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