

Request for Review of Emergency Use

I. STUDY INFORMATION	
Principal Investigator:	
Protocol Number:	
Sponsor name and/or Funding Agency:	

II. CONTACT INFORMATION		
PRIMARY CONTACT: (For phone calls, documents, and correspondence)		
Name:	Title:	
Company:		
MAILING ADDRESS:		
Address:		
City:	State:	Zip / Postal code:
Phone:	Fax:	
Email:		
PHYSICAL ADDRESS: (if different than above)		
Address:		
City:	State:	Zip / Postal code:
ELECTRONIC INVOICES SHOULD BE SENT TO:		
Name:	Title:	
Company:		
Address:		
City:	State:	Zip / Postal code:
Phone:	Fax:	
Email:		

III. QUESTIONS REGARDING EMERGENCY USE

1. Does the researcher hold a position with a hospital, university or other institution that requires review of his/her research by a local Ethics Review Board?

Yes (*Institutional Jurisdiction Waiver must be attached*)

No (Continue with emergency use request)

Comments:

2. Has a request for emergency use been reviewed and disallowed by any other Ethics Review Board for this project?

Yes (*Please attach a letter of explanation including written comments from other Ethics Board*)

No (Continue with emergency use request)

Comments:

3. Are you reporting a potential use of an investigational drug, biological product, medical device or other FDA-regulated test article with a human subject?

Yes (continue with emergency use request)

No, stop. FDA emergency use regulations do not apply

Comments:

4. Is it a life-threatening or severely debilitating situation?

Yes (continue with emergency use request)

No, stop. Does not qualify (FDA 21 CFR § 56.102(d)).

Comments:

5. Is there a standard acceptable treatment available?

- Yes, stop. Does not qualify (FDA 21 CFR § 56.102(d)).
- No (Continue with emergency use request)

Comments:

6. Is it an off-label use of an approved medical product in the practice of medicine (i.e., not in a research context)?

- Yes, stop. Is not research → No IRB review needed.
- No (Continue with emergency use request)

Comments:

7. Has the investigational drug, biological product, medical device or other FDA-regulated test article been previously used at your institution under the emergency use allowances?

- Yes (Provide additional information about the previous uses in the Comments section below.)
- No (Continue with emergency use request)

Comments:

8. Are you requesting a waiver to the requirement of informed consent?

- Yes (submit Informed Consent Waiver Request Form along with this form)
- No (Continue with emergency use request)

Comments:

9. Without risking harm to the patient due to delay, what is the latest possible date that you can receive notice of IRB review?

Comments:

IV. RATIONALE FOR USE**V. PERSON COMPLETING FORM**

I certify that the information contained in this form is complete and accurate and that no facts have been suppressed or misstated. I am requesting for Total IRB to review the information submitted and provide approval or disapproval information. I understand that Total IRB has the authority to oversee this study and suspend the research study at this site if necessary to protect the rights and welfare of the study subjects. I agree to provide all information requested to conduct initial and continuing reviews of this study on time. I understand that if information is not provided, Total IRB may suspend the study. I agree to conduct the study in accordance with the conditions above.

Form Completed By (signature)

Date

Printed Name

Title, Company**Phone:****Email:**