|  |
| --- |
| **Instructions** |
| * The investigator should notify the IRB prior to any emergency use so that the IRB chair or designated physician IRB member may determine if the emergency use exemption criteria are met.
* The investigator must report to the IRB within **5 working days** of the emergency use, even if the investigator notified the IRB prior to use.
* An activity must meet all of the following criteria for an emergency use exemption:
	+ Life-threatening situation or severely debilitating situation
	+ No standard acceptable treatment available
	+ Not sufficient time to obtain IRB approval
	+ Report to the IRB within 5 working days of use
	+ Any subsequent use of the test article is subject to IRB review
	+ The activity is not a systematic investigation designed to develop or contribute to generalizable knowledge
* CLICK™ IRB
	+ Do not include or upload to Click any protected health information.
	+ Include the template with a Reportable New Information Submission.
	+ Upload the completed template to the Reportable New Information SmartForm, Question 7.
	+ Also complete and upload the HRP-516 - Template - Expanded Access to the Reportable New Information SmartForm, Question 7.
* See HRPP Manual 7-3, Emergency Use of Investigational Drugs and Devices, for more information.
 |
| **Complete Questions 1 – 6.** |
| 1 | Investigator Name.        |
| 2 | Justification for use.       |
| 3 | Explain why it is a life threatening situation or severely debilitating situation.       |
| 4 | Explain why there is no standard acceptable treatment available.       |
| 5 | Explain why there is not sufficient time to obtain IRB approval.       |
| 6 | Upload to the Reportable New Information SmartForm, Question 7:* Consent document
* For investigational drugs, documentation of FDA authorization pursuant to 21 CFR 312 Subpart I.
* HRP-516 - Template - Expanded Access
 |
| NOTE: The investigator must report to the IRB within 5 working days of the emergency use, even if the investigator notified the IRB prior to use.  |
| **Complete Questions 7- 12 if the Investigator was NOT able to Notify the IRB Prior to Emergency Use**  |
| 7 | Date of emergency use of investigational drug or device occurred.       |
| 8 | Date reported to IRB (must be reported to the IRB within 5 working days of use).       |
| 9 | Explain why the prospective reporting to the IRB was not feasible.       |
| 10 | Explain how the investigator assured that the emergency use exemption criteria have been met.       |
| 11 | Explain how the investigator assured that the requirements for investigational drugs under 21 CFR 312 Subpart I have been met.       |
| 12 | Was informed consent obtained?  | [ ]  No [ ]  Yes |
| If yes, complete 12A.If no, complete 12B and 12C. |
| 12A | Explain the process for obtaining informed consent.       |
| 12B | Explain why informed consent was not obtained.      *The investigator and a physician who is not otherwise participating in the clinical investigation must certify in writing all of the following (21 CFR 50.23(a)):** *The human subject is confronted by a life-threatening situation necessitating the use of the test article.*
* *Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.*
* *Time is not sufficient to obtain consent from the subject’s legal representative.*
* *There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.*
* *Upload the investigator certification.*
* *Upload a certification from a physician who is not otherwise participating in the clinical investigation as to how the use met the criteria for exception from informed consent in 21 CFR 50.23(a) – (c).*

*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. 21 CFR 50.23(b).*  |
| 12C | Upload to the Reportable New Information SmartForm, Question 7:* Investigator certification.
* Certification from a physician who is not otherwise participating in the clinical investigation as to how the use met the criteria for exception from informed consent in 21 CFR 50.23(a) – (c) OR the independent evaluation.
 |