**EMERGENCY USE CHECKLIST – DEVICE**

**INSTRUCTIONS:**

• Use this checklist to assure compliance with [**FDA requirements**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.104) and [**UT Health San Antonio policy**](https://www.uthscsa.edu/sites/default/files/Services/forms/emergency_use_irbpolicy.pdf)for the emergency use of an unapproved device. A different checklist is available for the emergency use of an unapproved drug or biologic.

• The treatment physician must ensure that all of the qualifying criteria are met prior to the emergency use.

1. **PHYSICIAN INFORMATION**

|  |  |
| --- | --- |
| Treating Physician Name: | **Click here to Insert** |
| Name of Test Article: | **Click here to Insert** |
| Sponsor/Manufacturer of Test Article: | **Click here to Insert** |
| IDE #: | **Click here to Insert** |

**◊ ◊ ◊ ◊ ◊ ◊ ◊ ◊ PRIOR USE REQUIREMENTS ◊ ◊ ◊ ◊ ◊ ◊ ◊ ◊**

1. **QUALIFYING CRITERIA FOR EMERGENCY USE (REQUIRED – all must be TRUE)**

|  |  |  |
| --- | --- | --- |
|  | **TRUE** | **FALSE** |
| The patient has a condition that is life-threatening or severely debilitating |  |  |
| No standard treatment is available |  |  |
| Due to the immediate need to use the device, there is no time to use existing procedures  to obtain FDA approval for the use |  |  |
| There is not sufficient time to obtain IRB review and approval for the use of the test article |  |  |
| This is the first emergency use of this test article at UTHSCSA or the sponsor does not have plans to pursue marketing or change of marketing and there is no current planned subsequent use. |  |  |
| There is no known available IRB approved protocol using the same article, or the patient does not qualify for an existing protocol |  |  |

1. **CONTACT SPONSOR / MANUFACTURER**

* Prior FDA approval is not required for the shipment or emergency use
* FDA does not need to be contacted prior to the emergency use of the unapproved device.

Check ***one*** of the following:

|  |  |
| --- | --- |
| Authorization from the IDE sponsor, if an IDE exists (if possible) |  |
| Independent assessment from an uninvolved physician (if possible) |  |

NOTE: If the manufacturer requires a letter from the IRB prior to shipping, contact the IRB office at (210) 567-8250. After business hours, you can contact the Director at (210) 422-5932 or Associate Director at (210) 779-3629.

1. **CONTACT THE INVESTIGATIONAL PHARMACY & MEDICAL DIRECTOR**

|  |  |
| --- | --- |
| Concurrence from the Medical Director has been obtained. *For University Health only*  *Call (210) 743-6450 during normal business hours.* |  |
| The Research/Investigational Pharmacy at: **<<click here to insert NAME OF INSTITUTION (University Health, VA, etc)>>** has been contacted regarding the receipt, storage, and dispensation of the unapproved device. |  |
|  |  |

1. **CONTACT OIRB / CONTACT IRB CHAIR (optional, not required)**

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| Contact the OIRB to inquire whether the test article has been previously used at UTHSCSA |  |  |
| Contact the IRB Director or IRB Associate Director to discuss the emergency use (if possible) |  |  |

Contact the IRB office at (210) 567-8250. After business hours you can contact the Director at (210) 422-5932 or Associate Director at (210) 779-3629.

1. **OBTAIN INFORMED CONSENT**

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **YES** | **NO** |
| Written informed consent will be obtained from the patient or legally authorized representative  If Yes – *complete* [***informed consent template***](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_consent.doc) | |  |  |
| If No –  Waiver of written informed consent – the treating physician and an independent physician *not* involved in the emergency use must certify in writing that **all** of the following criteria are met:  *If* ***NO*** *to any of the following, or if you are unable to obtain a* [***written certification from an independent physician***](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_certification.docx)*, you must obtain informed consent using the* [***informed consent template***](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_consent.doc) | |  |  |
| 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 legally authorized representative; and |  |  |
| There is no available alternative method of approved or generally recognized therapy that provides equal or greater likelihood of saving the life of the patient. |  |  |

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1. **SUBMIT TO THE IRB (WITHIN 5 WORKING DAYS)**

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| --- | --- |
| [Notification of Emergency Use](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_notification.docx) |  |
| Copy of signed informed consent form (patient name redacted) or signed certification of waiver from independent physician |  |
| Copy of **this** Emergency Use Checklist – Device |  |

1. **NOTIFY THE IDE SPONSOR/FDA**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Submitted** | **Pending** | **N/A** |
| If an IDE exists (i.e., sponsor), the treating physician must provide the **IDE sponsor** with a report. The sponsor is required to report to the FDA within 5 working days. |  |  |  |
| If an IDE does not exist, the physician must submit a report to the FDA within  5 working days. |  |  |  |