

WORKSHEET: Emergency Use - Drugs and Biologics

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This worksheet is used to determine whether emergency use of a drug or biologic meets FDA criteria.

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All criteria in 1 must be met

1. Criteria for <Emergency Use> of a drug or biologic *21 CFR §56.102(d) 21 CFR §56.104(c)* (see Footnotes 1)

1.1	<input type="checkbox"/>	The treating physician [will document/has documented] in the medical record:
	1.1.1	<input type="checkbox"/> The patient [is/was] in a life-threatening or severely debilitating situation (see Footnote 2)
	1.1.2	<input type="checkbox"/> No standard acceptable treatment [is/was] available
	1.1.3	<input type="checkbox"/> There [is/was] insufficient time to obtain IRB approval
1.2	<input type="checkbox"/>	One of the following is true: (See Footnote 3)
		<input type="radio"/> The unapproved investigational drug or biologic [will have/has] an IND
		<input type="radio"/> FDA [will authorize/has authorized] shipment of the test article in advance of the IND submission
1.3	<input type="checkbox"/>	The emergency use with documentation of the above findings [will be/was] reported to the IRB within 5 working days after the use
1.4	<input type="checkbox"/>	The use is not <Human Research as Defined by HHS>
1.5	<input type="checkbox"/>	One of the following is true: (21 CFR §50.23)
		<input type="radio"/> Consent of the patient or the patient's LAR [will be/was] obtained and documented in accordance with Sections 2-4 of "WORKSHEET: Criteria for Approval (HRP-400)"
		All of the following are true:
		<input type="radio"/> • The treating physician and a physician who is not otherwise participating in the clinical investigation [will certify/have certified] in writing that the criteria in Section 2 are met
		• The written certification [will be/has been] submitted to the IRB within 5 working days after the use of the test article
		All of the following are true:
		<input type="radio"/> • In the treating physician's opinion, immediate use of the test article [is/was] required to preserve the life of the patient
		• In the treating physician's opinion, time [is/was] not sufficient to obtain in advance of using the test article the certification of a physician who is not otherwise participating in the clinical investigation
		• The treating physician [will certify/has certified] in writing that the criteria in Section 2 are met
		• Within 5 working days after the use of the article, a physician who is not otherwise participating in the clinical investigation [will review and evaluate/has reviewed and evaluated] in writing whether the criteria in Section 2 were met

2. Informed consent exception requirements *21 CFR §50.23*

2.1	<input type="checkbox"/>	The patient [is/was] confronted by a life-threatening situation necessitating the use of the test article
2.2	<input type="checkbox"/>	Informed consent [cannot/could not] be obtained from the patient because of an inability to communicate with, or obtain legally effective consent
2.3	<input type="checkbox"/>	Time [is/was] not sufficient to obtain consent from the patient's LAR
2.4	<input type="checkbox"/>	There is available no alternative method of approved or generally recognized therapy that provides equal or greater likelihood of treating the patient

3. Notes

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4. Footnotes

4.1	Emergency use of an unapproved drug or biologic is <Human Research as Defined by FDA>. Any subsequent use of the test article at an organization is subject to IRB review Handle a repeated emergency use of a test article at an organization as <Noncompliance>
4.2	<i>Life-threatening</i> means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the patients must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible. See Emergency Use of an Investigational Drug or Biologic - Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators. <i>Severely debilitating</i> means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke. See Emergency Use of an Investigational Drug or Biologic - Information Sheet: Guidance for Institutional Review Boards and Clinical.
4.3	Contact phone numbers at FDA: • Drug products: Division of Drug Information: (888) 463-6332 or (301) 796-3400 • Biological blood products: Office of Blood Research and Review, Office of Communication, Outreach and Development: (240) 402-8360 • Biological vaccine products: Office of Vaccines Research and Review: (240) 402-7800 • On nights and weekends: Office of Crisis Management & Emergency Operations Center: (866) 300-4374 or (301) 796-8240