

**CALIFORNIA PACIFIC MEDICAL CENTER  
INSTITUTIONAL REVIEW BOARD**

No: \_\_\_\_\_  
(STAFF USE ONLY)

**ONE TIME EMERGENCY USE**  
*PLEASE TYPE*

Principal Investigator:	Sutter Affiliation:	Dept.:
Mailing Address:	Phone Number: Fax No: E-mail address:	
IRB Number and Protocol Title:		
IND or IDE number:		
Drug/Device Sponsor:		
Date of Actual Use:		
Patient initials:		
Rationale for use:		
<b>Principal Investigator's Assurance</b> I certify that the information provided in this form is complete and correct.		
Principal Investigator's Signature		Date
<b>Administrative use only</b>		
Date received: _____		
Signature of IRB Chair:		Date
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## **GUIDELINES**

**Definition:** An emergency is defined as a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval (21 CFR 56.102(b)).

- **Emergency Use of an Investigational New Drug or Biologic(IND)**

Emergency use of an investigational drug or biologic requires that an IND application be on file with the FDA. If the intended subject does not meet the criteria of an existing study protocol, or if an approved study protocol does not exist, the usual procedure is to contact the manufacturer and determine if the drug or biologic can be made available for the emergency use under the company's IND. Exception: The need for an investigational drug or device may arise in an emergency situation that does not allow time for submission of an IND by the sponsor. In this instance, the FDA may authorize shipment of the test article in advance of IND submission. Requests for such authorization may be made to the FDA by telephone or other rapid communication means [21 CFR 312.36].

- **Emergency Use of Investigational Medical Devices**

Emergency use of an investigational medical device may arise when 1) an Investigational Device Exemption (IDE) for the device does not exist, 2) when a physician wants to use the device in a way not approved under the IDE or 3) when a physician or institution is not approved under the IDE. Each of the following conditions must exist to justify emergency use:

1. The subject is in a life-threatening condition that needs immediate treatment.
2. No generally acceptable alternative for treating the patient is available.
3. Because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use.

The FDA expects the physician to determine whether such an emergency exists, and to have substantial reason to believe that the subject will benefit from the use of the device. The physician is further expected to obtain the following for subject protection:

1. An assessment by an independent physician.
2. Informed consent from the subject or a legal representative.
3. Chair of the IRB's concurrence.
4. If an approved IDE for the device exists, approval from the holder of the IDE. If an IDE does not exist, the physician must notify the FDA of the emergency use of the device and provide the agency with a written summary of the conditions constituting the emergency, patient protection measures taken, and any scientific results.

- **Waiver of informed consent**

Waiver of informed consent requires a signed statement from an independent physician who is not participating in the clinical investigation to certify in writing to all of the following [21 CFR 50.23]: (1) The subject is confronted by a life-threatening situation necessitating the use of the test article; (2) Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent; (3) Time is not sufficient to obtain informed consent from the subject's legal representative; and (4) there is no available method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

## **PROCEDURES:**

### **A. Prior to Emergency Use:**

1. The investigator contacts the manufacturer or FDA to determine if the drug/device can be made available for the emergency use under the company's IND/IDE. The investigator arranges for shipment of the drug or device and obtains the IND/IDE number.

Note: Some manufacturers will agree to allow the use of the test article, but may require an IRB approval letter before the test article will be shipped. If there is insufficient time for this, the investigator contacts the IRB CHAIR. The IRB staff prepares a WRITTEN STATEMENT to be signed by the IRB Chair, to indicate that the IRB is aware of the proposed use and considers the use to meet the requirements of 21 CFR 56.104 (c). An acknowledgment letter has been acceptable to manufacturers who have allowed shipments to proceed under these circumstances.

2. The investigator contacts the IRB Chair to notify of the prospective emergency use of the test article. This is intended for purposes of discussing the circumstances for the use, to determine if use should proceed prior to IRB review, to initiate tracking and to ensure that the investigator files a report within the five day time-frame required by the FDA regulations. If conditions for emergency use are met and it is not possible to convene a quorum within the time available, the use may proceed without IRB approval. **Emergency authorization is for one time, one subject only.**
3. The investigator completes and submits **within five (5) working days** this form following emergency use of the test article.
4. The investigator obtains any approvals or notifications required by his/her department or facility.
5. For drugs administered at this facility, the research pharmacist is notified by the investigator after obtaining IRB approval.
6. Having completed steps 1 through 5, the drug or device may be used on an emergency basis for one subject only.

### **B. Following Emergency Use:**

1. Within five (5) working days after the emergency use of the drug/device, the investigator completes this form, and submits it to the IRB, along with the signed consent form. This is a requirement of the FDA.
2. This form and consent are reviewed at the next convened meeting of the IRB.
3. The emergency use is noted in the minutes of the meeting of the IRB.