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When isn't an IND application needed? - IND Application is not needed if investigation does not support change in labeling.

What information must the general IND include? (21 CFR Part 312.23) - -FDA Form 1571 -FDA Form 1571 cover sheet

- Table of contents
- -Investigative Plan
- -Investigator's brochure
- -Protocol
- -Chemistry/Manufacturing information
- -Pharmacology/Toxicology
- -Previous human research/literature information
- -Additional information (drug dependence and abuse potential)

How many days after FDA receives IND submission does the IND go into effect? 21 CFR 312.40 - (Administrative Actions) An IND goes into effect 30 days after the FDA receives the submission unless the FDA notifies the Sponsor of a clinical hold.

When must an IND amendment be submitted and which section outlines this? - (21 CFR Part 312.31)

-If there are changes to the protocol that affects safety of subjects, scientific quality of study, or scope of investigation

- -If a new Investigator is added to the study
- Information amendments must be submitted for chemistry/microbiology. pharm/toxicology, or clinical

Other submissions:

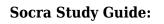
- -- IND safety reports
- -- Response to clinical hold
- -Response to FDA request for information
- -- IRB Annual report

What are the requirements for expanded access? 21 CFR Part 312.300 (Subpart 1) --Population must have serious or life-threatening disease or condition

- -No comparable/significant alternate therapy/treatment
- Patient cannot obtain drug under another IND or protocol
- Potential benefit outweighs risks of treatment.
- -Expanded access won't interfere with completion of studies that could support marketing approval
- -Must apply to treatment protocols and should be for individual use (1 person)

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R Bogdan



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