Emergency Use Process

Easy as 1, 2, 3



**Complete the Checklist**

Drugs:

Use the [***Emergency Use Drug/Biologic Checklist***](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_drug_checklist.docx)

Devices:

Use the [***Emergency Use Device Checklist***](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_device_checklist.docx)

Is prior IRB approval needed?

Some Sponsors require IRB approval or chair concurrence before shipping a test article:

If you need this approval, call the IRB Director immediately at (210) 854-5671 or IRB Associate Director at (361) 548-7904 and have your completed checklist ready when you call.

Written determination will be provided to the treating physician as to whether the IRB Chair or Designee agrees the Emergency Use meets regulatory criteria.

**Informed Consent & Use**

Obtain **informed Consent**:

Develop the Consent Form using the [***Emergency Use Consent Template***](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_consent.doc)

If you are unable to obtain consent from the subject (based upon criteria identified in the checklist) obtain a written assessment from an independent physician certifying that the waiver of consent criteria are met. You may use this template: [***Certification from Independent Physician***](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_certification.docx)

Emergency Use of a test article requires prior consent. If you are able to obtain informed consent (as determined in step 1); speak to the patient or LAR to obtain this consent.

You will be required to provide the IRB with a copy of the completed informed consent (names redacted) after the use.

**Use** the drug/device to treat the patient:

If all conditions are met and appropriate approvals are obtained (as applicable), the treating physician may use the Drug, Device or Biologic *after* obtaining informed consent (unless the emergency use meets the waiver conditions as determined by the criteria on the checklist).

**Notify the IRB**

**Notify the IRB:**

The treating physician must submit a [***Notification of Emergency Use***](https://www.uthscsa.edu/sites/default/files/Services/forms/eu_notification.docx), including the signed consent form (or certification of informed consent waiver) and the Emergency Use Checklist **within 5 days** following the use of the test article (THIS IS A FEDERAL REQUIREMENT).

The IRB office staff will review the checklist and confirm there were no prior emergency uses in this circumstance.

The convened IRB will review the materials and determine whether the regulatory criteria were met and whether the plan for obtaining informed consent was appropriate.

If the convened IRB determines that the regulatory criteria were not followed, the circumstance will be treated as Noncompliance according to the [***Noncompliance Policy and Procedure***](https://www.uthscsa.edu/sites/default/files/Services/forms/noncompliance_policy.pdf)***.***

The IRB will send communication to the treating physician summarizing the Board’s conclusion.

The IRB will track the Emergency Use to ensure there is no repeated use (repeated use would necessitate a research protocol).