Investigational New Drug (IND) Decision Tool for Investigators

Any protocol that involves the use of a drug[1] that is not approved by the FDA requires an IND[2]. If your protocol investigates any approved drugs, use the table below to determine whether you need to submit an IND application to the FDA.

Not all clinical investigations of drugs require an IND application to the FDA. Some investigations of drug products that are legally marketed in the United States may be exempt from the IND requirements at 21 CFR 312.2, provided the study meets **all** the criteria in the table below. If your response to any of the following criteria is "false", you must submit an IND application to the FDA.

IND Exemption Criteria	True	False
1(a) The investigation is *not* intended to be reported to the FDA as a well-controlled study in support of a new indication for use.		
1(b) The investigation is *not* intended to be used to support any other significant change in the labeling for the drug.		
2(a) The drug being used in the investigation *is* lawfully marketed as a prescription drug product.		
2(b) The investigation *is not* intended to support a significant change in the advertising for the product.		
3(a) The investigation *does not* involve a route of administration that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.		
3(b) The investigation *does not* involve a dosage level that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.		
3(c) The investigation *does not* involve the use of a drug product in a patient population that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.		
3(d) The investigation *does not* otherwise significantly increase the risk (or decrease the acceptability of the risk) associated with the use of the drug product.		
4(a) The investigation is conducted in compliance with FDA requirements for review by an IRB (21 CFR 56) and for informed consent (21 CFR 50).		
5(a) The investigation is conducted in compliance with 21 CFR 312.7 (*i.e.*, the investigation is not intended to promote or commercialize the drug product).		
5(b) The investigation *does not* provide for Exception from Informed Consent (21 CFR 50.24)		

1. "Drug" and "drug product" includes biologics
2. Products overseen by Radioactive Drug Research Committees do not require INDs