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DOES MY STUDY NEED AN IND?

In general, an Investigational New Drug (IND) application is required when the principal intent of any clinical research study is to develop information that proposes the use or evaluation for safety and/or effectiveness of an unapproved drug. Please note in research, "off-label use" of a lawfully marketed drug would be considered an unapproved drug.

The following criteria are used to determine whether your protocol is exempt from IND review and submission. ***If any of your answers are in a red box you will likely need to file an IND.***

	Yes	No
Is the drug/biologic product lawfully marketed in the United States?		
Is there any intent to report the findings of your investigation to the FDA as a well-controlled study in support of a new indication or any other significant change in the labeling of the drug?		
Is the study intended to support a significant change in the advertising of the prescribed drug/biologic?		
Will the investigation involved a change in any of the following factors:		
• Route of administration		
• Dosage level (either raising or lowering dose, frequency or duration compared to approved label)		
• Patient population		
• Any other factor that significantly increases (or decreases the acceptability of the risk) risk associated with the use of the drug product (21 CFR 312.2(b) (1)(iii)).		
Is the Investigation intended to promote or commercialize the drug product (21 CFR part 312.7)		
Is the investigation 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		

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Further Exemptions

If the primary purpose of your clinical investigation involves any of the following you may also be exempt from IND requirement:

- 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. **I**n this situation the FDA is the one who determines that your protocol is exempt.

***Please note there are exceptions to every regulation, if you have any doubt whether an IND is required you should file an "IND Exemption Request" with the FDA**

For more information about whether your particular study is exempt from IND submission please review the draft FDA guidance entitled, *Investigational New Drug Applications (IND) – Determining Whether Human Research Studies Can Be Conducted Without an IND:* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf