LSU Health NEW ORLEANS Human Research Protection Program	HUMANITARIAN USE DEVICES (HUD)			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	4.09	02.08.2020	5.19	03.25.2019

Introduction

FDA regulations (21CFR814.3(n)) allow for treatment of diseases or disorders affecting fewer than 4,000 individuals per year in the United States under a Humanitarian Device Exemption (HDE). The use of HUDs is not considered to be research under the FDA regulations since they are considered to be legally-marketed devices being used for clinical purposes, and there is no requirement for documentation of informed consent or authorization under the HIPAA Privacy Rule. However, IRB approval is required for the use of a HUD and in some cases informed consent may be required by the IRB. In most cases a well-prepared informational brochure describing the device and related procedures approved by the IBR may be used. Re-approval by the IRB is required at a minimum of a one-year duration, although other requirements such as a shorter approval period or certain reporting requirements may be imposed by the IRB. All information requested in the LSUHSC-NO re-approval application must be provided for consideration of re-approval for the use of a HUD.

Off-Label use of a HUD

Use of a HUD for a condition other than the approved indication may be subject to Investigational Device Exemption (IDE) requirements. However, in an emergency, or if the physician determines that there is no alternative device for the patient's condition a HUD may be used. If a physician wants to use a HUD outside its approved indication(s), FDA recommends that the physician obtain informed consent from the patient and ensure that reasonable patient protection measures are followed, such as devising schedules to monitor the patient, taking into consideration the patient's specific needs and the limited information available about the risks and benefits of the device. FDA further recommends that the physician submit a follow-up report on the patient's condition to the HDE holder and first check with the IRB before such use to review any institutional policy.

Emergency use of a HUD

If a physician in an emergency situation determines that IRB approval for the use of the HUD at the facility cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be used without prior IRB approval. The physician must report the emergency use within five days, provide written notification of the use to the IRB chair including identification of the patient involved, the date of the use, and the reason for the use (21 CFR 814.124).