MD Anderson HRPP	**Exemption from IRB Review: Emergency Use of a Test Article**	THE UNIVERSITY OF TEXAS MD Anderson Cancer Center Making Cancer History®

Principal Investigator (PI):

Protocol:

Name of Test Article:
include IND/IDE Number, if applicable

Date of Use of Test Article:

Date of Submission by PI:
(Must be within 5 working days of the Emergency Use of the Test Article)

Verification of IRB Chair or Designated Member of the IRB

Complete the information in one or both columns, as appropriate:

Emergency Use of a Test Article With Informed Consent	Emergency Use of a Test Article Without Informed Consent
I verify that all of the following statements are true: ☐ The participant was confronted by a life-threatening or severely debilitating situation. ☐ No standard acceptable treatment was available. ☐ There was not sufficient time to obtain IRB approval in advance of the use of the test article.	I verify that all of the following statements are true: ☐ The participant was confronted by a life-threatening situation necessitating the use of the test article. ☐ Informed consent could not be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant. ☐ Time was not sufficient to obtain consent from the participant's legal representative. ☐ No alternative method of approved or generally recognized therapy that provided an equal or greater likelihood of saving the life of the participant was available. ☐ Independent Physician Certification

_____
Name of IRB Chair or Designated IRB Member

_____ _____
Signature of IRB Chair or Designated IRB Member Date

Versions

Date	Version Number	Action	Initials	Description
11/1/2018	1	New	MT	New document created