**EMERGENCY USE CHECKLIST – DRUG/BIOLOGIC**

**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 drug or biologic. A different checklist is available for the emergency use of an unapproved device.

• 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** |
| IND #: | **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 |  |  |
| 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 UT Health San Antonio 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 / FDA**

• Check ***one*** of the following:

|  |  |
| --- | --- |
| The manufacturer has authorized this use under an existing IND |  |
| I have obtained an IND for this use from the [FDA](http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm) |  |
| I have obtained FDA authorization of shipment in advance of an IND submission |  |

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**

|  |  |
| --- | --- |
| 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 drug or biologic. |  |

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

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| Contact the IRB Director or IRB Associate Director to discuss the emergency use (if necessary) |  |  |

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***](http://research.uthscsa.edu/irb/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)**

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

1. **NOTIFY THE FDA**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Submitted** | **Pending** | **N/A** |
| Drugs/biologics: if treating physician is IND holder, any follow-up with FDA |  |  |  |