INSTITUTION LOGO/LETTERHEAD

Month XX, 20XX

Food and Drug Administration

Center for Drug Evaluation and Research

Division of [Therapeutic Area]

Central Document Room

5901-B Ammendale Rd.

Beltsville, MD 20705-1266

RE: **Request for IND Waiver**

Dear Dr. [Division Director]:

*In response to our conversation on [date],* I am formally requesting guidance on whether the proposed study of [drug name] in [disease] patients qualifies for exemption from an IND (21 CFR Part 312.2). The proposed clinical investigation is not being conducted to support a label-change of the product or to support a significant change in the marketing of the product.

This investigation does (or does not) involve a change in the [dose or route of administration], but does not represent a significant increase of risk to the population intended for study. The rationale for this statement is provided below.

**Proposed Study: Provide brief description of study.**

**Rationale for Safety of Proposed Study**

We respectfully ask that you review this request and inform us in writing if the IND requirement will be waived. If you require additional information, please contact me at the phone number or email address provided below, or xxxxxxxx who may act on my behalf.

Sincerely,

[Sponsor Name], MD

Title

Institution

Phone number

Email address

Attachments:

Protocol

FDA form 1571

FDA form 1572