KELLY
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& ASSOCIATES

KW

RESEARCH.
COMPLIANCE.
CONSULTING.

# IND EXEMPTION ATTESTATION

| THE CLINICAL INVESTIGATION OF A DRUG PRODUCT THAT IS LAWFULLY MARKETED IN THE UNITED STATES IS **EXEMPT** FROM IND REQUIREMENTS IF ALL OF THE FOLLOWING APPLY | **YES** | **NO** |
|---|---|---|
| The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug. | ☐ | ☐ |
| If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product; | ☐ | ☐ |
| The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the product; | ☐ | ☐ |
| The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and | ☐ | ☐ |
| The investigation is conducted in compliance with the requirements of 21CFR312.7. | ☐ | ☐ |

PI Signature _____ Date _____

PI Name _____