MEMORIAL HEALTH UNIVERSITY MEDICAL CENTER
Savannah, Georgia

EMERGENCY EXEMPTION FROM PROSPECTIVE IRB APPROVAL

Emergency use is defined as the use of an investigational drug or biologic product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)]. The emergency use provision in the FDA regulations [21 CFR 56.104(c)] is an exemption from prior review and approval of the IRB. The exemption, which may not be used unless all of the conditions described in 21 CFR 56.102(d) exist, allows for one emergency use of a test article without prospective IRB review. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. **This form must be submitted to the IRB within five (5) working days after the use of the test article.**

DATE: _____ MHUMC #: _____ (*provided by IRB*) IND#: _____

COMPLETE STUDY TITLE:
_____
_____
_____

Principal Investigator:_____ Phone:_____

❑ Drug ❑ Biologic ❑ Generic
Name:_____

Subject Identification:
Name:_____ Age:_____ DOB:_____

Sex: ❑ Male ❑ Female Hospital #:_____

Diagnosis:_____
_____
_____

Date Used:_____ Date Informed Consent Obtained (attach copy:)_____

Outcome:_____
_____
_____

Signature:_____ Date:_____
Principal Investigator

To be completed by Institutional Review Board

_____ _____
Chairman, Institutional Review Board Date

Please place on agenda for next IRB meeting.