



EMERGENCY USE OF A MEDICAL DEVICE

WHO	 <p>Yes you – the emergency use requestor</p>
WHAT	 <p>Submission of emergency use documentation</p>
WHY	Your patients requires use of an investigational medical device in order to save his or her life but the patient does not meet protocol criteria for an IDE.
HOW	<p>BEFORE USE:</p> <ul style="list-style-type: none"> Obtain a written assessment for the emergency use by a physician uninvolved in the patient’s care. NOTE: If there is no time to obtain uninvolved physician assessment, the use may proceed, however, the assessment must be obtained and forwarded to the PHCIRB (per below) with a statement that it was not obtained prior to the use and the reason why. Obtain documented informed consent from the patient or his/her legally authorized representative. NOTE: This does NOT have to follow research consent requirement. If unable to obtain consent, within the waiver or alteration of informed consent parameters, this must be noted and provided to the PHCIRB Obtain documented authorization from the IDE holder for emergency use, if applicable. Notify the PHCIRB of intended emergency use with justification/rationale for use. Email (to ORS@piedmont.org) is sufficient until formal notification with other documentation as outlined below. <p>AFTER USE (submit to the PHCIRB with 5 business days of emergency use):</p> <ul style="list-style-type: none"> Written description of patient case detailing need for emergency use and treatment plan. Uninvolved physician concurrence with treatment plan. Patient specific informed consent document. Authorization or cross reference of IDE or permission for use for this specific purpose.

Emergency use qualifications:

- The patient has a life-threatening or serious disease or condition; and
- There is no generally acceptable alternative treatment; and
- There is no time to obtain FDA approval because there is immediate need to treat the patient
- There is a substantial reason to believe that there is potential benefit

Serious disease or condition means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.