AdventHealth Orlando

WORKSHEET: Compassionate Use - Devices

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

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All criteria in 1 must be met

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

1.1	☐	The treating physician will document in the medical record:	
		1.1.1	☐ The patient has a serious condition
		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 patient does not meet inclusion criteria for an IDE study
		1.1.5	☐ The probable risk to the patient from the device is not greater than the probable risk from the disease
1.2	☐	If an IDE exists for the device, the sponsor has authorized the use (see Footnote 2)	
1.3	☐	FDA has concurred with the use (see Footnote 3)	
1.4	☐	The treating physician will obtain:	
		1.4.1	☐ Clearance from the institution as specified by their policies
		1.4.2	☐ Concurrence of an IRB chair
		1.4.3	☐ Informed consent from the patient or legal representative (see Footnote 4)
		1.4.4	☐ A physician who is not participating in the device use will assess that the criteria in Section 1.1 are met
1.5	☐	The treating physician [will devise/has devise] an appropriate schedule for monitoring the patient, taking into consideration the investigational nature of the device and the specific needs of the patient.	
1.6	☐	The use is not <Human Research as Defined by HHS>	
1.7	☐	Any problems will be reported to the IRB and the sponsor within 5 working days after the use (see Footnote 5)	

2. Notes

3. Footnotes

3.1	Compassionate use of an unapproved device is not <Human Research as Defined by FDA>. A physician can use an unapproved device to treat, diagnose, or monitor a patient with a serious disease or condition. See FDA Presentation: Institutional Review Board: Compassionate and Emergency Use.
3.2	If sponsor disagrees with the use, the treating physician cannot use the device.
3.3	If sponsor authorizes the use, the sponsor will need to submit an IDE supplement to FDA requesting approval for a protocol deviation 21 CFR §812.35(a). FDA's bases its concurrence on information submitted, including evidence that safety and effectiveness justifies the use and that the use would not interfere with the conduct of a clinical trial to support marketing approval. Prior FDA concurrence is required before compassionate use occurs.
3.4	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.
3.5	The physician should provide to the sponsor within 5 working days after the compassionate use a summary of the use and any problems