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.