Seton IRB: Request for Emergent Use of an Investigational Drug, Device, or Biologic

Date of Submission			
Treating Physician Name			
Protocol Title (*if protocol is available*)			
Phone Number		Fax Number	
Pager Number		E-Mail	

INSTRUCTIONS:
Please use this document to assist you with completing all of the steps needed to use an investigational drug, biologic, device, or other test article that is subject to FDA regulations but does not possess appropriate prior approvals. The physician who requests emergency use of the test article or uses an article emergently must comply with the federal requirements listed in 21 CFR 56.104.

Criteria for Request of Emergent Use

1. The patient has a life-threatening situation or severely debilitating disease or condition;
2. There are no standard or generally recognized alternative treatment options with an equal or greater likelihood of treating the patient's condition; AND
3. The patient's condition requires immediate intervention before review at a convened meeting of the IRB is possible to avoid major irreversible morbidity or death.

NOTE: Permission for Emergency Use may only be granted one (1) time for one (1) patient under the three (3) conditions listed above. If any of the above three conditions do not apply or if there is a desire to use the test article again on the same or different patient, a complete IRB Application must be submitted for review and approval by the Full Board.

Type of Request

☐	**Notification of Emergency Use of an Investigational Device, Drug or Biologic** NOTE: This must be reported to the IRB **within 5 working days** of administering the test article.
☐	**Request for Permission for Emergency Use of an Investigational Drug or Biologic**

Emergent Use Information

1. Name of investigational drug/biologic/device:	
2. Indication for intended use:	
3. Manufacturer:	
4. IND/IDE Number:	
5. Dosage:	

6. Does the manufacturer require an acknowledgement letter from the IRB prior to the patient receiving the test article?	☐ Yes	☐ No
7. Can the patient receive this drug or biologic under an already approved protocol?	☐ Yes	☐ No
8. Will/was Informed Consent obtained?	☐ Yes	☐ No
9. Describe the patient's condition and explain why emergency use of the test article is being requested.		
10. Please provide the date/time the test article will be/was administered.		
11. Please provide a brief description of the results of the emergent use of the test article.		

Waiver of Consent

If unable to obtain informed consent prior to emergency treatment, please complete this section. If informed consent will be obtained, leave this section blank.

In some emergency circumstances, it may not be feasible to obtain informed consent prior to using the test article. For an exception of informed consent requirements to apply, the emergency circumstances must meet each of the following four (4) conditions:

1. The patient is confronted with a life-threatening situation necessitating an immediate use of the test article;
2. The patient is/was unable to provide effective consent;
3. There is/was insufficient time in which to obtain consent from the patient's legally authorized representative; and
4. There is/was no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of treating the patient's condition.

NOTE: A physician who is not otherwise participating in the clinical treatment of the patient must also certify in writing that the above four (4) conditions have been met.

Request for Waiver of Informed Consent			
By signing below, I certify, that this emergency circumstance meets all four (4) of the conditions listed above (on the previous page) for a waiver of informed consent.			
Signature of Treating Physician		Date	
Signature of Independent (Non-Treating) Physician		Date	

CERTIFICATION OF INDEPENDENT (NON-TREATING) PHYSICIAN

I certify that this patient is in a life-threatening situation for which no acceptable treatment is available and that there is insufficient time to obtain approval of the full board IRB for use of the test article. I acknowledge that the patient may not considered a research subject and any data generated may not be claimed as research. I further acknowledge that the outcome of this emergency use may not be included in any report of research activity. I also certify that I am not involved with the medical treatment of this patient and agree with the assessment of the treating physician.

_____
Name of Independent (Non-Treating) Physician (please print)

_____ _____
Signature of Independent (Non-Treating) Physician Date

CERTIFICATION OF TREATING PHYSICIAN

By signing this form, I certify the information provided is accurate and that this emergent use situation qualifies under the criteria listed above. I also understand that the patient may not be considered a research subject and any data generated may not be claimed as research. The outcome of this emergent use may not be included in any report of research activity; and I acknowledge that any subsequent use of the test article in the same or different patient requires full submission to the IRB for Full Board review.

_____ _____
Signature of the Treating Physician Date

IRB OFFICE USE ONLY

The IRB certifies that permission for this one-time emergent use of the test article is granted or the notification of the one-time emergent use of the test article is acceptable per the criteria for request of emergent use.

☐ **Approval**
☐ **Action/Stipulations Required**

IRB Chair/Designee: _____ Date: _____

Date reported to Full Board: _____

Comments/Stipulations: