V. 04.28.2023

PROCESS MAP: INVESTIGATIONAL DRUG EMERGENCY USE CRITERIA

Is the patient case an emergency situation?

1. Life or limb threatening situation in which NO standard acceptable treatment is available

AND

2. Another physician, not directly involved with immediate care of patient, has reviewed the situation agrees that emergency use criteria is met and puts this into writing.

AND

3. Insufficient time to convene a quorum for full board IRB approval
(Consult IRB office)

NO → Criteria for Emergency Use NOT met

Options:
1. Use FDA approved drug product – contact Pharmacy Prior Authorization team & CMU team if restricted or non-formulary

2. Enroll patient in ongoing clinical trial open at FMLH or expanded access program

3. Consider opening or initiating a clinical trial (requires full IRB approval)
   a. Submission of Sponsor protocol *or*
   b. Develop and submit investigator initiated protocol (requires submission of IND to FDA)

YES

Is the drug FDA approved?

YES → Does drug have Orphan drug approval and meets the criteria for orphan drug use?

YES → (Criteria for Emergency Use NOT met)

NO

NO

Is the drug available through expanded access or ongoing clinical trial for intended use?
(Visit FMLH Drug Study Database, FDA.gov and clinicaltrials.gov)

YES → (Criteria for Emergency Use NOT met)

NO

Has this drug product been used in the past for emergency use for another patient at FMLH?
(Consult IDS & IRB)

YES → Full IRB approval required BEFORE any subsequent use
AND
May require local submission of protocol, including approved IND

NO

Meets preliminary emergency use criteria. See Investigational Agent Emergency Use Workflow for further steps.

Contact Information:

- IRB Office – please include ALL of the following persons on email communication:
  - -irboffice@mcw.edu
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