

**Emergency Use of a Test Article Worksheet**

**Required Documentation**

1. Name and title of physician/investigator that used the test article:

1. Name of the test article (**attach** test article information supplied by the maker/manufacturer; **attach** any relevant protocols, as applicable):

1. Has test article already been administered/used on the patient? Yes / No

Date of administration:

1. Name of the maker/manufacturer of the test article:

1. Indicate the IND/IDE number for the test article (**attach** documentation) and indicate who holds the IND/IDE:

1. Describe the clinical circumstances for the individual requiring the test article under “Emergency Use” regulations (See UMCIRB SOP Emergency Use of a Test Article):

1. Describe the indication for which the test article will be (was) used:

1. Provide documentation that other available treatments are unproven or unsatisfactory:

1. Describe whether additional uses are anticipated, and any plans to submit a research protocol seeking prospective UMCIRB approval:

**Attach** a copy of the informed consent document that was used or will be used to consent the participant or the participants legally authorized representative.

OR

If there was not time to obtain informed consent from the potential participant or legally authorized representative, then documentation verifying the necessity of emergency use without consent should be **attached** by both the physician/investigator and an independent, objective physician from a relevant clinical area.

**The following statements must be initialed by the physician/investigator:**

1. Any serious adverse events or unanticipated problems that occur as a result of the emergency use protocol will be reported as soon as possible to the UMCIRB:\_\_\_\_\_\_\_
2. After the emergency use take place, the initial response of the patient and an update on the patient upon conclusion of the emergency use treatment will be provided to the UMCIRB: \_\_\_\_\_\_\_
3. No data has been/will be collected for human research purposes as a result of this Emergency Use event:\_\_\_\_\_\_

**\*This Page for UMCIRB Use Only\***

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| --- | --- | --- |
| Drug/Device: | | |
| Test Article Administered/Used Prior to UMCIRB Notification | | Yes / No |
| If UMCIRB Notified Prior to Administration/Use of Test Article | Date Chair Notified |  |
| Chair Concurrence Granted | Yes / No / NA |
| Date Concurrence Granted |  |
| Date Emergency Use Initially Reported to the Convened UMCIRB | |  |
| Dates of Follow-up Updates Reported to the Convened UMCIRB | |  |
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**Supporting Document Checklist^**

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| Chair Concurrence (if Obtained) | Yes / No / NA |
| Consent Document | Yes / No |
| Investigator’s Brochure/Instructions for Use | Yes / No |
| FDA Emergency IND/IDE Approval Letter | Yes / No |
| Sponsor Approval Letter | Yes / No / NA |
| Patient Treatment Plan | Yes / No |
| Other Supporting Documents (List) |  |
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**^Attach copies of these documents to this worksheet**