Emergency Use Informed Consent Form for Clinical Investigations

Protocol Title: _____

Researcher/Investigator Name: _____

Institution: _____

Site: _____

1. Introduction

You are being asked to participate in a clinical investigation under emergency circumstances. Please read this form carefully and ask any questions you may have before making your decision.

2. Why is this treatment/research being offered?

Describe the condition and reason for emergency use.

3. What will happen if you choose to participate?

Describe procedures, duration, and what participation inv

4. Risks and Discomforts

- The possible risks of the drug/device/procedure include:

  List or describe risks.

- There may be risks that are unknown at this time.

5. Potential Benefits

Describe anticipated benefits to the patient or others.

6. Alternatives

List available alternative treatments, including no treatme

7. Voluntary Participation

Participation is voluntary. You may choose not to participate or to withdraw at any time without penalty or loss of benefits to which you are otherwise entitled.

8. Confidentiality

Reasonable efforts will be made to protect your privacy. Your information may be disclosed as required by law and to authorized individuals overseeing this investigation.

9. Contact Information

For questions about this investigation or your rights, contact:

Investigator Name

Phone Number

Email

Consent

I have read (or someone has read to me) this consent form. I have been given the opportunity to ask questions and those questions have been answered to my satisfaction.

Participant Name

Signature of Participant or Legally Authorized Representative

Date

Person Obtaining Consent (Printed Name)

Signature of Person Obtaining Consent

Date

This form is a sample Emergency Use Informed Consent Template for Clinical Investigations. Adapt content as appropriate for your institution and specific emergency use situation.