UCLA Office of the Human Research Protection Program,
Institutional Review Board

EMERGENCY USE CHECKLIST – DEVICE

INSTRUCTIONS:

- Use this checklist to assure compliance with FDA requirements and UCLA policy 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.
- For additional information see OHRPP Guidance and Procedure: IRB Review – Emergency Use of a Test Article.

BASIC INFORMATION

Treating Physician:

Name of Test Article:

Sponsor/Manufacturer of Test Article:

IND #:

➢ PRIOR USE REQUIREMENTS

QUALIFYING CRITERIA FOR EMERGENCY USE (REQUIRED)

- 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 ❑
- This is the first emergency use of this test article at UCLA ❑
- There is no known available IRB approved protocol using the same article, or the patient does not qualify for an existing protocol ❑

CONTACT SPONSOR / MANUFACTURER

- Prior FDA approval is not required for the shipment or emergency use ❑
  NOTE: FDA does not need to be contacted prior to the emergency use of the unapproved device.
- Authorization from the IDE sponsor, if an IDE exists (if possible) ❑
- Independent assessment from an uninvolved physician (if possible) ❑

CONTACT OHRPP / CONTACT IRB CHAIR

- Check the OHRPP website or inquire whether the test article has been previously used at UCLA ❑
- Contact the Medical IRB Chair or Vice Chair to discuss the emergency use (if possible) ❑

OBTAIN INFORMED CONSENT

Complete ***one*** of the following:

- Written informed consent will be obtained from the patient or legally authorized representative ❑

- 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: ❑

  - 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 ❑

➢ POST- USE REQUIREMENTS

SUBMIT TO THE IRB (WITHIN 5 WORKING DAYS)

- Emergency Use Report Form ❑
- Copy of signed informed consent form or certification of waiver ❑
- Copy of the Emergency Use Checklist – Device ❑

NOTIFY THE FDA

- Other regulatory requirements of the FDA
  - 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. ❑