Emergency Use Request of an Investigational Drug or Biologic

Please follow these steps:

1. Read the FDA's Emergency Use of an Investigational Drug or Biologic – Information Sheet
2. Contact the FDA to obtain an emergency IND (FDA contact numbers are listed on the above Information Sheet)
3. Once the emergency IND is obtained from the FDA, email the following to IRB@UCSF.edu with "Emergency Use Request" in the Subject line:
    a. Request for Emergency Use Form (This Form)
    b. FDA approval correspondence or eIND if FDA approval was given over the phone

Please note: If the FDA has issued an emergency IND and states that you may proceed, you may do so without IRB concurrence if waiting could jeopardize the patient's well-being. Per the regulations, Emergency Use of an investigational drug or biologic is exempt from prospective IRB approval, provided the FDA has approved the emergency use request.

Also note: Emergency Use is not the same as a non-emergency Single Patient IND. The physician should discuss with the FDA if there are questions about whether a case is emergency use or non-emergency. Read this guidance.

Per FDA, the following conditions must apply for Emergency Use:
Life-threatening means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life threatening or to immediately result in death. Rather, the patients must be in a life-threatening situation requiring intervention before obtaining FDA approval.

Severely debilitating means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

Treating Physician Information

First name

Last name

Department

Office Address

Phone Number

Email Address

Secondary Contact (Optional)

First Name

Last Name

Email

Department

Patient Information

Patient Initials

Patient Age (years)

Treatment Information

Name of Drug/Biologic

Entity supplying (generally the manufacturer)

Proposed date of use:

Emergency IND# provided by FDA:

Patient History

Provide a summary of the situation:

- Patient's condition
- Standard treatments that have been attempted and results
- Proposed test article and indication

This summary must justify that:

- The patient has a life-threatening/severely debilitating situation
- No standard treatment is available
- There is insufficient time to obtain IRB approval of a research study and doing so could jeopardize the patient

Consent Process

Select one:

☐ Informed consent will be obtained from the patient.

☐ Informed consent will be obtained from the patient's legally authorized representative.

☐ Informed consent of the patient or representative is not possible because:

- The patient is confronted by a life-threatening situation necessitating the use of the drug or biologic.
- Informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent.
- There is insufficient time to obtain consent from the patient's LAR.
- An alternative method of approved or generally recognized therapy that provides equal or greater likelihood of treating the patient is unavailable.

If informed consent of the patient or legal representative is not possible, confirm that:

☐ Before the use of the drug or biologic, the treating physician will have an independent physician who is not otherwise participating in the treatment evaluate in writing the treating physician's justification for not obtaining informed consent.

Location of Treatment

Special Instructions (Optional)
Provide any additional relevant information for this request.

Acknowledgements
By submitting this form, I confirm that:

• I am the treating physician or treating physician's designee authorized to submit on behalf of the treating physician.
• The treating physician has full awareness of the information within this form.
• The information within this form is accurate and complete.
• The treating physician will provide the IRB with a summary of the conditions constituting the emergency and documentation of the above findings within 5 working days on the emergency use follow-up form.