



IND DECISION WORKSHEET

For Investigator-Initiated Clinical Investigations

Note: The following worksheet is intended to help determine whether an IND submittal to the FDA is required prior to initiating your Investigator-Initiated Clinical Trial or if you qualify for an IND exemption.

Does your study meet ALL of the following criteria for IND exemption?

Investigation of a drug product that is lawfully marketed in the United States may be exempt from IND requirements provided **ALL** of the following statements are true (per 21 CFR Part 312.2):

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 your 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 USE 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 involve ANY OTHER FACTOR that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.		
4(a) The investigation IS conducted in compliance with the requirements for Institutional Review (IRB) per 21 CFR Part 56 and the requirements for Informed Consent, per 21 CFR Part 50.		
5 (a) The investigation is conducted in compliance with 21 CFR Part 312.7 which means you are NOT PROMOTING the drug being studied as safe or effective.		
6 (a) The investigation DOES NOT provide for exception for Informed Consent (21 CFR Part 50.2).		