Emergency Research Informed Consent Waiver Template

Project Information

Study Title:

Principal Investigator:

IRB Protocol Number:

Date:

Waiver of Informed Consent Request

Describe the research context and why obtaining informed consent is not possible prior to enrollment:

Justification for Waiver:

Regulatory Criteria for Waiver

1. The research involves no more than minimal risk to the subjects.
2. The waiver will not adversely affect the rights and welfare of the subjects.
3. The research could not practicably be carried out without the waiver.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Explain how the proposed research meets each criterion above:

Emergency Research Justification

Describe the emergency context and how it relates to inability to obtain prior consent:

Provisions for obtaining informed consent from a legally authorized representative or subject as soon as feasible:

Additional Protections

Describe plans for community consultation and public disclosure, if applicable:

Describe other protections for subjects:

Signature

Name:

Date: