**Concurrence of Exemption Request**

***Instructions for Completing the Exemption Request***

In accordance with University policies, the Cover Letter and attached materials should be submitted to the FDA through IND and IDE Support (IIS) and include the IIS address as the correspondence address for the Principal Investigator. Please see below:

*Name: Sponsor-Investigator*

*Academic Department of Sponsor-Investigator*

University of Pittsburgh

Hieber Building, Suite 401

3500 Fifth Avenue

Pittsburgh, PA 15213

***Documents to accompany Request for Exemption:***

Complete and attach a Form FDA 1571

The Form FDA 1571 should also include the address of the IIS as the address of the Sponsor-Investigator of the IND application in Box 3 and Box 20. The only box you should check under item 11 of the Form FDA 1571 should be the “Other” box; wherein you should specify “Request for Concurrence of Exempt Status”.

* A cover letter requesting the requirement for the submission, and FDA acceptance, of a sponsor-investigator IND and IDE application
* A copy of the Clinical Protocol
* Publications to support exemption (if applicable)

**To submit a request for concurrence of exemption, please include the following items listed above as a single PDF file to** **IIS@pitt.edu** **and we will submit via the FDA Electronic Submissions Gateway.**

*Date*

Food and Drug Administration

Center for Drug Evaluation and Research

Central Document Room

5901-B Ammendale Road

Beltsville, MD 20705-1266

Dear Division Director:

It is felt that the attached, proposed clinical evaluation of the FDA-approved drug, *specify drug*, for an “off-label” indication meets the regulatory criteria (21 CFR Sec. 312.2(b)(1)) for an exemption from the requirement for the submission, and FDA acceptance, of a sponsor-investigator IND application. Specifically:

1. The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for the use of *specify drug*, nor intended to be used to support any other significant change in the labeling of the *specify drug*.
2. The investigation is not intended to support a significant change in the advertising for the *specify drug*.
3. 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 *specify drug*.

***Do not copy the template language written in the paragraph below in your cover letter; you will need to rewrite in your own words. The paragraph provided is to guide you in writing your exemption request.***

***It is advisable for the Investigator (i.e., principal investigator)to incorporate, under this criterion, a brief discussion as to why s/he feels that the proposed off-label use of the drug does not present a significant increase in risk (or decrease in acceptability of risk) to the study participants. This justification should specify, if applicable, that the drug will be administered at the same (or lower) dosage level and by the same route as specified in the current FDA-approved product labeling. If the “off-label” use involves a different patient population than currently specified in the FDA-approved product labeling, use of the drug in this “off-label” patient population should be supported by literature references or personal clinical experience, if available or applicable.***

1. The investigation is subject to prior approval by the University of Pittsburgh Institutional Review Board, which operates in compliance with the FDA regulations at 21 CFR Parts 50 and 56.
2. Neither the participants in this clinical investigation, nor their insurance providers, will be charged for the *specify drug*.

Respectfully,

*Principal Investigator’s name*

*Principal Investigator’s academic department*

University of Pittsburgh

3500 Fifth Avenue, Suite 401

Pittsburgh, PA 15213