DOES MY PATIENT NEED EXPANDED ACCESS TO TREATMENT?

Is there sufficient time to obtain prior IRB approval?

My patient doesn’t meet all the criteria for expanded access = Patient isn’t eligible for expanded access

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;

Patient enrollment in a clinical trial is not possible;

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

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.

For FDA & IRB support:
INDIDE@vcu.edu

Single patient use (prior IRB and FDA approval required)

Emergency use (prior FDA approval required; prior IRB approval not required)