## COMPASSIONATE (a.k.a EXPANDED) USE

<table>
<thead>
<tr>
<th>WHO</th>
<th>Yes you – the compassionate / expanded use requestor</th>
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</thead>
<tbody>
<tr>
<td>WHAT</td>
<td>Submission of compassionate / expanded use to the PHCIRB</td>
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<tr>
<td>WHY</td>
<td>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.</td>
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</table>
| 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.