



According to Food and Drug Administration (FDA) regulations at 21 CFR 312.2, the following studies of drugs and biologics are exempt from requirements to submit an Investigational New Drug (IND) application to the FDA.

1. The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from IND requirements if all the following apply:
  - a. The investigation is not intended to be reported to 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;
  - b. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
  - c. 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 risks (or decreases the acceptability of the risks) associated with the use of the drug product;
  - d. The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and
  - e. The investigation is conducted in compliance with the requirements of 21 CFR 312.7.
2. A clinical investigation involving blood grouping serum, reagent red blood cells, or anti-human globulin, is exempt from IND requirements if:
  - a. it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure, and
  - b. it is shipped in compliance with 21 CFR 312.160.
3. A drug intended solely for tests in vitro or in laboratory research animals is exempt from IND requirements if shipped in accordance with 21 CFR 312.160.
4. The FDA will not accept an IND application for an investigation that is exempt under the provisions of section (1) above.
5. A clinical investigation involving use of a placebo is exempt from IND requirements if the investigation does not otherwise require submission of an IND.

Note that IND requirements do not apply to the use in the practice of medicine for an unlabeled indication of a new drug product approved under part 21CFR314 or of a licensed biological product.