



Statement of Request for IND Exemption for Proposed Protocol [protocol title]:

By virtue of this statement, I am requesting an exemption from filing an Investigational New Drug Application (IND) to conduct a clinical investigation with [name of study drug/agent] in patients with [diagnosis]. Up to [number] patients between the ages of [age] and [age] will be included in this study.

The primary objective of this study is to determine [objective].

[Pharmaceutical Company Name] has agreed to provide the non-investigational [drug/agent] for the duration of the above referenced research study at no charge to study participants or their insurance providers. The [name of study drug/agent] is lawfully marketed in the United States.

I have herewith attached the IRB-approved protocol and consent for your review. I believe that this study would not significantly increase risk (or decrease the acceptability of risk) to the patient. It is in my opinion that these patients will benefit from use of the [name of study drug/agent] because [reason]

This request for exemption is based on 21 CFR 312.2(b), wherein:

- (i) 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;
- (ii) 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;
- (iii) 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;
- (iv) 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
- (v) The investigation is conducted in compliance with the requirements of 312.7.

I will not proceed with this study until the FDA notifies me of whether or not an IND is necessary. I understand that, if the FDA determines that an IND is necessary, I must file an IND application and may not initiate this study until 30 days after the date of the FDA's receipt of the application, unless I am notified sooner by the FDA that the study may commence. Furthermore, I understand that I must comply with the institutional review requirements as described in CFR part 56 as well as the informed consent requirements as described in CFR part 50, regardless of whether or not the FDA deems this trial exempt from an IND.