Step By Step

Emergency Single Patient IND Expanded Access Drugs/Biologics Submission

*Emergency Single Patient IND Expanded Access Drugs/Biologics Submission

*Emergency means the treatment of the patient must occur within a very limited number of hours or treatment must occur before the next business day after regular business hours

STEP 1

Physician calls manufacture & obtains their agreement to provide product

- Find manufacture contact & policies at EAP Navigator's Company Directory
- Find existing expanded access treatments at Project Facilitate and ClinicalTrials.gov
- Obtain a permission and Letter of Authorization (**LOA**) from manufacturer
- Call the appropriate institutional investigational pharmacy

STEP 2

Physician obtains verbal authorization of the emergency use from FDA

- **Investigational drugs** → Call 301-796-3400 or email druginfo@fda.hhs.gov
- **Oncology drugs** → Call 240-402-0004 or email ONCProjectFacilitate@fda.hhs.gov
- **Investigational biologics** → Call 240-402-8020 or email industry.biologics@fda.hhs.gov

After business hour and weekends, call FDA Emergency Call Center at 1-866-300-4374

STEP 3

Physician obtains informed consent (ICF) and begin treatment

- Obtain ICF from patient or their legally authorized representative per 21 CFR Part 50
- Use a written Emergency Use Consent (Form E.M) form approved by the IRB
- Document treatment outcome and adverse events

STEP 4

Physician notifies IRB and files written request to FDA retrospectively

IRB Within 5 days
- Emergency Use Post Notification (Form U2)
- Signed redacted Informed Consent
- Certification of Emergency Use (Form U3) if applicable

FDA Within 15 days
- Form 3926
- Treatment Outcome
- Safety information (AEs)

STEP 5

Physician closes or withdraws IND

- Submit summary of expanded access use per 312.310(c)(2) and close the IND or withdraw IND
- Submit Form 3926 (select 3b Follow-up) to FDA via either CDERNextGen Portal or EAP eRequest