Single Patient IND

IRB Training

October 22, 2015

Submit an Investigational New Drug Application (IND)

To obtain an unapproved drug for an individual patient …

- First ensure that the manufacturer of the unapproved drug is willing to provide the drug
- If the manufacturer agrees to provide the drug, the physician should submit an IND to the appropriate FDA review division.

Submit an Investigational New Drug Application (IND)

- Emergency IND
  - Request to use the drug may be made via telephone
  - Authorization to ship and use the drug may be given by the FDA official over the telephone.
  - Shipment of and treatment with the drug may begin prior to FDA's receipt of the written IND submission that is to follow the initial request.
- Individual IND (non-emergency)
  - Written request for individual patient use of an investigational drug must be received by the FDA before shipment of and treatment with the drug may begin

IND should include the following information to FDA:

- Statement that this is a request for an individual patient IND for treatment use
- Brief clinical history
- Proposed treatment plan
- Chemistry, manufacturing, and controls information and pharmacology and toxicology information
- Statement that IRB approval & informed consent will be obtained
- Investigator CV
- FDA Form 1571
- Contact information

IRB Review of Individual IND

- Often manufacturer will not ship to site until IRB approval
- Full IRB review required
  - Simple protocol
  - Simple ICF
  - Modified application
- Convened meeting review required
- Exception = Emergency use