*Sponsor-Investigator’s Name*

*Academic Department of Investigator-Sponsor*

University of Pittsburgh

Hieber Building, Suite 303

3500 Fifth Avenue

Pittsburgh, PA 15213

Food and Drug Administration

Center for Devices and Radiological Health

Document Mail Center

10903 New Hampshire Avenue

WO66-G609

Silver Spring, MD 20993

*Date:*

Re: **IDE Unanticipated adverse device effects** - (*IDE XXXXX*)

Dear Division Director:

Enclosed please find an unanticipated adverse device effect for a serious, unexpected and possibly related adverse event. The following are enclosed for your review.

1. Narrative description of the event
2. DSMB Review of the event *(if applicable)*
3. IRB review of the event *(if available at the time this submission)*

Thank you for your review of this information. Please contact me at [insert phone number] or [insert e-mail address].

Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Sponsor-Investigator Printed Name of Sponsor-Investigator