Emergency Use of a Test Article Worksheet
Required Documentation

1) Name and title of the physician /investigator: ____________________________

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

3) Name of the maker/manufacturer of the test article: ____________________________

4) Indicate the IND/IDE number for the test article (attach documentation) and indicate who holds the IND/IDE: ____________________________

5) Describe the clinical circumstances for the individual requiring the test article under “Emergency Use” regulations (See ECU IRB SOP at http://www.ecu.edu/cs-acad/rgs/irb/policies-procedures.cfm): ____________________________

6) Describe the indication for which the test article will be (was) used: ____________________________

7) Provide documentation that other available treatments are unproven or unsatisfactory: ____________________________

8) 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 physicians/investigator:

9) 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: __________

10) 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: __________