[Recipient Information – see relevant [FDA Review Division](https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm075128.htm)]

[Address line 1]

[Address line 2]

[City, State, Zip]

Sent via email to [email address]

Dear Sir or Madam:

The purpose of this correspondence is to obtain the Agency’s opinion on the need for an Investigational New Drug Application, for a clinical trial using [drug name] in patients with [disease].

**Background**

The drug [drug name; manufacturer; city, state] is currently FDA-approved for use in patients with [FDA-approved indications]. The approved dosage of [drug name] is [approved dosage or use of drug].

**Proposed clinical trial**

[Describe the clinical trial, including purpose and design.]

The findings of this study are intended to advance scientific knowledge *only* and are not intended to be used to support a change in prescribing information for [drug name].

The [drug name] used in this trial will be provided by [manufacturer] at no charge to study participants or their insurance providers.

As the Sponsor-Investigator, I believe this proposed trial meets the IND exemption criteria as presented in 21 CFR 312.2 (b)(1) but would like to confirm this with the FDA before proceeding.

**Request**

I am asking the Agency to help determine whether an IND submission is required for the use of [drug name] in patients with [disease] in the clinical trial described above.

I will not proceed with this study until the Agency notifies me of whether or not an IND is necessary.  Please respond within 30 days after receipt of this letter.  If the FDA determines that an IND is necessary, I understand I must file the appropriate 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 the requirements an IND or IDE.

Thank you for your review and assistance with this request. A full protocol is included for your review. If you need any additional information or have any questions during your review, please contact me at [contact information].

Sincerely,

[PI name]