Emergency Use of a Test Article

Basic Details

1. Principle Investigator [Search list]
2. Test Article
   1. Name [FREE TEXT]
   2. Description [FREE TEXT]

Test article means any drug, biological product or medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.

1. Patient’s Full Name [Free Text]
2. Patient’s Diagnosis [Free Text]
3. Treatment Location [Dropdown?]
4. Are you submitting a notification of intended emergency use (emergency use will occur in the future) or an emergency use follow-up report (emergency use has already occurred)?
   1. Intended emergency use [NO FOLLOW-UP REPORT SECTION]
   2. Emergency use follow-up report [NO NOTIFICATION SECTION]

Whenever possible, notify the IRB prior to the emergency use of a test article.

Notification

1. Date Test Article will be used [calendar?]
2. Is the patient in a life-threatening or severely debilitating situation? [Yes/No]

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.

1. Is standard acceptable treatment available for the patient? [Yes/No]
2. Is there sufficient time to obtain IRB approval? [Yes/No]
3. Describe the rationale for emergency use of this test article: [Free Text]

Follow-up Report

1. Date and Time Test Article was used [calendar?]
2. Was the patient in a life-threatening or severely debilitating situation? [Yes/No]

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.

1. Was standard acceptable treatment available for the patient? [Yes/No]
2. Was there sufficient time to obtain IRB approval? [Yes/No]
3. Describe the rationale for emergency use of this test article: [Free Text]
4. Was an IRB acknowledgement of intended emergency use received prior to the date of emergency use? [Yes/No]
   1. If yes, Date of IRB acknowledgement [calendar?]
5. Are initial treatment results available now? [Yes/No]
6. If Yes, Please describe
7. If No, I will submit a report of initial results by the following date [Calendar?]
8. Did any adverse events or unanticipated problems occur as a result of the emergency use? [Yes/No]
9. If yes, Please describe
10. Was informed consent obtained? [Yes/No]
11. If yes, get screen that says Provide a copy of the signed consent document.
12. If no, get screen that says Provide assurance letters from the Principle Investigator and the independent physician that the following conditions were met:

1. Patient was in a life threatening situation;

2. All other available treatments were either unproven or unsatisfactory;

3. Patient was unable to give consent due to their medical condition; and

4. There was no time to obtain consent from a legally authorized representative (LAR).

An independent physician is one who is not otherwise participating in the decision related to the emergency use.

Submission

1. Physician’s Signature and Date
2. [IF NOTIFICATION]

Your notification of intended emergency use is complete. The IRB will review the notification to determine whether FDA regulatory requirements are met. You will be notified xxx.

A follow-up report must be submitted to the IRB within five working days of the initial emergency use of a test article.

1. [IF FOLLOW-UP REPORT]

Your emergency use follow-up report is complete. The IRB will review the follow-up report to determine whether FDA regulatory requirements were met. You will be notified xxx.

A protocol must be submitted for review by the convened IRB within 30 working days of the initial emergency use of a test article.

An expanded access submission must be submitted to the FDA within 15 working days of FDA’s authorization of the use of the test article.