PROCESS MAP: INVESTIGATIONAL DRUG EMERGENCY USE WORKFLOW

PI/IRB: Confirm emergency use criteria are met.
(Copy/Forward email communication with IRB to IDS)

RC/IDS:
- Contact sponsor/manufacturer to ensure can supply IP.
- Request drug product information (protocol, dosing information, drug information, etc.) and forward to IDS
- Identify if pharmacy will have to purchase drug or if it will be provided free of charge

(Process may happen simultaneously with IRB and FDA communication)

RC/PI: Develop informed consent form and obtain informed consent from patient or LAR
(Consult IRB for draft consent)

PI/RC: Notify IRB **within 5 days** of use of the emergency drug product via Ebridge
(see *MCW Emergency Use of Investigational Drugs, Devices or Biologics SOP*)

IDS:
- Submit urgent request for Epic Willow or Beacon build of the IDR to Help Desk.
  - If build not complete on time, use the following generic templates in Epic:
    -INV PO MED 80161