Mount Sinai	**WORKSHEET:** Emergency Use of a Test Article		
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Study #:	**Reviewer:**	**Date:**

The purpose of this worksheet is to provide support for investigators conducting an emergency use of a test article in a life threatening situation and IDS (Research Pharmacy) representatives reviewing an emergency use of a test article in a life threatening situation. This worksheet is to be used when overseeing emergency use of a test article in a life-threatening situation. It does not need to be completed or retained.

1 Exemption Criteria (All of the following are **"Yes"**)

☐ Yes ☐ No	The subject is (was) confronted by a disease or condition that is (was) life threatening meaning either:					
	☐ Yes ☐ No	The likelihood of death is high unless the course of the disease is interrupted;				
	☐ Yes ☐ No	A disease or condition with a potentially fatal outcome, where the end-point of clinical trial analysis is survival.				
	☐ Yes ☐ No	The disease or condition causes major irreversible morbidity.				
☐ Yes ☐ No	The situation necessitates (necessitated) the use of the investigational article:					
☐ Yes ☐ No	No standard acceptable treatment is (was) available.					
☐ Yes ☐ No	There is (was) NOT sufficient time to obtain IRB approval.					
☐ Yes ☐ No	The emergency use will be (was) reported to the IRB within 5 working days.					
☐ Yes ☐ No	Any subsequent use of the investigational product at the institution will have prospective IRB review and approval.					
☐ Yes ☐ No	If the research involves (involved) an investigational drug, and the FDA has (had) issued an IND.					
☐ Yes ☐ No	The research is (was) **NOT** subject to DHHS regulation (See **WORKSHEET: Human Research Determination**)					
☐ Yes ☐ No	Consent will be (was) obtained and documented or the criteria for the exception to the requirement for consent are (were) met. **(One of the following are "Yes")**					
	☐ Yes ☐ No	Consent will be (was) sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 21 CFR §50 and informed consent will be (was) appropriately documented, in accordance with and to the extent required by 21 CFR §50.27. (See WORKSHEET: Criteria for Approval and Other Considerations)				
	☐ Yes ☐ No	The criteria for the exception to the requirement for consent are (were) met. (All of the following are "Yes")				
		☐ Yes ☐ No	The subject is (was) confronted by a life-threatening situation necessitating the use of the test article.			
		☐ Yes ☐ No	Informed consent cannot (could not) be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.			
		☐ Yes ☐ No	Time is (was) not sufficient to obtain consent from the subject's legal representative.			
		☐ Yes ☐ No	There is (was) no available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.			
		☐ Yes ☐ No	Certification requirements are (were) met: **(One of the following are "Yes")**			
			☐ Yes ☐ No	Before the use of the test article a physician who is (was) not otherwise participating in the clinical investigation will certify (has certified) in writing that the above items under Section #3 are true.		
			☐ Yes ☐ No	Before the use of the test article a physician who is (was) not otherwise participating in the clinical investigation was unable to certify in writing that the above items are true but all of the following are true.		
				☐ Yes ☐ No	Immediate use of the test article is (was), in the investigator's opinion, required to preserve the life of the subject.	
				☐ Yes ☐ No	Time is (was) not sufficient to obtain the independent determination a physician who is (was) not otherwise participating in the clinical investigation.	
				☐ Yes ☐ No	The investigator will submit (has submitted) the above written certification to the IRB within 5 working days after the use of the test article	
				☐ Yes ☐ No	After the use of the test article a physician who is (was) not otherwise participating in the clinical investigation will certify (has certified) in writing within 5 working days after the use of the article that the above are true.	