**Consent to an Emergency Experimental Treatment**

**Title:** Emergency treatment of (**name of patient)** using (**name of drug, biologic, or device**)

**Responsible Physician and Contact Information**: [Type text]

This is consent for emergency use of an unapproved experimental treatment using (**name of drug, biologic, or device**). This treatment is not approved by the Food and Drug Administration (FDA).

You are being offered this emergency experimental treatment because you have (patient’s diagnosis requiring emergency treatment) which is life-threatening, requires immediate treatment and for which there are no generally acceptable alternative treatments currently available. The other options available to you include (**list alternatives which may be no further treatment**). It is felt that this experimental treatment may be of benefit because (**patient specific rationale**). There is no guarantee that you will benefit from this experimental treatment and it is possible that it may worsen your condition.

Listed below are the procedures you will undergo if you decide to be treated with the experimental (**name of drug, biologic, or device**). It is expected that the experimental treatment will last for (**define in timeline or until a certain event**).

The following procedures will performed:

* List, in sequence, **each of the specific procedures** that will be performed for the purpose of the emergency experimental treatment. Do not include procedures that are performed as part of the subject’s routine medical care. Indicate, where applicable:
  1. dose, route, and dosage schedule of the experimental drug and of any other drugs that will be used in the emergency treatment;
  2. all procedures associated with the use of the experimental device, including the number and frequency of patient exposures to these procedures;
  3. FDA approval status of any other drugs or devices that will be used in the treatment; and/or complete descriptions of diagnostic or treatment procedures and the number of times each will be performed
  4. volume (in teaspoon/tablespoons or ounces) of blood to be drawn

Since this is an experimental treatment, it is impossible to provide a list of all possible risks. In addition to the risks listed below, there may be unforeseen reactions or even death associated with the treatment use of any experimental drug or procedure.

The following risks have been identified in other studies:

* address all reasonably foreseeable risks (e.g., physical, psychological, legal, or economic) and discomforts.
  1. List expected side effects/adverse reactions associated with the experimental drug/device and their expected frequency of occurrence
  2. Include radiation risk statements, if applicable (i.e., the research study involves exposure to ionizing radiation)
  3. Indicate any special precautions taken to avoid or minimize risks

You will be promptly notified if any new information, either good or bad, that develops during this treatment and which may cause you to change your mind about continuing to participate.

You and your insurance provider will be responsible for all costs associated with this emergency experimental treatment. It is important that you obtain an estimate of the charges associated with this because certain third-party insurance providers may not pay for care that is delivered as part of experimental care. Under such circumstances, you, the patient, will be held directly accountable for the costs.

Information about you or your emergency experimental treatment will be handled in a confidential manner consistent with other hospital medical records. However, in unusual circumstances, your records may be inspected by appropriate government agencies or be released in response to an order from a court of competent jurisdiction. Scientifically trained and properly authorized employees of the Food and Drug Administration may inspect your records as a result of the use of an experimental drug (or device) for your treatment.

You understand that you do not have to take part in this emergency experimental treatment and, should you change your mind, you can withdraw from the treatment at any time. Your other care and benefits will be the same whether you participate in this treatment or not. You also understand that you may be removed from the experimental treatment by the responsible physician in the event of (**indicate reasons for physician-directed withdrawal**). (**Indicate if there are any circumstances that you would recommend follow-up monitoring should they decide to withdraw).**

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**Voluntary Consent**:

(**Responsible physician**) has explained all of this to me and has answered all my questions. I also understand that any future questions I have about this emergency experimental treatment will be answered by (name of responsible physician) whom I may call at (telephone and/or pager number).

By signing this form, I agree to participate in this emergency experimental treatment.

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Patient Name Date Time

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\*Patient Signature Date Time

If applicable, include the following standard statements to document permission for the participation of mentally incapacitated adult subjects or child <18 years of age:

\*The patient is unable to consent because: (**insert reason**)

I, therefore, consent to participation for the patient.

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Signature Date Time

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Relationship to patient

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Witness Signature Date Time

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Include the following standard statements to document the assent of mentally incapacitated or incompetent adult patient, or child 6-13 years of age.

**Verification of Explanation**:

I certify that I have carefully explained the purpose and nature of this emergency experimental treatment to (**name of patient**) in age appropriate language. I have answered all his/her questions and they he/she provided affirmative agreement to participate in this emergency experimental treatment.

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**Responsible Physician’s Certification**:

I declare that I have personally discussed the above information with the patient or the patient's representative and answered any questions he/she may have:

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Physician's Signature Date Time

\***Note that only the physician responsible for the emergency experimental treatment is permitted to sign the Responsible Physician's Certification.**