB review is not merely confirmation of the emergency use but is an **assessment of the circumstances, the appropriateness of the emergency waiver, and the consent process employed.** Following the meeting, the physician will be provided confirmation of IRB review and any noted concerns or requests for additional information. This confirmation should be maintained with the physician's records for audit purposes. |
| 1. NAME OF THE INVESTIGATIONAL DRUG OR BIOLOGIC (TEST ARTICLE): |
| 1. IND/IDE #:       *IF NOT ALREADY PROVIDED WITH PART I THEN PROVIDE A COPY OF THE FDA LETTER GRANTING THE EMERGENCY USE IND WITH THIS REPORT.* |
| 1. MANUFACTURER: |
| 1. DOSAGE: |
| 1. INDICATION FOR EMERGENCY USE: |
| 1. DATE TEST ARTICLE ADMINISTERED/UTILIZED: |
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| 1. WAS INFORMED CONSENT OBTAINED FROM THE PATIENT OR THE PATIENT’S LEGALLY AUTHORIZED REPRESENTATIVE?   YES  NO, SKIP TO J; ALSO COMPLETE SECTION II. |
| 1. PROVIDE A BRIEF DESCRIPTION OF THE INFORMED CONSENT PROCESS (INCLUDE A UNSIGNED COPY OF THE CONSENT DOCUMENT PROVIDED THE PATIENT): |
| 1. PROVIDE A BRIEF DESCRIPTION OF THE RESULTS OF THE EMERGENCY USE: |
| 1. PROVIDE AN EVALUATION OF THE LIKELIHOOD FOR A SIMILAR NEED FOR EMERGENCY USE OF THIS TEST ARTICLE. NOTE THAT IF FUTURE USE IS LIKELY, [A NEW IRB APPLICATION](https://apps.research.uci.edu/irbapp/index.cfm?CFID=eeb4b855-b92b-4f84-b9b5-00f14b52eac9&CFTOKEN=0&action=log_in&a=c) MUST BE SUBMITTED: |

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| **Section B: IRB DETERMINATION OF APPROPRIATENESS OF EMERGENCY USE OF A TEST ARTICLE** |
| **By signing below, the convened board confirms:**   * that the patient is in a life-threatening situation for which no standard acceptable treatment is available; * that there was insufficient time to obtain approval of the full board IRB for use of the test article; * the emergency use was reported to the IRB within 5 working days of the emergency use * Investigator has obtained a legally effective consent from the subject   + OR   + Informed consent cannot be obtained from the subject because of an inability to communicate with the subject   + Time is not sufficient to obtain consent from the patient's legal representative; and   + There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject. |
| TO BE SIGNED BY THE IRB CHAIR, IRB VICE CHAIR OR MEDICAL PHYSICIAN DESIGNEE AFTER AN ASSESSMENT BY THE IRB AT A CONVENED MEETING. |
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| NAME OF IRB CHAIR, VICE CHAIR OR MEDICAL PHYSICIAN DESIGNEE (print) SIGNATURE DATE |
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| COMMENTS: |

1. “Investigator” in this context is generally the attending physician. Confirmation of emergency use requests from “House” staff, fellows, or nurses are inappropriate and should not be initiated. [↑](#footnote-ref-1)
2. “Investigator” in this context is generally the attending physician. [↑](#footnote-ref-2)
3. A non-treating physician is a physician who is not participating in the clinical treatment of the patient. [↑](#footnote-ref-3)