FDA-Regulated Research

**Investigational Drug Studies**

Studies involving the use of an investigational drug will be conducted in compliance with 21 CFR 312 Subchapter D, Drugs for Human Use / Investigational New Drug Application (IND).

An IND is required for experimental drugs if the drugs are used for the purpose of developing information about their safety or efficacy. Approved, marketed drugs also require an IND if the proposed use in research is different from its previously FDA-approved use or administered by an unapproved route or method of delivery or an altered dosage.

**Examples of when an IND may be required include:**

- When the principal intent of the investigational use of a test article is to develop information about the product’s safety or efficacy, including FDA approved drugs
- If the intent of the research is to generate data that will lead to a new advertising claim, a new clinical indication, or a new formulation of the product

When an IND is required, the sponsor (usually a pharmaceutical company, but sometimes an individual) must submit to the FDA a completed and signed FDA Statement of Investigator Form 1572 in order to participate in the research investigation. Unless contacted by the FDA, an investigator may begin clinical trials 30 days after the FDA receives the IND application.

Investigators will be responsible for conducting the investigation in accordance with the signed investigator statement, the investigational plan, and applicable regulations and policies; and for protecting the rights, safety and welfare of participants in their care.

**Exemptions from 21 CFR 312**

The IRB may determine that a clinical investigation of a lawfully marketed drug(s) is exempt from the regulation if all of the following conditions apply:

- the investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
- if the drug is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
- the investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product;
- the investigation is conducted in accordance with the requirements of institutional review and informed consent as set forth in 21 CFR 50;
- the investigation is conducted in compliance with part 312.7 regarding the promotion and charging for investigational drugs
A clinical investigation involving an in vitro diagnostic biological product (blood grouping serum; reagent red blood cells; and anti-human globulin) is exempt if it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and it is shipped in compliance with the requirements set forth in 312.160.