**IND SAFETY REPORT COVER LETTER**

*<Date>*

*<Name>*

Chairperson

Institutional Review Board

*<Hospital>*

*<City, State, Zip code>*

**RE: *<Protocol Title>***

Dear Chairperson:

Please find the enclosed IND Safety Report #\_\_\_\_\_\_\_\_\_\_, submitted to us by *<sponsor>* for the above referenced study. The federal regulations require that sponsors notify investigators immediately of reportable adverse events that have occurred worldwide in connection with the test article. I am, in turn, notifying you of this event.

The information contained in this IND Safety Report (does/does not) require a change to our approved informed consent form (*enclose revised consent form when a change is being requested)*.

If you have any questions, please call.

Sincerely,

*<Signature>*

Copy: Study file