Step By Step

Non-Emergency Single Patient or Intermediate-Size Population IND Expanded Access Drugs/Biologics Submissions

*Non-Emergency Single Patient or Intermediate-Size Population IND Expanded Access Drugs/Biologics Submissions

*Non-Emergency means the treatment of the patient does NOT need to occur within a very limited number of hours or does NOT need to occur before the next business day after regular business hours

STEP 1

Physician discusses treatment options with patient

- Clinical trial?
- **Expanded access?**
  - unable to participate in a clinical trial?
  - have a serious of immediately life-threatening disease or condition?
  - have no other comparable medical options?
- Off-label use?

STEP 2

Physician identifies EA treatment & request permission from manufacture

- Find various company policies for expanded access at EAP Navigator's Company Directory
- Find existing expanded access treatments at Project Facilitate and ClinicalTrials.gov
- Obtain permission and Letter of Authorization (**LOA**) from manufacturer

STEP 3

Physician determines size and types of Expanded Access

- Single patient (Emergency Use or Non-Emergency Use)
- Intermediate-size patient
- Large patient population

- Expanded Access Protocol (Submitted as a protocol amendment to an existing IND)
- Expanded Access (new) IND
  (New IND submission Intended only to make a drug available for treat)

STEP 4

Physician obtains authorization from FDA (contact sisupport@uthsouthwestern.edu for assistance)

- **Single patient**
  - Provider CV
  - Form 3926
  - LOA
- **Intermediate-size patient** or **Large patient population**
  - LOA
  - Form 1571
  - Form 1572

STEP 5

Physician obtains approval from an IRB

- **Single patient**
  Eligible to obtain IRB approval via Chair Concurrence
  - Informed Consent (Form E.M)
  - Form U1
  - Protocol (if available)
  - Form 3926
- **Intermediate-size patient** or **Large patient population**
  Requires Convened IRB Review
  - IRB required information Per 21 CFR Part 56
  - Protocol, Informed consent
  - FDA authorization

STEP 6

Physician signs contracts/agreement if applicable

- Submit Treatment Use Agreement (TUA) via eAgreement if manufacture requires agreement
- Contact Tiffany Moneit, Clinical Research Contracts Manager with SPA
  Facility name, shipping address, receiving point-of-contact, IRB number, ICF, FDA letter

STEP 7

Physician coordinates shipment and receives the investigational product

- Email approved documents to appropriate pharmacy
  IDSUTSWCUH@UTSouthwestern.edu for Clements University Hospital patients
  IDS-Aston@UTSouthwestern.edu for Clinical Research Unit patients
  azadeh.mozaffari@phhs.org, susan.partridge@phhs.org, allison.beaver@phhs.org for Parkland patients

STEP 8

Physician obtains informed consent (ICF) from patient

- Obtain ICF from patient or their legally authorized representative per 21 CFR Part 50
  Use a written consent form approved by the IRB

STEP 9

Physician treats patient

- Begin treatment 30 days after application is received by FDA (or earlier if notified by FDA)
- Document treatment outcome and adverse events

STEP 10

Physician reports AEs, amendments, follow-up documentation to IRB & FDA

- Report adverse events ASAP (within 5 days to IRB and within 15 days to FDA)
- Submit protocol and information amendments to FDA for any changes to initial EA IND
- Annual Report Within 60 days of the anniversary date (not required if tx completed within 1 year)

STEP 11

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