HARRISON IRB
AN INDEPENDENT REVIEW BOARD

Emergency Use Checklist

Principal Investigator: _____ Protocol: _____

Incident Date: _____ Submission Date: _____

Per requirements of 45 CFR 46.103(b)(4) and 21 CFR 56.108(a)(3)(iv), changes in approved research cannot be initiated without IRB review and approval unless necessary to eliminate apparent immediate hazards to the subjects. Harrison IRB has provided a check list for emergency use of an investigational drug/device to ensure that the Principal Investigator (or Physician) has complied with all requirements for emergency use.

Emergency Use Requirements Checklist

☐ Human subject is in life-threatening situation in which no standard acceptable treatment is available.

☐ There is not sufficient time to obtain IRB approval, based on the life-threatening situation.

☐ Informed Consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent form the subject or the subject's legally authorized representative

☐ If, in the Principal Investigator's opinion, immediate use of the test article is required to preserve the subject's life.

☐ Attempts to solicit informed consent must be made prior to emergency use of an investigational drug.

☐ The Principal Investigator must notify Harrison IRB within 5 days of the event and submit ALL appropriate documentation as required by federal regulations.

_____ _____
Principal Investigator's Signature Date

**********Harrison IRB Use Only**********

Emergency Use Reviewed on: _____ By: _____

☐ Additional Information/Follow Up Required
☐ Submission Complete

Comments: _____
_____
_____
_____