AdventHealth Orlando

WORKSHEET: Criteria for Approval HUD

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This worksheet is used to determine whether a clinical use of a humanitarian use device can be approved. (see Footnote 1)

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All criteria in 1 and 2 must be met

1.		Criteria for approval *21 CFR §56.111*
1.1	☐	Risks to patients are minimized by using procedures which are consistent with sound clinical care and which do not unnecessarily expose patients to risk (see Footnotes 1 and 2)
1.2	☐	Risks to patients are reasonable in relation to the proposed use of the device
1.3	☐	There are adequate provisions to protect the privacy of patients
1.4	☐	There are adequate provisions to maintain the confidentiality of data
2.		Additional Criteria *FDA Guidance: Humanitarian Device Exemption (HDE) Regulation: Questions and Answers*
2.1	☐	The device is not being evaluated for safety or effectiveness *If so, use "WORKSHEET: Criteria for Approval (HRP-400)"*
2.2	☐	The health care provider is qualified through training and expertise to use the device.
2.3	☐	The device has a valid HDE number (see Footnote 2)
2.4	☐	If a patient information packet is available, the physician will give them to patients or representatives before receiving the device whenever feasible (see Footnotes 3 and 4)
3.		Notes
4.		Footnotes
4.1		A device with an approved HDE is approved for marketing, but the approval is based on evidence of safety and probable benefit. The Act and implementing regulations exempt Humanitarian Use Devices from the requirement to establish a reasonable assurance of effectiveness. The Humanitarian Use Device is intended for use in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the US per year. Clinical uses of HDEs are not <Human Research>.
4.2		A list of approved HDEs may be found here
4.3		The IRB will determine whether the patient information packet is sufficient or if a HUD specific consent is required.
4.4		For HDE patient information packets, click here and select the HDE number.