Request for Waiver from the Requirement to Submit an IND Application to the FDA

All studies that utilize products regulated by the Food and Drug Administration (FDA) need to have either an approved IND application from the FDA, or an approved Waiver from the Requirement to Submit an IND Application from an Institutional Review Board (IRB).

Under *21 CFR Part 312.2(b)(1)* - the clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if all the following apply ***(provide justification for each criteria in the text box below)***:

1. 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

2. 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

3. 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 drug product

4. 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

5. The investigation is conducted in compliance with the requirements of Sec. 312.7.