**The physician must obtain informed consent from the individual receiving the emergency use/compassionate use drug/biologic or device. This document should be used to develop a consent form if a specific consent for emergency use/compassionate use is not provided by the sponsor.**

**Prior to uploading the consent document into iStar, delete all text and instructions in blue and all sections which are not applicable.**

* We recommend that prior to filling out the informed consent form, first review all sections of this template.
* The Blue highlights will help provide guidance. Please review carefully.
* Please delete all blue highlights when completed writing the informed consent form.
* Use font size 12 and leave a one-inch right margin to accommodate the IRB stamp.
* Use simple language (layman’s terms) and be concise.

**Treating Physician:** [Name of physician]

## Experimental Subject’s Bill of Rights

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

**California Law Requires That You Must Be Informed About:**

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Patient)

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Parent or Legally Authorized Representative)

If signed by other than the patient, indicate relationship: \_\_\_\_\_\_\_\_

**Permission for Treatment with an Experimental Item**

Dr. [Name of physician] is offering to treat you, your child (in which case the word “you” will refer to “your child” throughout this document), or the person you represent (in which case the word “you” will refer to the person you are representing) with [Name of unapproved drug, device, or biologic] because you have a serious condition called [Name of Condition] and there are no standard acceptable options.

## How long will this experimental treatment last?

We expect that the experimental treatment will last [hours/days/months/weeks/years, until a certain event]**.**

## What happens if I get this experimental treatment?

[Tell the patient what to expect using lay language and simple terms.]

## Is there any way this experimental treatment could be bad for me?

[Describe the risks/possible side effects of the treatment]

This treatment may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

If you are or become pregnant, this treatment may hurt your baby or your pregnancy in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

**What are the costs?**

[Describe the costs of the treatment]

Getting this treatment may lead to added costs to you. Insurance may not pay for this treatment because it is considered experimental. Please check with your doctor and your insurance.

## Can this experimental treatment help me?

We cannot promise that this treatment will help you. The goal of this treatment is to [Describe the potential benefits of the treatment].

## What else do I need to know?

Efforts will be made to limit your personal information, including medical records, to people who have a need to review this information. Organizations that may inspect and copy your information include appropriate representatives of the University of Southern California and the Food and Drug Administration. [NOTE: a research HIPAA Authorization is not required because this does not meet the HIPAA definition of research.]

If you are injured or made sick from taking part in this treatment, medical care will be provided. Generally, this care will be billed to you or your insurance. However, it is possible that your insurance will not pay for the care, because the treatment is experimental. Contact your doctor and insurance for more information.

## Who can I talk to?

If you have questions, concerns, complaints, would like to withdraw from treatment, or think the treatment has hurt you, you can talk to your doctor at [Insert contact information].

Contact the IRB if you have questions about your rights, concerns, or complaints as a person receiving an experimental treatment. You may contact the IRB at (323) 442-0114 or by email at HRPP@usc.edu.

**Signature of Patient:**

I agree to receive the experimental treatment.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_**

Name of Patient Signature Date Signed

**Signature of Legally Authorized Representative (LAR):**

I am a legally authorized representative of the patient named below. I agree for the patient to receive the experimental treatment.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Name of Patient

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_**

Name of LAR Signature Date Signed

**Signature of Treating Physician or Designee:**

I have provided this patient and/or their legally authorized representative(s) with information about this treatment that I believe to be accurate and complete. The patient and/or their legally authorized representative(s) indicated that they understand the nature of the treatment, including risks and benefits of its use.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_**

Name of Treating Physician/Designee Signature Date Signed