Checklist: Determination of IND Exemption Status

CHECKLIST: DETERMINATION OF IND EXEMPTION STATUS at CHOP		
Not all clinical research studies require a Food and Drug Administration (FDA) Investigational New Drug (IND) application. The following checklist is intended to help investigators determine whether their clinical research study may be exempt from filing an IND application with the FDA, according to the Code of Federal Regulations (CFR) part 312 guidelines. • **A clinical investigation of a marketed drug is exempt from the IND requirements if all of the criteria for an exemption in § 312.2(b) are met.** • **Complete the following checklist to determine if the use of a lawfully marketed drug in your clinical research study meets criteria for IND exemption.**		
1. The drug product is **lawfully marketed in the United States**.	NO	**YES**
2. The investigation 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.	NO	**YES**
3. In the case of a prescription drug, the investigation is **not intended to support a significant change in the advertising for the drug**.	NO	**YES**
4. The investigation does not involve a route of administration, dose, 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 (21 CFR 312.2(b)(1)(iii)). **This criterion has 4 elements (route of administration, dose, patient population, or other factor) to be considered separately, as indicated in the 4 following risk considerations:**		
4a. The investigation **does not involve a route of administration** that significantly increases the risk (or decreases the acceptability of the risk) associated with use of the drug product (21 CFR 312.2(b)(1)(iii))	NO	**YES**
4b. The investigation **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)).	NO	**YES**
4c. The investigation **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)).	NO	**YES**
4d. The investigation **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)).	NO	**YES**
5. The investigation is **conducted in compliance with the requirements for review by an IRB** (21 CFR part 56) and with the requirements for informed consent (21 CFR part 50).	NO	**YES**
6. The investigation is conducted in compliance with the requirements of § 312.7 (i.e., the **investigation is not intended to promote or commercialize the drug product**).	NO	**YES**
IS THE CLINICAL STUDY IND EXEMPT?		
If <u>each</u> of the responses to points #1-6 above is in the green box, the study may qualify for exemption. If <u>one</u> of the responses is outside the green box for any point, the study is NOT IND exempt. When there is uncertainty about IND exemption status, the relevant FDA division can be contacted to determine status.		

References and Resources

IND Application Procedures: Exemptions from IND Requirements

Investigational New Drug Applications (INDs) - Determining Whether Human Research Studies Can Be Conducted Without an IND Guidance for Clinical Investigators, Sponsors, and IRBs

IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer

CHOP CONTACT INFORMATION FOR IND EXEMPTION	
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