UCSD Human Research Protections Program
Biomedical Project: Emergency Use

Instructions for submitting
1. Complete all pages of this form. **To do this, open the form using your Web Browser** to fill in the form (requires Acrobat Reader or plug- in). 2. Click the **Print button** on the last page to make a copy for signatures. 3. Click the **Submit button** on the last page to submit the data from the Facesheets to the HRPP Office via the Internet. 4. **HRPP Office will e-mail** you your HRPP project number. Log into your "My Protocols at a Glance" through eIRB services, click on the project number, and upload the Emergency Use Notification form; Emergency Use Notification, 5-day Post Use form, consent, and other documents, as appropriate. Both Notification forms must be submitted. 5. **Mail one copy signed Facesheets** to the HRPP Office, mail code 0052, unless it can be **uploaded.**

Section 1: PROJECT TITLE*

*Ensure the title clearly includes "Emergency Use of [insert name of test article]"

Section 2: KEY PERSONNEL

Principal Investigator	Last name		First Name		Degree	
	Title		Department		Mail code	
	E-mail		Phone		Fax	
	Principal Investigator is salaried UCSD employee (check Yes or No): Yes ☐ No ☐					
Contact	Last name		First Name		Degree	
	Title		Department		Mail code	
	E-mail		Phone		Fax	

Section 3: PROJECT CHARACTERISTICS

Yes	No	
☐	☐	Will involve a participant who is **under age 18**
☐	☐	Will involve a participant who is **woman of child-bearing potential**
☐	☐	Will involve a participant who is **pregnant women and/or involve human fetus**
☐	☐	Will involve a participant who is **cognitively impaired**
☐	☐	Will involve a participant who is a **prisoner**
☐	☐	Will involve a participant who a **non-English speaking individual**

Section 4: EMERGENCY IND/IDE

DRUG/BIOLOGIC

Yes	No	N/A	
☐	☐	☐	**The Drug/Biologic is made available** for emergency use under the manufacture's IND
☐	☐	☐	**The PI has obtained an IND** for this use from the FDA
☐	☐	☐	**The PI has obtained FDA authorization for shipment** of drug/biologic in advance of the IND submission

Enter Drug/Biologic **name and associated IND number**.	Drug/Biologic name:		IND number:			
Project will use UCSD Medical Center Investigational Drug Service:			Yes: ☐	No: ☐		
Project will use RCHSD Investigational Pharmacy Service:			Yes: ☐	No: ☐		
If the Investigational Drug Service **will not be used**, enter the following:	**Location** where drugs will be stored:					
	Name of person responsible for dispensing study drug(s):					
	Phone number of person responsible for dispensing study drug(s):					

DEVICE

Yes	No	N/A	
☐	☐	☐	Prior FDA approval has been received for the shipment of the device or emergency use (NOTE: FDA approval is not required prior to emergency use of an unapproved device)
☐	☐	☐	The device sponsor has agreed to this use of the device (if possible)
☐	☐	☐	An independent assessment from an uninvolved physician is provided (if possible)

Enter device name and associated FDA-assigned IDE (if appropriate):	Device name:		IDE number:	

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Section 5: CONSENT		
Yes	No	
☐	☐	Written informed consent will be obtained from the patient or legally authorized representative
☐	☐	Circumstances exist for exemption from informed consent requirement (additional information must be provided)

Section 6: FACILITIES WHERE STUDY WILL BE CONDUCTED		
Yes	No	
☐	☐	UCSD Healthcare hospitals or clinics
☐	☐	UCSD Center for Clinical Research Services (CCR)
☐	☐	Rady Children's Hospital - San Diego hospital or clinics
☐	☐	Other: Describe facilities here:

Section 7: SIGNATURES

By signing below, you verify the following statements are true:

- The patient has a condition that is life-threatening or severely debilitating.
- No standard acceptable treatment is available.
- There is not sufficient time to obtain IRB approval in advance of the use of the test article.
- There is no known available IRB-approved protocol using the same test article or the patient does not qualify for an existing protocol.

For device emergency use, you verify the following statement is also true:

- There was not sufficient time to obtain FDA approval using existing procedures.

If emergency use of the test article will be done *without informed consent*, you verify the following statements are true:

- 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 legal representative.
- No alternative method of approved or generally recognized therapy is available that provides an equal or greater than likelihood of saving the patient's life.

Principal Investigator		Date:	

If you are the Independent Physician and emergency use of the test article will be done *without informed consent,* by signing below, you verify the following statements are true:

- 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 legal representative.
- No alternative method of approved or generally recognized therapy is available that provides an equal or greater than likelihood of saving the patient's life.

Independent Physician		Date:	

If you are filling out this form online:

Click the Print button to make copies for signatures and for your records.

Click the Submit button to submit the data from the application to the HRPP office via your web browser; you will receive an acknowledgement page back with your assigned Temporary project identifier (your "T-number"). Once your information has been imported into the HRPP database, the project will receive a HRPP project number, and you will receive an e-mail with the HRPP project number. Log into your "My Protocols at a Glance" through eIRB services and upload the Emergency Use Notification form, consent and other documents, as appropriate, to that project number.

Click Here to Print **Click Here to Submit Data via Web**