# Revision History

|  |  |  |
| --- | --- | --- |
| **Requestor** | **Change(s)** | **Date** |
|  |  |  |
|  |  |  |

Start

1. What’s the title of this study?
2. Treatment Location:
   * 1. UAMS
     2. ACH/ACHRI
3. Test article Name:
4. Test article description:
5. Patient’s Initials:
6. Patient’s Diagnosis:
7. 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
     2. Emergency use follow-up report

Notification

1. Is the patient in a life-threatening or severely debilitating situation?

*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?
2. Is there sufficient time to obtain IRB approval?

*The IRB meets the first four Tuesdays of every month.*

1. Describe the rationale for emergency use of this test article:

Follow-up Report

1. Was an IRB acknowledgement of intended emergency use received prior to the date of emergency use?

**If yes**,

* + 1. Date of IRB acknowledgement:

SKIP TO QUESTION 7

1. Date Test Article was used:
2. Was the patient in a life-threatening or severely debilitating situation?

*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?
2. Was there sufficient time to obtain IRB approval?

*The IRB meets the first four Tuesdays of every month.*

1. Describe the rationale for emergency use of this test article:
2. Are initial treatment results available now?

**If Yes**, Please describe

**If No**,

* + - 1. I will submit a report of initial results by the following date

1. Did any adverse events or unanticipated problems occur as a result of the emergency use?

**If yes**, Please describe

1. Was informed consent obtained?

**If yes**, get popup that says Please upload a copy of the signed consent document in the Documents section.

**If no**, *get popup that says Please upload assurance letters in the Documents section, from the Principal Investigator and the independent physician, attesting 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.*

*A follow-up report must be submitted to the IRB within 5 working days of the initial emergency use of a test article.*

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

[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.

In order for this investigational drug to be used on a future patient, a protocol must be submitted for review by the convened IRB.

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.