**UT SOUTHWESTERN MEDICAL CENTER AT DALLAS**

**INSTITUTIONAL REVIEW BOARD**

Emergency Use of an Investigational Drug, Biological, Device for Patient Care

|  |  |  |
| --- | --- | --- |
| Treating Physician |  |   |
| Department: |  |  |
| Mail Code at UT Southwestern: |  |  |
| Phone Number: |  |  |
| Pager Number: |  |  |
| Fax Number: |  |  |

**Criteria for Request:**

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, an IRB Application must be submitted for review and approval by the Full IRB Board*

**Section I – Type of Request:**

|  |  |
| --- | --- |
|  | Notification of Emergency Use of an Investigational Device, Drug or Biologic *(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 |

**Section II - Emergency Use Information**:

|  |  |  |
| --- | --- | --- |
| 1. | Name of Drug/Biologic/Device |  |
| 2. | Indication for intended use |  |
| 3. | Manufacturer |  |
| 4.  | IND/IDE Number |  |
| 5. | Does the manufacturer require an acknowledgement letter from the Institutional Review Board prior to the patient receiving the drug or biologic? |  | Yes |
|  | No |
| 6 | Dosage |  |
| 7. | Describe the Patient’s condition and explain why the emergency use of the test article is being requested. |  |
| 8. | Can the patient receive this drug or biologic under an already approved protocol? |  | Yes. |
|  | If yes, IRB No: |
|  | No |
| 9. | What is/was the time frame in which the drug, biologic or device will be/was administered? |  |
| 10. | Date and time the test article will be/was administered/utilized |  |
| 11. | Will/was Informed Consent obtained? |  | Yes (skip to Section IV and provide a copy of the signed consent form) |
|  | No |
| 12. | Please provide a brief description of the results of the emergency use of the test article: [insert description] |

**Section III: - 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 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 for a waiver of informed consent*

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Signature of Treating Physician Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Non-Treating Physician Date

“Treating Physician” in this context is generally the attending physician. Permission for emergency use requests from “house” staff, fellows, or nurses are inappropriate and **should not be initiated**.

**Section IV - Signature**

By signing below, I certify as the treating physician:

* This patient is in a life-threatening situation for which no acceptable treatment is available;
* There is insufficient time to obtain approval of the full IRB Board for use of the test article;
* Acknowledge that the patient may not be considered a research subject and any data generated may not be claimed as research. The outcome of this emergency use may not be included in any report of research activity; and
* Acknowledge that any subsequent use of the test article in the same or different patient requires submission of a research protocol to the IRB for full board review.

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Signature of Treating Physician Date

**Section V – Independent Physician’s Evaluation**

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.

By my signature below, I certify that I am not involved with the medical treatment of this patient and agree with the assessment of the treating physician.

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Signature of Non-Treating Physician Department

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Name of Non Treating Physician (print) Email:

Office Address: Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Fax: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Pager: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

**Section VI - Permission for Emergency Use:**

I certify that my permission for this Emergency Use was granted on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

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Name of IRB Chair (print) Signature of IRB Chair

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_