SUNY UPSTATE MEDICAL UNIVERSITY INSTITUTIONAL REVIEW BOARD

EMERGENCY USE WRITTEN REPORT FORM

Federal regulations require the following information to be submitted to the IRB within **5** working days of an emergency use of an unapproved test article (drug, biologic or device).

Physician Information	
Physician's full name (Last, First, Middle)	
Department Address	**Phone Number**

Test Article Information	
Check one: Drug/Biologic ☐ Device ☐ IND/IDE #:	
Name of Test Article	**Sponsor Name (if any)**

Emergency Use Information	
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Date (mm-dd-yyyy) the test article was used	**Date (mm-dd-yyyy) the IRB was contacted**
Patient's full name (Last, First, Middle)	**Facility where procedure occurred**
Was informed consent obtained?	☐ Yes Please upload a copy with this report. ☐ No Please upload the written determination for waiver (21 CFR 50.23)
Rationale for use: Provide information justifying use: The condition was "life-threatening" or "severely debilitating," and no standard acceptable treatment was available, and there was "not sufficient time" to obtain IRB approval before using the test article.	
Results of use: Must be submitted within 10 working days from the occurence if not available for the initial reporting requirement (within 5 working days).	

Please complete signature section if not submitted via IRBNet:

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Physician Signature Date