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| **Notification of Emergency Use** of a Test Article |
| Use of Investigational drug, device or biologic per FDA regulations [21 CFR 56.104](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.104)(c) |

*Nothing in UTHSCSA policy is intended to prevent a physician from preserving life, for example, if in the investigator's opinion, immediate use of the test article is required to preserve the participant's life, and if time is not sufficient to submit as Treatment Use Protocol, or conform to the Emergency Use policies as outlined in local policy (e.g., IRB notification, obtaining an independent physician's determination), the clinical investigator should make the determination and then, 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 then notify the IRB within 5 working days after the use of the test article [***[***21 CFR 50.23***](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.23)***(c)].*** *This form will serve as the IRB notification.*

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| **1. Treatment Sites - List all sites where your treatment occurred:** | |
| **Check all that apply** | **Name of Institution / Site**  *(list all participating sites below)* |
|  | **UTHSCSA** |
|  | **South Texas Veteran’s Healthcare System (STVHS)** |
|  | **University Health System (UHS)** |
|  | **Christus Santa Rosa Health Care (CSRHC)** |
|  | **Baptist Health System (BHS)** |
|  | **Other ⭢** |

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| **2. Who is responsible for the cost of the test article and any other services?** |
| |  |  |  |  | | --- | --- | --- | --- | |  | **Sponsor** | **Institution** | **Patient/3rd Party** | | **Test Article (Drug/Device)** |  |  |  | | **Administration/ancillary services** |  |  |  | | **Other ⭢** |  |  |  | |

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| **3. Information about the test article** | | |
|  | **Yes** | **No** |
| 1. Do you intend to use this drug or device again in the future?   *Any subsequent use of the drug/device will require convened IRB approval* |  |  |

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| **4. Treating Physician Assurance that Emergency Use Criteria was met** | | |
| **The Treating Physician certifies that all of the following statements are true** | | **Yes** |
| 1. The patient was confronted with a life-threatening or severely debilitating situation necessitating the use of the investigational test article   Below: explain the nature of the situation and why the use of the drug or device was necessary: | |  |
| Explain here | |
| 1. No alternative method of approved or generally recognized therapy was available that provides an equal or greater likelihood of saving the patient’s life.   Below: Describe available alternative treatment methods: | |  |
| Describe here | |
| 1. There is (was) insufficient time to obtain IRB approval   Below: explain why there was not sufficient time to obtain IRB approval prior to the emergency use of the drug or device | |  |
| Explain here | |

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| **5. Informed Consent:**  **Was informed consent obtained?** | | |
|  | **Yes** | |
| Enter the date informed Consent was obtained Enter date here  and **attach** the signed consent (**with patient identifiers** ***redacted***). [Click here for the informed consent template](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_consent.doc). | |
|  | **No. Answer questions (a) and (b) and (c):** | |
| 1. Informed consent could not be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from the patient.   *Below: Describe why the patient was unable to provide consent:* | |
| Describe here |
| 1. Time was not sufficient to obtain Informed consent from the patient’s legally authorized representative.   *Below: Explain why there was insufficient time and describe any efforts made to contact the LAR to obtain informed consent:* | |
| Explain here |
| 1. Attach a Certification of Independent Physician to certify the Emergency Use without Informed Consent.   [Click here for the Certification template](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_certification.docx) | |

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| **6. Adverse Events:**  **Were any adverse events identified during the treatment?** | |
|  | **Yes** |
| Provide details of the adverse event here |
|  | **No.** |
|  | **Treatment continues, a follow-up report will be submitted to the IRB** |