**VCU Concurrence of Exemption Template Letter 1/7/2016**

**Concurrence of Exemption Template for an IND**

**Exemption from the requirement for the submission of an IND**

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

In accordance with University policies, the Cover Letter and attached materials should be submitted to the VCU Clinical Research Compliance Officer, Betsy Ripley, MD, MS as well as to the FDA.

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

Complete and attach a revised Form FDA 1571

The Form FDA 1571 should include 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 exemption from the requirement for the submission, and FDA acceptance, of a sponsor-investigator IND and IDE application

A copy of the Clinical Protocol

Submit in triplicate (original and two photocopies) to the FDA and one copy electronic copy to the CRCO via the REDCap survey.



*Date*

*Choose Appropriate Address*

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| --- | --- |
| **For a Drug:**  Food and Drug Administration Center for Drug Evaluation and Research Central Document Room 5901-B Ammendale Rd. Beltsville, Md. 20705-1266 | **For a Therapeutic Biological Product:**  Food and Drug Administration Center for Drug Evaluation and Research Therapeutic Biological Products Document Room 5901-B Ammendale Road Beltsville, MD 20705-1266 |

Dear Madam/Sir:

I have determined 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 Virginia Commonwealth University Institutional Review Board, which operates in compliance with the FDA regulations at 21 CFR Parts 50 and 56.
2. The investigation will not promote or commercialize specify drug. Neither the participants in this clinical investigation, nor their insurance providers, will be charged for the *specify drug*. (verify that this is a true statement)

I am requesting your concurrence with this determination of exemption from IND regulations.

Respectfully,

*Principal Investigator’s name*

*Principal Investigator’s academic department*

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