**FORM 5.2C REPORT OF EMERGENCY USE OF A TEST ARTICLE TO TREAT A LIFE-THREATENING CONDITION**

**INVESTIGATOR: IDI REC #**

**STUDY TITLE**

|  |  |
| --- | --- |
| **1. Physician Phone:****Title of research project**:Emergency use of TEST ARTICLE in a single patient facing a life-threatening condition. | **Important: Please Note** |
|  |  |
| **2. SPONSOR / FUNDING INFORMATION**Is this protocol supported by an external funding agency?If yes, provide Grant Review Form | [ ]  No [ ] Yes |  |
|  |
| **3. WHERE DID THE EMERGENCY USE TAKE PLACE?** | Include all locations for |
| [ ]  Hospital (Name) | [ ] Private Practice (Name) | [ ] Agency (Name) | study related activities |
| [ ]  Clinic (Name) | [ ]  Public area | [ ] Other |  |
|  |
| **4. PATIENT INFORMATION** |  |  |
|  | [ ]  Male [ ]  Female |
| Name of Patient |  |
| Date of birth | Medical record number |
| Ethnicity/race |
| **Was the patient any of the following potentially vulnerable groups?** |
| [ ]  Prisoners | [ ]  Mentally retarded /impaired | [ ]  Nursing home resident |
| [ ]  Fetuses | [ ]  Economically disadvantaged | [ ]  Students |
| [ ] Pregnant women | [ ] Investigator's staff member | [ ]  Homeless |
| [ ]  Investigator's patient | [ ] Other (describe) |
|  |  |

|  |  |
| --- | --- |
| DESCRIPTION OF LIFE-THREATENING CONDITION **A** Diagnosis* 1. Why was the condition considered life-threatening?

What were the symptoms and signs that made the physicians conclude that the patient?* 1. was facing a life-threatening condition?

What made the physicians conclude that there was no standard acceptable treatment* 1. available, so that an investigational treatment had to be offered?

On what date did the administration or application of the test article to the patient begin, and when did it or will it end? |  |
|  |  |
| 1. **IS THE TEST ARTICLE REGULATED BY FDA?** [ ]  No [ ] Yes

If yes, complete this section* 1. [ ]  This study involves a drug or biologic: IND #, if applicable: This study is: [ ]  Phase 1 [ ]  Phase 2 [ ]  Phase 3 [ ]  Phase 4 [ ]  Treatment
	2. [ ]  This study involves a device:

This device is: [ ]  Investigational [ ] MarketedThis is a: [ ]  Significant Risk Device Study [ ]  Non-Significant Risk Device* 1. Who is the Sponsor of the IND?
	2. What was the generic name and/or code name of the test article? **E** What was the source (supplier or manufacturer) of the test article? **F** How did the physicians gain possession of the test article?
1. What is the proposed mechanism of action of the test articles?
2. If the test article is a drug, what is the drug trial phase status, as assigned by the NDA?

**I** If the test article is a device, what is the significant risk or non-significant risk device status, as assigned by the NDA?**J** What was the dosage, route of administration or application, and frequency & totalduration of use of the test article? | Submit the Investigator BrochureInclude justification of Non- Significant Risk |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **COSTS**
	1. **Study procedures and products**

Will the patient or his/her health care provider be required to pay for any related procedures or products? If yes, explain:* 1. **Compensation for injury**

Who is responsible for costs incurred due to adverse events? | [ ]  No | [ ]  Yes |  |
|  |  |
| 1. **RISKS**
	1. Identify the risks (current and potential).
	2. Describe the expected frequency, degree of severity, and potential reversibility.
	3. Describe possible late effects. [ ]  NA
	4. Risks from study article: [ ]  NA
	5. Risks from research procedures (i.e., washout risks, placebo assignment, e.t.c [ ] NA
	6. How will participants be assessed for the occurrence of adverse events described above? [ ] NA

**H** Describe your monitoring plan. [ ]  NA**I** What information is available on the response of the patient’s life-threatening condition to the test article at the time of this report? | Consider all risks: |
| physical, |
| psychological |
| social, legal |
| economic |
|  |
| **9. FOLLOW-UP PROCEDURES**1. What will be the duration of participants' active participation?
2. Will the patient be followed after their active participation ends?

If yes, describe: | [ ]  No | [ ] Yes |  |
|  |  |

1. **INFORMED CONSENT**
2. What type of informed consent process was implemented prior to administration or application of the test article to the patient?
3. Was the patient able to give informed consent? [ ]  No [ ]  Yes
4. If the mental acuity of the patient was in doubt, the person who gave the informed consent was:

[ ]  Legally appointed guardian

1. Patient advocate named in a Durable Power of Attorney for Health Care

Next-of-kin [ ]  Spouse [ ]  Adult child [ ]  Parent [ ]

Adult brother/Sister [ ]

1. If the patient was age <18 years, did he or she provide assent? [ ] No [ ] Yes
2. How will pertinent information be provided to the patients, if appropriate, at a later date?
3. Describe or attach your debriefing plan.
4. Who explained the study to the patient?
	1. If circumstances prevented obtaining informed consent, explain why the patient was unable to provide effective consent; and why there was insufficient time in which to obtain consent from a legal representative of the patient.
	2. Please submit the informed consent document used or to be used.
	3. If already executed, please provide a copy of the document that bears signatures of the patient or his/her legal representative, the Investigator (or designee) providing information and others (as applicable) witnessing the consent.
5. **CONFIDENTIALITY**

See consent form template.

1. Are the participant’s social security number, hospital record number, or any identifier (other than study number & initials) being sent off site? If yes, describe and explain reasons.

[ ] No [ ]  Yes

1. Will any external entity other than the investigative staff have access to or be provided with confidential medical or health related?

Information about the participant.

1. **EXPLANATION OF REPORTING DELAY**

 [ ] No [ ]  Yes If the interval between the date of initial administration of the test article and the date of submission of this application is more than five days, what was the reason for the delay in reporting?

Physician administering the test article Date

Concurring physician (if consent is not obtained) Date