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Serial #0000 Request for IND Exemption

[Date]

Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

IND Exemption Determination Request for Proposed Protocol [protocol title]:

Dear FDA Reviewers:

The purpose of this submission is to request confirmation of my opinion that the above noted protocol meets the requirements for Exemption from the Investigational New Drug regulations. My intention is to conduct a clinical investigation with the marketed drug [name of study drug/agent] in patients with [diagnosis]. The primary objective of this proposed trial is to determine [primary objective].

It is in my opinion that the proposed research with [name of study drug/agent] meets the exemption requirements noted in 21 CFR 312.2b. I also believe that this study would not significantly increase risk (or decrease the acceptability of risk) to the patients.

I will not proceed with this study until the FDA notifies me of whether or not an IND is necessary.

Three copies (original and 2 copies) of the following documents are enclosed:

- Protocol
- IND Exemption application
- FDA Form 1571 [write serial # 0000 where indicated on the form]
- FDA Form 1572
- Sponsor-Investigator CV
- Investigator Brochure [or package insert if IB is not available]

If you have any questions regarding the submitted information, please do not hesitate to contact me by telephone at [number] or by email at [email].

Thank you in advance for your attention and consideration of this request.

Sincerely,

Your name
Address
Contact information (email, telephone #)