**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). |  |  |