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

In accordance with University policies, the Cover Letter and attached materials should be submitted to the FDA through the Office for 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 303

3500 Fifth Avenue

Pittsburgh, PA 15213

 “Request for Concurrence of Exempt Status”

* A cover letter requesting the FDA’s concurrence of your belief that the use of said device in this clinical trial is exempt from the requirement to submit an IDE application. See sample cover letter on page 2 and 3.
* A copy of the Clinical Protocol (part of the eCopy)
* 1 eCopy (FDA) that **must include a signed cover letter**
* Any publications to support your case (part of the eCopy)

**Formatting Requirements for IDE Submission**

.     Please see the link for Formatting and Submission requirements for IDE submissions: <http://www.o3is.pitt.edu/ide/templates>

Following receipt, the IIS will promptly forward, to the FDA, all University-based IND or IDE applications and all related communications initiated by the IND or IDE Sponsor (i.e., unless an IIS review of the application is requested prior to its submission to the FDA).

Date

Food and Drug Administration

Center for Devices and Radiological Health

Document Mail Center

10903 New Hampshire Avenue

WO66-G609

Silver Spring, Maryland 20993

Request for concurrence of exempt from the requirement for an IDE application

Device Information:

Device name:

Specify the name of the device under investigation

Intended use of device:

Specify the intended use of the investigational device; i.e., as per the objective(s) of the planned clinical investigation.

Sponsor-Investigator Contact Information:

Sponsor-investigator name and degree(s)

Academic department or division affiliation

University of Pittsburgh

Hieber Building, Suite 303

3500 Fifth Avenue

Pittsburgh, PA 15213

Telephone number

FAX number

Manufacturer Information:

Name of device manufacturer

Address

Contact person

Telephone number

Dear Division Director:

It is felt that the attached, proposed clinical evaluation of the *name of device* for an “off-label” indication meets the regulatory criteria (21 CFR Sec. 812.3 for an exemption from the requirement for the submission, and FDA approval, of a sponsor-investigator IDE application.

We do not believe that the device in this clinical trial is a Significant risk device.

Specifically:

1. It is not intended as an implant and does not present a potential for serious risk to the health, safety, or welfare of a subject;
2. It is not purported or represented to be for a use in supporting or sustaining human life and does not present a potential for serious risk to the health, safety, or welfare of a subject;
3. It is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health; however, it does not present a potential for serious risk to the health, safety, or welfare of a subject; and,

*Add statements here to justify*

1. It does not otherwise present a potential for serious risk to the health, safety, or welfare of a subject.
2. 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.

Respectfully,

*Principal Investigator’s name*

*Principal Investigator’s academic department*

University of Pittsburgh

3500 Fifth Avenue, Suite 303

Pittsburgh, PA 15213