This document is a fillable PDF form. Please complete the application and either apply your electronic signature or print the document and sign. This document should then be uploaded to the appropriate question in Section 15 of your eResearch application.

IND DECISION WORKSHEET

For UM Investigators / Clinical Investigations

INVESTIGATOR NAME: _____ **DRUG NAME**: _____

STUDY TITLE:

_____

NOTE: The following worksheet is intended to help UM investigators determine if an IND application to the FDA may be required prior to initiating a new clinical study. This document should be completed by clicking on 1 answer for each question below, and then provided to the IRB in support of an e-Research application prior to initiating a Clinical Trial.

QUESTION - Does your study require an IND? Or does it meet ALL of the criteria for IND exemption?

***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).* Please answer all questions below:**

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: The drug used in the investigation is **LAWFULLY MARKETED** as a prescription drug product and the investigation **IS NOT** intended to support a significant change in advertising for the product.			
4: The investigation **DOES NOT** involve a **ROUTE OF ADMINISTRATION** that significantly increases the risks (or decreases the risk/benefit ratio) 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 risk/benefit ratio) 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 risk/benefit ratio) 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 risk/benefit ratio) associated with the use of the drug product.			
8: The investigation **IS** conducted in compliance with the IRB regulations (21 CFR 56) and the Protection of Human Subjects regulations (21 CFR 50).			
9: The investigation **IS** conducted in compliance with the regulations regarding Promotion of an Investigational Drug (21 CFR 312.7), that you are **NOT PROMOTING** the drug as safe or effective.			
10: The investigation **DOES NOT** request an exception of Informed Consent (21 CFR 50.24).			

The MIAP Team is available to meet with any UM investigator(s) to discuss the issues outlined above. MIAP can provide advice regarding the IND process, discuss FDA filing strategies, make recommendations for protocol improvement and give input / feedback regarding the FDA IND exemption status for any project. MIAP Team can be reached via email at MICHRMIAP@med.umich.edu.

_____ _____

Principal Investigator Signature **Date**