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
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 50.24).		

UCLA Principal Investigator Signature **Date**

For Regulatory Binder
□ IND Exempt
□ IND FDA Approval Required