

Investigational New Drug (IND) Protocols

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A magnifying glass with a wooden handle and a metal frame, set against a blue background. The lens is white and slightly reflective.

IND

(Investigational New Drugs)



Centers for Disease Control and Prevention

What is an IND?

- Permits distribution of a drug during an investigational period
- Broadly, refers to a body of regulations that guide the administration of an investigational drug (Found in 21 CFR 312)
- Three basic constituents
 - informed consent
 - protocol review (IRB)
 - outcome collection (safety and efficacy)



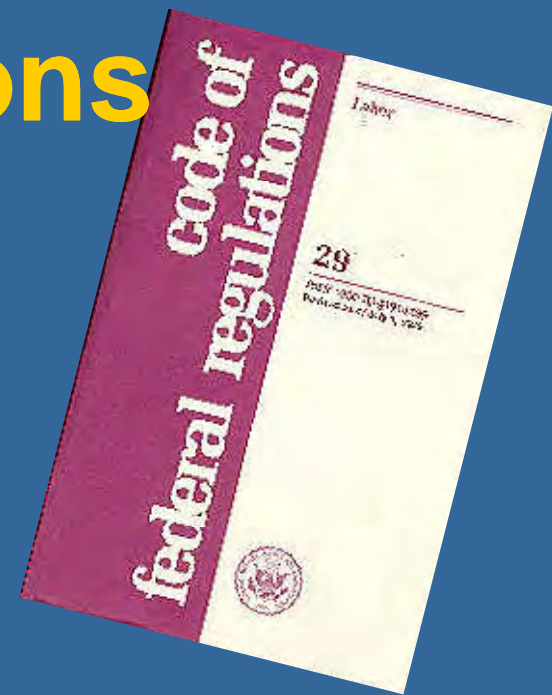
Why is an IND needed?

- The use of an unapproved drug and/or vaccine (product)
- The use of an approved product for a new, unlabeled use
- Disease
 - occurs infrequently (e.g., anthrax)or
 - no longer occurs naturally to be studied (e.g. smallpox)
- Unethical to perform studies in humans





Practice of Medicine vs. IND Regulations



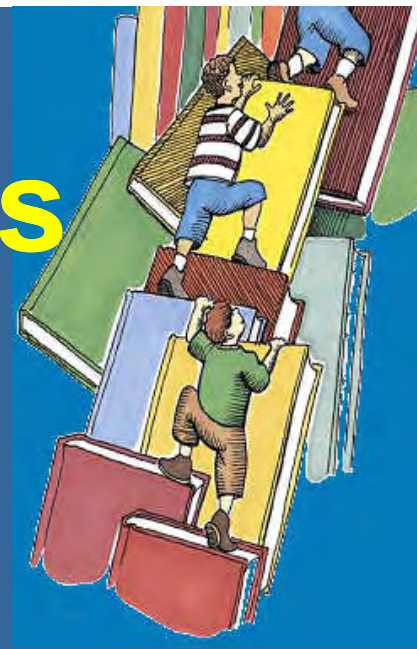
Current CDC Protocols

- Anthrax
 - Post-Exposure (ATB + 3 doses of vaccine)
 - AIP and AIG for treatment
- Smallpox
 - Pre/Post vaccination
 - Protocols for vaccine adverse reactions (VIG & cidofovir)

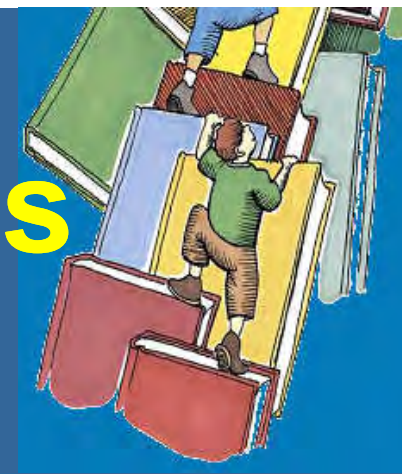


Current CDC Protocols

- Plague
 - Treatment protocol (gent)
 - Pre and post-exposure protocol (cipro)
- Tularemia
 - Treatment protocol (gent & cipro)
 - Post-exposure protocol (cipro)



Current CDC Protocols



- Botulism
 - Treatment protocol (*BAT-heptavalent, equine)



*IND			
Agent	Treatment	Prophylaxis	Vaccine
Anthrax	Cipro Doxy Clinda* Rifampin* PCN	Cipro Doxy Amoxicillin*	Pre-exposure Post-exposure*
Plague	Doxy Gentamicin*	Cipro* Doxy	NONE
Tularemia	Cipro* Doxy Gent*	Cipro* Doxy	NONE
Smallpox	Treatment of adverse reactions to Vaccine VIG* & Cidofovir*	NONE	Wyeth 1:1, 1:5* Aventis Pasteur* Acambis*
Botulinum	Antitoxin Type: Heptavalent*, E*, AB	NONE	NONE

*Indicates drugs are not approved for the agent

•Indicates that drugs are subject to use under a CDC IND



CDC Responsibilities

- Sponsor of IND
- Supply protocol & related documents
- Supply drug/biologic/device
- IRB Approval
- Report to FDA
- Deployment of the IND for an Event



State/Local Responsibilities

- Provide infrastructure
 - Points of distribution/clinics
 - Communications
 - State and IND team
 - Public
- Local Investigators



Project BioShield

A comprehensive effort to develop and make available modern, effective drugs and vaccines to protect against attack by biological and chemical weapons or other dangerous pathogens.



Project BioShield

- Ensure that resources are available to pay for "next-generation" medical countermeasures
- Strengthen NIH development capabilities by speeding research and development
- Give FDA the ability to make promising treatments quickly available in emergency situations



Project BioShield: New FDA Emergency Use Authorization

- For promising medical countermeasures under development
- Supplement traditional licensure process
- Very narrowly focused & targeted
- Finding by Secretary of HHS & expert analysis by FDA
- Limited
- One year



Project BioShield: New FDA Emergency Use Authorization

- Must have a declaration of a state of emergency by secretary of DHHS, DHS, DOD
- Will allow for unapproved drugs or approved drugs for non approved indications to be distributed in an emergency:
 - No patient consent form required
 - Minimum adverse event reporting
 - Patient and provider information mandatory





Questions



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