*Sponsor-Investigator’s Name*

*Academic Department of Investigator-Sponsor*

University of Pittsburgh

Hieber Building, Suite 401

3500 Fifth Avenue

Pittsburgh, PA 15213

Food and Drug Administration

Center for Drug Evaluation and Research

Central Document Room

5901-B Ammendale Road

Beltsville, MD 20705-1266

*Date:*

Re: **IND Safety Report** - (*IND XXXXX*)

Dear Division Director:

Enclosed please find an IND Safety Report for a serious, unexpected, and possibly related adverse event. The following are enclosed for your review.

1. Completed Form 1571
2. Completed Form FDA 3500A
3. Narrative description of the event
4. DSMB Review of the event *(if applicable)*
5. IRB review of the event *(if available at the time this submission)*

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

Sincerely,

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

Signature of Sponsor-Investigator Printed Name of Sponsor-Investigator