|  |  |
| --- | --- |
| Institutional Review Board | **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, device, or humanitarian use 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 72 hours after the date of the emergency use.  *If you have any questions on how or when to use this form contact us at the IRB Office 513-585-2742.* | | | | | | | | |
| **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.  Do not include any Private Health Information (anything that will identify the patient) on this form. | | | | | | | | |
| 1. **Administrative Information** | | | | | | | | |
| Submitting Physician | | | Click or tap here to enter text. | | | | | |
| Email | | Click or tap here to enter text. | | | | Phone- | | Click or tap here to enter text. |
| Regulatory Contact | | | Click or tap here to enter text. | | | | | |
| Email | | Click or tap here to enter text. | | | | Phone- | | Click or tap here to enter text. |
| Date of Notification | | | Click or tap here to enter text. | | | | | |
| Date of Use | | | Click or tap here to enter text. | | | | | |
| Department | | | Click or tap here to enter text. | | | | | |
| 1. **Circumstances** | | | | | | | | |
| Drug/Device Name | | | Click or tap here to enter text. | | | | | |
| Classification | | | Choose an item. | | | | | |
| IND/IDE/HDE# | | | Click or tap here to enter text. | | | | | |
| FDA Status | | | Click or tap here to enter text. | | | | | |
| Sponsor Name | | | Click or tap here to enter text. | | | | | |
| Restrictions | | | Click or tap here to enter text. | | | | | |
| Patient is | | | Choose an item. | | | | | |
| 1. **Emergency Use Exemption from Prior Board Review** | | | | | | | | |
| Medical Indication | | | Click or tap here to enter text. | | | | | |
| Emergency Use Situation: ***All*** three of the following must apply for exemption from prior board review: | | | YES 1. A life-threatening or severely debilitating situation exists necessitating the use of the investigational drug, biologic or device; AND  YES 2. No standard acceptable treatment is available; AND  YES 3. There is not sufficient time to obtain IRB approval | | | | | |
| Agent(s) | | | Click or tap here to enter text. | | | | | |
| Dose | | | Click or tap here to enter text. | | | | | |
| Duration | | | Click or tap here to enter text. | | | | | |
| Location of Treatment | | | Click or tap here to enter text. | | | | | |
| Explain Condition Requiring Use | | | Click or tap here to enter text. | | | | | |
| Prior Course of Treatment (include medication) | | | Click or tap here to enter text. | | | | | |
| Current Patient Status/Result of Use | | | Click or tap here to enter text. | | | | | |
| 1. **Informed Consent/Emergency Waiver** | | | | | | | | |
| Informed Consent was obtained from the subject or the subject's legally authorized representative: | | | | | YES- Attach a copy of the signed consent form and skip to section 5  NO- Complete questions 1-4 in 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 Principal 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. | | | | | | | | |
| 1. | YES- The subject is confronted by a life-threatening situation necessitating the use of the test article. | | | | | | | |
| 2. | YES- Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject. | | | | | | | |
| 3. | YES- Time is not sufficient to obtain consent from the subject's legal representative. | | | | | | | |
| 4. | YES- No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life. | | | | | | | |
| 1. **Independent Physician’s Assessment** | | | | | | | | |
| Assessment *prior to the 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: The subject was confronted by a life-threatening situation necessitating the use of the test article; and informed consent could not be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject; and time was not sufficient to obtain consent from the subject's legal representative; and 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 the 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. | | | | | | | | |
| **Name** | | Click or tap here to enter text. | | **Phone** | | | Click or tap here to enter text. | |
| **Signature** | |  | | **Date** | | | Click or tap here to enter text. | |
| 1. **Investigator’s Assurance** | | | | | | | | |
| In notifying the IRB of the emergency use, I agree to adhere to the treatment protocol as herein described. I agree not to extend the use of this protocol beyond the patient and treatment involved in this request and to report to IRB any unexpected side effects at any time they occur. | | | | | | | | |
| **Name** | | Click or tap here to enter text. | | | | | | |
| **Signature** | |  | | **Date** | | | Click or tap here to enter text. | |
| 1. **Department Chair’s Signature** | | | | | | | | |
| **Name** | | Click or tap here to enter text. | | **Department** | | | Click or tap here to enter text. | |
| **Signature** | |  | | **Date** | | | Click or tap here to enter text. | |
| 1. **IRB Chairman’s Signature** | | | | | | | | |
| **Name** | | **Steve Roberts, MD** | | | | | | |
| **Signature** | |  | | **Date** | | | Click or tap here to enter text. | |