# Appendix: Notification of Emergency Use of Investigational Drug or Device

## When to Use this Form

This form should be used to notify the Institutional Review Board of the emergency use of an investigational drug or device on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)].

This form should be submitted as soon as possible after the emergency use, but in no case later than 5 working days after the date of the emergency use.

Do not include any Private Health Information (anything that will identify a patient) on this form.

## Submission Instructions

Our website provides full instructions on submitting applications to the IRB: <http://irb.med.nyu.edu/esubmission> Please contact the IRB office at 212 263-4110 with any questions.

## Definitions

#### Emergency Use

Emergency use means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)].

#### Test Article

A test article includes any drug, biological product, or medical device for human use [21 CFR 56.102(l)].

#### Life-threatening

For an emergency use of a test article, FDA regulations define a “life threatening” situation to include the scope of both life-threatening and severely debilitating, as defined below.

*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 subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

*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.

## Circumstances

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| I am informing the IRB of the use of  list your drug or device and IND/IDE/HUD# | |  | | |
| FDA status |  | | IND sponsor’s name |  |
| Restrictions | |  | | |
| Patient is | | Under the age of 18  18 or older | | |

## Emergency Use Exemption from Prior Board Review

|  |  |  |
| --- | --- | --- |
| The medical indication is | |  |
| Emergency use situation  **All** three of the following conditions must apply for exemption from prior board review | | A life-threatening or severely debilitating situation exists necessitating the use of the investigational drug, biologic or device  No standard acceptable treatment is available  There is not sufficient time to obtain IRB approval |
| Agent(s) |  | |
| Dose |  | |
| Duration |  | |
| Location of treatment (hospital & service) |  | |
| Prior course of treatment (include medication) |  | |
| Current Patient Status/Result of Use |  | |

## Informed Consent/Emergency Waiver

|  |  |
| --- | --- |
| Informed Consent was obtained from the subject or the subject's legally authorized representative: | YES If yes, attach a copy of the consent form and skip the rest of this section (move to INDEPENDENT PHYSICIAN’S ASSESSMENT)  NO If no, complete this section |
| If informed consent was not obtained from the subject or the subject's legally authorized representative, the emergency use may proceed if the Primary Investigator and an independent physician agree that all four of the conditions below apply.  However, if time was not sufficient to obtain an independent physician's determination that the four conditions apply, the clinical investigator should make the determination and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. | |
| Condition 1 | The subject is confronted by a life-threatening situation necessitating the use of the test article. |
| Condition 2 | Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject. |
| Condition 3 | Time is not sufficient to obtain consent from the subject's legal representative. |
| Condition 4 | No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life. |

## Independent Physician’s Assessment

Check one of these two boxes:

#### Assessment prior to Use of the Test Article

By my signature below, I certify that all four of the conditions for the emergency waiver of informed consent are met in this emergency situation:

1. the subject was confronted by a life-threatening situation necessitating the use of the test article
2. informed consent could not be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject
3. time was not sufficient to obtain consent from the subject's legal representative
4. no alternative method of approved or generally recognized therapy was available that provided an equal or greater likelihood of saving the subject's life

I am not participating in the clinical investigation.

#### Assessment after Use of the Test Article

My written evaluation of the appropriateness of the determination of the clinical investigator to waive informed consent in the emergency use of the test article follows/is attached.

I am not participating in the clinical investigation.

### Independent Physician’s Signature

|  |  |
| --- | --- |
| Date |  |
| Print Name |  |
| Signature | I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS A TRUE AND ACCURATE REPRESENTATION |

#### Notice

The independent physician’s assessment must be made within 5 business days of the date of the use of the test article. The investigator must notify the IRB of the use within 5 working days after the use of the test article.

The emergency use exemption from prior IRB review is intended to allow a one-time use for a course of treatment for a single individual. If the physician determines that a similar future need for the drug or device is likely, the physician should immediately initiate efforts to obtain IRB and FDA approval for the subsequent use of the drug or device.