

**ST. JOSEPH'S HEALTH (SJH) AND ST. PETER'S HEALTH PARTNERS (SPHP)  
INSTITUTIONAL REVIEW BOARDS**

**EMERGENCY USE WRITTEN REPORT FORM**

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

<b>Physician Information</b>	
<i>Physician's full name (Last, First, Middle)</i>	
<i>Department Address</i>	<i>Phone Number</i>
<b>Test Article Information</b>	
Check one: Drug/Biologic <input type="checkbox"/> Device <input type="checkbox"/> IND/IDE #:	
<i>Name of Test Article</i>	<i>Sponsor Name (if any)</i>
<b>Emergency Use Information</b>	
<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<i>Date (mm-dd-yyyy) the test article was used</i>	<i>Date (mm-dd-yyyy) the IRB was contacted</i>
<i>Patient's full name (Last, First, Middle)</i>	<i>Facility where procedure occurred</i>
Was informed consent obtained? <input type="checkbox"/> yes <i>Please upload a copy with this report.</i> <input type="checkbox"/> no <i>Please upload the written determination for waiver (21 CFR 50.23)</i>	
<b>Rationale for use:</b> <i>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.</i>	
<b>Results of use:</b> <i>Must be submitted within 10 working days from the occurrence if not available for the initial reporting requirement (within 5 working days).</i>	

SJH and SPHP IRB Office of the Human REsearch  
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