

Protecting people who participate in research

*CITI Training Study Guide
FDA-Regulated Research*

What Does FDA Regulate?

- The Food and Drug Administration reviews drugs, biological medicines and medical devices for safety and effectiveness before granting approval for marketing.
- When approved, the packaged insert, or label, summarizes what FDA considers the safe and effective use of the product.

How does FDA determine safety & effectiveness?

The product sponsor (company) proposes research to FDA with either:

- Investigational New Drug (IND) application
- Investigational Device Exemption (IDE) application
- Research begins after FDA grants the application and an IRB approves the study.
- The company submits the data to FDA for approval or rejection of the drug or device.

How does FDA decide to grant an IND or IDE?

- **FDA will approve the IND or IDE research on humans if it determines the risk is reasonable, based on:**
 - Data from prior animal or human testing;
 - Methods of manufacturing;
 - Plans for testing and reporting significant toxicities;
 - A well-developed clinical research plan that minimizes risks to the subjects.

When is FDA approval required?

- **When the principal intent of the drug research is to develop information about safety or efficacy.**
- **When an investigational medical device presents a “Significant Risk” to the subject’s health, safety, or welfare and:**
 - It will be implanted into the body;
 - It will be used to support or sustain life; or
 - It is important in diagnosing, curing, mitigating, or treating disease, or otherwise prevents impairment of human health.

When is an IND not required?

When all of the following criteria are met:

- The data will not be used to support a new indication, new labeling, or change in advertising;
- The research does not involve a route of administration/dosage level or subject population that significantly increases the risks of the drug product;
- The research is conducted in compliance with IRB review and informed consent requirements;
- The research is conducted in compliance with requirements for promotion and sale.

When else is an IND not required?

- When physicians, according to their best knowledge and judgment, prescribe a drug for an indication not listed in the approved labeling.
- The physician has the responsibility to be well informed and to base the proposed use on scientific rationale and medical evidence.

Other FDA Requirements

For drug or device research, the following statement added to an informed consent form:

- "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

Other Significant FDA Rules

Federal Regulation 21 CFR Part 11:

- allows the use of electronic documents and signatures in the regulatory process for drugs and devices.
- Part 11 specifies processes that must be in place to ensure that electronic documents and signatures are equivalent to paper documents and handwritten signatures.
