

What is an IND?

- Application to FDA to seek permission to test a new drug (or biologic) in human
- Notice of Claimed Investigational Exemption for a New Drug
- Usually starts with Phase I Study
- 21 CFR 312

When do you submit an IND

- Whenever clinical studies are initiated:
 - On a new drug or biologic in the US
 - For a new indication or different route of administration of an already approved drug for FDA Submission
 - Not all studies require an IND

When is an IND not required?

- Marketed drugs using approved dosage or indication already

And

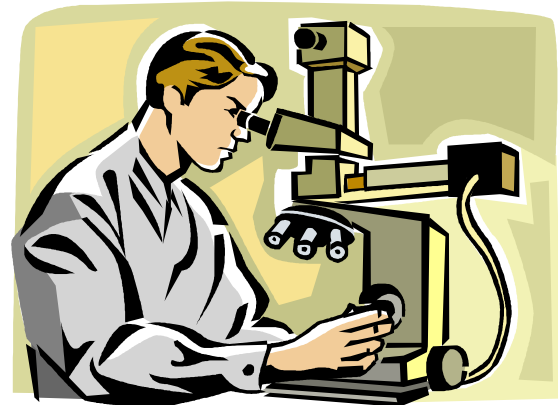
- Does not support significant labeling change

And

- Does not put patients at increased risk

When is an IND not required?

- Intended only for in vitro or animal testing
- Certain Bioavailability/Bioequivalence studies
 - Generic Drugs



Types of IND

Sponsor-Investigator IND



What's the difference?

- SPONSOR
- INVESTIGATOR
- SPONSOR-INVESTIGATOR
- SUPPLIER

Sponsor-Investigator IND

- 21 CFR 312.22, Part D
 - General Principals of IND Submission
- IND Sponsor by an Individual Investigator
- Same requirements at manufacturer-sponsored INDs
- Not intended to replace traditional sponsor INDs as a mechanism to initiate clinical trials

Content of IND Submission

- Form 1571
- Form 1572
- Protocol, Protocol Summary
- Investigator's Brochure/Package Insert
- Cross Reference Letter
- IRB Roster
- IRB Meeting Dates

Contents of IND Submission

- IRB Compliance Letter (21 CFR 56)
- Status with IRB
(Submitted/Provisos/Approved)
- Current Consent Form
- CAP/CLIA (If using KU Lab)
- CV's for all Investigators involved

Contents of IND Submission

- Medical Licenses for each Investigator
- Statement of exclusion

“I claim categorical exclusion (under 21 CFR 25.31[e]) for the study under this IND. To my knowledge no extraordinary circumstances exist.”

What is a 1571?

- Primary application for new drug/drug usage
- General outline of what is included with the application or what is involved in the submission

What is a 1572?

- Statement of Investigator
 - Who
 - What
 - Where

Cross Reference Letter

- Letter from supplier of drug stating the investigator may reference another IND for drug information

Categorical Exclusion

- “I claim categorical exclusion (under 21 CFR 25.31[e]) for the study under this IND. To my knowledge, no extraordinary circumstances exist.”
- 21 CFR 25.31[e] – Environmental impact considerations concerning human drugs and biologics

How do you submit to the FDA?



Filing

- Change cover letter template
- Collect documents in order on cover letter
- 5 copies are needed
 - 1 original and 2 copies sent to FDA
 - 1 original for study coordinator
 - 1 copy for RI binder

Is it ok to start the study?

- 30 days from the day the packet is sent to the FDA
 - Will hear back from FDA for clarification or additional documentation
 - Clinical HOLD or request for modification
 - If no word is heard, the investigator may begin the study after 30 days; “No news is good news”

Start up and beyond

- Amendments made for:
 - Protocol Amendments
 - Study Personnel Amendments
 - Annual Reports
 - Change in Safety Information
- Code of Federal Regulations outlines exactly what needs to be submitted and how, always in triplicate