

DOES MY STUDY NEED AN IND?

When the principal intent of the investigational use of a test article is to develop information about the product's safety or efficacy, submission of an IND may be required. The following criteria are used to determine whether your protocol is exempt from IND review and submission:

- Clinical investigations of a drug product that is lawfully marketed in the United States, provided that **all** of the following conditions apply:
 1. The study is not intended to be reported to the FDA as a well-controlled study in support of a new indication or use; or support any significant change in the drug's labeling;
 2. The study is not intended to support a significant change in the advertising for a prescribed drug;
 3. The study does not involve a change in route of administration, dosage level, patient population, or other factors that significantly increases the risks associated with use of the drug product;
 4. The study complies with IRB evaluation and informed consent requirements;
 5. The study sponsor and/or investigator do not represent in a promotional context that the drug is safe and effective for the purposes in which it is under investigation;
- Drugs intended solely for testing in vitro or in laboratory research animals, provided the drug labels and shipments comply with FDA regulations.
- Clinical investigations involving the use of a placebo provided that investigators do not involve the use of a new drug.
- Certain in vivo bioavailability and bioequivalence studies in humans (generic drugs). FDA regulations state that INDs are required for in vivo bioavailability or bioequivalence studies in humans if the test product is a radioactively labeled drug product, is a cytotoxic drug product, or contains a new chemical entity.

Still, situations arise when studies could be exempt from IND submission, even though they do not meet the criteria above. These types of exemption are granted usually because there is significant information about these treatments already in the literature. For example, when a drug has been used clinically off-label regularly for the treatment of the studied condition and there is significant information in the literature about this use. In this situation the FDA is the one who determines that your protocol is exempt. If you still have any doubts whether your study requires an IND or not, contact the appropriate department at FDA.

For more information about whether your particular study is exempt from IND submission please review the FDA guidance entitled, *IND Exemptions for Studies of Lawfully Marketed Drug or Biologic Products for the Treatment of Cancer*:

<http://www.fda.gov/cber/gdlns/indcancer.pdf>