AdventHealth Orlando

WORKSHEET: Emergency Use - Devices

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This worksheet is used to determine whether emergency use of a device meets FDA guidance.

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All criteria in 1 must be met

1. Criteria for <Emergency Use> of a device *FDA Guidance: IDE Early/Expanded Access* (see Footnote 1)

1.1	☐	The treating physician [will document/has documented] in the medical record:	
		1.1.1	☐ The patient has a life-threatening or severely debilitating condition (see Footnote 2)
		1.1.2	☐ The condition needs immediate treatment, diagnosis, or monitoring
		1.1.3	☐ No generally acceptable alternative for the condition exists
		1.1.4	☐ The treating physician has assessed the potential for benefits from the unapproved use
		1.1.5	☐ The treating physician has substantial reason to believe that benefits will exist
		1.1.6	☐ There is no time to use existing procedures to get FDA approval for the use
1.2	☐	One of the following is true:	
		○ There [is/was] no IDE	
		○ The treating physician [wants/wanted] to use the device in a way not approved under an existing IDE	
		○ The treating physician [is/was] not part of an IDE study	
1.3	☐	The treating physician [will follow/has followed] as many of the patient protection procedures listed below as possible: (check all that apply)	
		1.3.1	☐ Clearance from the institution as specified by their policies
		1.3.2	☐ Concurrence of an IRB chair
		1.3.3	☐ If an IDE exists for the device, authorization from the sponsor
		1.3.4	☐ Informed consent from the patient or a legal representative (see Footnote 3)
1.4	☐	One of the following is true:	
		○ An uninvolved physician [will assess/has assessed] prospectively that the criteria in Section 1.1 are met	
		○ An uninvolved physician [will assess/has assessed] retrospectively that the criteria in Section 1.1 were met	
1.5	☐	The emergency use with documentation of the above findings [will be/was] reported to the IRB within 5 working days after the use	
1.6	☐	The use is not <Human Research as Defined by HHS>	

2. Notes

3. Footnotes

3.1	Emergency use of an unapproved device is not <Human Research as Defined by FDA>. See FDA Presentation: Institutional Review Board: Compassionate and Emergency Use.
3.2	*Life-threatening* 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. *Severely debilitating* 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.
3.3	Consent does not have to follow the informed consent requirements at 21 CFR §50.25. The IRB does not require written documentation of informed consent for compassionate use of devices.
3.4	FDA contact for emergency uses of devices: Office of Crisis Management & Emergency Operations Center (866) 300-4374 (301) 796-8240