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| **Instructions for use of the Emergency Use[[1]](#footnote-2) of an Investigational Drug or Biologic Physician Attestation Form:**   1. **Use this form to address the** [**FDA exception from informed consent requirement**](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-investigational-drug-or-biologic) **in the Emergency Use of an Investigational Drug or Biologic (i.e., INFORMED CONSENT WILL NOT BE OBTAINED FROM THE PATIENT).** 2. **Obtain both required physician attestations.[[2]](#footnote-3)** 3. **Upload this form to the Attachment Section of the Emergency Use protocol in Kuali Research Protocols (**[**KRP**](https://uci.kuali.co/protocols/)**).** 4. **For additional information and resources on this topic, see page 2.** 5. **For additional questions, please contact** [**HRP Staff**](https://research.uci.edu/human-research-protections/contact-hrp-staff/)**.** |

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| **Physician Attestation** |
| * **Confirm the following information and provide your signature/s below.** * **Note: An independent physician is one not otherwise participating in the clinical investigation.** |
| **As the physician holding the Emergency IND or the independent physician (*BOTH are required*), I have:** |
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| 1. Confirmed that the patient is confronted with a life-threatening[[3]](#footnote-4) situation necessitating the use of the test article; and 2. Confirmed that informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from the patient; and 3. Confirmed that time is not sufficient to obtain consent from the patient's legal representative; and 4. Confirmed/ agree that 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 patient.   **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Name of Physician Holding the Emergency IND**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of Physician Holding the Emergency IND Date** |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**    **Name of Independent Physician**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of Independent Physician Date** |

**Resources:**

For more information about Emergency Use, visit the following:

FDA Webpage:

* [Emergency Use of an Investigational Drug or Biologic](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-investigational-drug-or-biologic)

Office of Research Webpages:

* [Expanded Access to Unapproved Drugs or Biologics](https://research.uci.edu/human-research-protections/clinical-research/expanded-access-to-unapproved-drugs-or-biologics/)
* [Expanded Access to Unapproved Devices](https://research.uci.edu/human-research-protections/clinical-research/devices-used-in-clinical-research/expanded-access-to-unapproved-medical-devices/)

1. **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)]. [↑](#footnote-ref-2)
2. 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)]. [↑](#footnote-ref-3)
3. **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. [↑](#footnote-ref-4)