# **Compassionate, expanded access and emergency use of drugs/devices**

DECISION TREE: EMERGENCY USE VERSUS SINGLE PATIENT USE

Criteria for expanded access to treatment:

1. Patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;
2. Patient enrollment in a clinical trial is not possible;
3. The potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context of the disease or condition to be treated; and
4. The expanded use of the investigational drug for the requested treatment will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the product.

Decision tree:

Question 1: Does my patient need expanded access to treatment:

* Yes: My patient meets all the criteria for expanded access
* No: My patient doesn’t meet all the criteria for expanded access = Patient isn’t eligible for expanded access

Question 2 (branches from Question 1 yes): Is there sufficient time to obtain prior IRB approval?

* Yes: Single patient use (prior IRB and FDA approval required)
* No: Emergency use (prior FDA approval required; prior IRB approval not required)

For FDA & IRB support: INDIDE@vcu.edu