



## IND DECISION WORKSHEET

### For Investigator-Initiated Clinical Investigations

#### Does Your Study Require an IND Submittal to the FDA?

**Note:** The following worksheet is intended to help determine whether an IND is required prior to initiating your Investigator-Initiated Clinical Trial.

**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
<b>1 (a)</b> The investigation <b>IS NOT</b> intended to be reported to the FDA as a well-controlled study in support of a new indication for use.		
<b>1 (b)</b> The investigation <b>IS NOT</b> intended to be used to support any other significant change in the labeling for the drug.		
<b>2 (a)</b> The drug being used in your investigation <b>IS</b> lawfully marketed as a prescription drug product.		
<b>2 (b)</b> The investigation <b>IS NOT</b> intended to support a significant change in the advertising for the product.		
<b>3 (a)</b> The investigation <b>DOES NOT</b> involve a <b>ROUTE OF ADMINISTRATION</b> that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.		
<b>3 (b)</b> The investigation <b>DOES NOT</b> involve a <b>DOSAGE LEVEL</b> that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.		
<b>3 (c)</b> The investigation <b>DOES NOT</b> involve <b>USE IN A PATIENT POPULATION</b> that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.		
<b>3 (d)</b> The investigation <b>DOES NOT</b> involve <b>ANY OTHER FACTOR</b> that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.		
<b>4 (a)</b> The investigation <b>IS</b> 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.		
<b>5 (a)</b> The investigation is conducted in compliance with 21 CFR Part 312.7 which means you are <b>NOT PROMOTING</b> the drug being studied as safe or effective.		
<b>6 (a)</b> The investigation <b>DOES NOT</b> provide for exception for Informed Consent (21 CFR Part 50.24).		

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Principal Investigator Signature

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Date

For Regulatory Binder

- IND FDA Approval Required
- IND Exempt