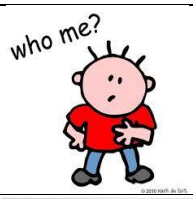
COMPASSIONATE (a.k.a EXPANDED) USE

WHO	 Yes you – the compassionate / expanded use requestor
WHAT	 Submission of compassionate / expanded use to the PHCIRB
WHY	You want to take advantage of a potential pathway to treat (outside of a clinical trial) patients with immediately life-threatening or serious disease conditions with investigational medical products.
HOW	Submit the following documentation to the PHCIRB: • A brief clinical history of the patient including diagnosis, disease status, prior therapy and rationale for requesting the proposed treatment. • The proposed treatment plan including the dose, route, duration, monitoring procedures and modifications for toxicity. • Uninvolved physician concurrence with treatment plan. • Patient specific informed consent document. **NOTE**: This does NOT have to follow research consent requirement. • Authorization or cross reference of IND (drug) or IDE (device) or permission for use of article for this specific purpose. • FDA concurrence with proposal.

What the regulations say:

- 21 CFR 312.300 b): ***Immediately life-threatening disease or condition*** means a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

- ***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.