Cover Letter Template - IND Exemption Determination Request

*(on your letterhead)*

[Date]

Center for Drug Evaluation and Research

Central Document Room

5901-B Ammendale Rd.

Beltsville, Md. 20705-1266

**Re:** IND Exemption Determination for proposed protocol: [name of protocol]

Dear FDA Representative:

The purpose of this submission is to request a written confirmation of my opinion that the above noted protocol meets the requirements for exemption from the Investigational New Drug regulations, 21 CFR 312. I believe the proposed research with [name of drug] meets the exemption requirements noted in 21 CRF 312.2, specifically:

1. The investigational drug is lawfully marketed in the United States;
2. The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use of the drug product;
3. The investigation is not intended to support a significant change in advertising to an existing lawfully marketed prescription drug product;
4. 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;
5. The investigation will be conducted in compliance with the requirements for institutional review set forth in FDA regulations 21 CFR 56, and requirements for informed consent as set forth in FDA regulations 21 CFR 50; and
6. The investigation will be conducted in compliance with FDA regulations 21 CFR 312.7: Promotion and charging for investigational drugs.

Please see attached documents for details about the study design and risk/benefit information.

I authorize Sheila Austin, Clinical Research Coordinator within the Clinical and Translational Science Institute here at the University of Florida, to communicate with the FDA on my behalf regarding all issues relating to this IND Exemption request.

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

Sincerely,

[Name, contact information]

Instructions: IND Exemption Determination Request

* Submission to FDA should include
  + IND Exemption Determination Request Cover Letter
  + Study protocol
  + Package insert
  + FDA Form 1571 (<https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083533.pdf>)
* Determine appropriate FDA division
* Check with division contact to see if ok to email IND Exemption Determination Request

(<https://www.fda.gov/downloads/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/overview/ucm166356.pdf>)

* If ok to email verify what supporting documentation is required. If not ok to email, fedex submission to the address on the cover letter