



IND EXEMPTION WORKSHEET

For Investigator-Initiated Clinical Investigation of a Drug or Biologic

Whether an IND is needed to conduct a clinical investigation of a marketed drug primarily depends on the intent of the investigation and the degree of risk associated with the use of the drug in the investigation. A clinical investigation of a *marketed* drug is exempt from the IND requirements if *all* the criteria are met. IRB approval is required before the study may commence.

IND EXEMPTION CRITERIA	YES	NO
1. The drug product is lawfully marketed in the United States.		
2. The study is not intended to be reported to FDA as a well-controlled study in support of a new indication and there is no intent to use it to support any other significant change in the labeling of the drug.		
3. In the case of a prescription drug, the study is not intended to support a significant change in the advertising for the drug.		
4.a. The study does not involve a route of administration, significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product (21 CFR 312.2(b)(1)(iii)).		
4.b. The study does not involve a dose that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product (21 CFR 312.2(b)(1)(iii)).		
4.c. The study does not involve a patient population, that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product (21 CFR 312.2(b)(1)(iii)).		
4.d. The study does not involve another factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product (21 CFR 312.2(b)(1)(iii)).		
5. The study is conducted in compliance with the requirement for review by an IRB (21 CFR part 56) and with the requirements for informed consent (21 CFR par 50).		
6. The study is conducted in compliance with the requirement of § 312.7 (i.e. the investigation is not intended to promote or commercialize the drug product).		