Newton-Wellesley Hospital
Human Research and Investigation Committee

Emergency Use of an Investigational Drug/Device/Procedure

The emergency use of an investigational drug, device or procedure is only allowed in a life-threatening situation and when standard therapy/treatment is either ineffective or nonexistent.

PRINCIPAL/OVERALL INVESTIGATOR (cannot be resident)

Name:

☐ Check here if any of the following information has changed

Dept/Service: Division:

Address:

Telephone: Fax:

E-Mail:

STUDY TITLE:

EMERGENCY USE OF WHICH INVESTIGATIONAL TYPE:

Drug/Biologic: ☐ NO ☐ YES If **Yes**, Describe

Who will dispense drug? ☐ Pharmacy ☐ Nursing ☐ Investigator

Device: ☐ NO ☐ YES If **Yes**, Describe

Procedure: ☐ NO ☐ YES If **Yes**, Describe

PATIENT INFORMATION:

Patient Initials: Medical Record #:

Diagnosis: Location:

CHECK ONE OF THE FOLLOWING THREE CHOICES:

☐ Informed Consent has already been obtained

☐ Informed Consent will be obtained **before emergency treatment**

☐ Waiver of Consent: Must meet **ALL** the following criteria (Signatures required to verify that all criteria are met)

- ☐ The subject is confronted by a life-threatening situation necessitating the use of the Investigational drug
- ☐ Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject

☐ Time is not sufficient to obtain consent from the subject's legal representative

☐ No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the life of the subject

Signature of Principal Investigator Date

_____ _____

Signature of Independent Physician Date

_____ _____

REASON WHY CONVENTIONAL THERAPY/TREATMENT CANNOT BE USED:
Provide a clinical synopsis of the patient treated or to be treated emergently with the investigational drug. Describe why conventional therapy is not appropriate, why this is an emergency and why this use may prevent death or severe disability. Reference the patient by medical record number only. Refer to emergency use of drugs or biologics guidance document on the PHRC website (http://healthcare.partners.org/phsirb/euse.htm)

COSTS (Please check the appropriate box)

☐ Patient Self Pay ☐ Insurance/Third Party ☐ Manufacturer

Prior approval of payor is required

Under this emergency approval process, since there is no full IRB review of the emergency care, any data generated may not be claimed as research and the outcome may not be included in any report of research activity.

A written report will be submitted to the IRB within 5 working days that will include current patient status, the protocol followed and a copy of the signed consent.

I acknowledge that the patient is confronted by a life-threatening situation necessitating the use of this investigational drug/device/procedure and that no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patients life:

_____ _____

Signature of Principal Investigator Date

_____ _____

Signature of IRB Chairman Date