THE OHIO STATE UNIVERSITY
CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

IND DECISION WORKSHEET GUIDE

For Investigator-Initiated Clinical Investigations

INVESTIGATOR NAME:

DRUG NAME:

PROTOCOL / STUDY TITLE:

NOTE: The following worksheet is intended to help researchers determine if an IND may be required prior to initiating a new clinical study.

Investigational use 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 (21 CFR 312.2).

IND EXEMPTION CRITERIA	TRUE	FALSE	NOT SURE
1: The investigation **IS NOT** intended to be reported to the FDA as a well-controlled study in support of a new indication for use.			
2: The investigation **IS NOT** intended to be used to support any other significant change in the labeling for the drug.			
3: IF the drug being used in your investigation is lawfully marketed as a prescription drug product, the investigation **IS NOT** intended to support a significant change in advertising for the product. **(NA if NOT an Rx drug product- for example nutritional supplements)**			
4: 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.			
5: 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.			
6: 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.			
7: 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.			
8: 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.			

9: 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.			
10: The investigation **DOES NOT** provide for exception for Informed Consent (21 CFR Part 50.24).			

CTSI Regulatory Support personnel will meet with you to discuss any concerns or questions regarding the above. CTSI can help advise regarding the IND process. Contact us at CTSI-Regulatory@osumc.edu.