EMERGENCY USE CHECKLIST – DRUG/BIOLOGIC

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 
• There is not sufficient time to obtain IRB review and approval for the use of the test article 
• 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 / FDA

• Check one of the following:
  ▪ The manufacturer has authorized this use under an existing IND 
  ▪ I have obtained an IND for this use from the FDA 
  ▪ I have obtained FDA authorization of shipment in advance of an IND submission 

NOTE: if the manufacturer requires a letter from the IRB prior to shipping, contact OHRPP at (310) 825-5344

CONTACT THE UCLA INVESTIGATIONAL PHARMACY

• The UCLA Investigational Pharmacy has been contacted regarding the receipt, storage, and dispensation of the unapproved drug or biologic.

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 – Drug/Biologic

NOTIFY THE FDA

- Drugs/biologics: if treating physician is IND holder, any follow-up with FDA