Month XX, 201X

Food and Drug Administration

Center for Drug Evaluation and Research

Division of Therapeutic Area

Central Document Room

5901-B Ammendale Rd.

Beltsville, MD 20705-1266

RE: **IND XX,XXX, Serial Number 000X**

DRUG Trade Name® (generic name)

**IND Safety Report**

Dear Dr. [Division Director]:

Per 21 CFR 312.32 we are submitting this IND Safety Report for the above referenced IND XX,XXX for use of DRUG in the treatment of disease or condition.

The report Protocol Number SAE Title describes the adverse event of event term requiring hospitalization and treatment with describe treatment that occurred in X patient(s). The patient was participating in the clinical Protocol Number and Name. The event was classified as serious, unexpected, and possibly related to the study agent, DRUG. The information, received on Date, is incorporated in the attached MedWatch Form (FDA 3500A). A copy of the IND Safety Report will be sent to all Protocol Number clinical trial investigators, to the Data Safety Monitoring Board, and to DRUG Manufacturer Name.

The event has been classified as possibly related to DRUG, as [*discuss reasoning and provide citations*]. The treatment allocation has been unblinded.

Event term is not listed among the adverse events in the Prescribing Information for DRUG, so the event has been classified as unexpected.

We searched our database for safety reports previously filed with the IND concerning a similar serious adverse experience. The search [did] [did not] identify any similar reports. *If similar reports were identified, the medical monitor provides analysis and discussion.*

If you have any questions regarding this submission, please contact myself or Name of Sub-Investigator or other contact at phone number or email address. Name of Sub-Investigator or other contact can act on my behalf on any issue relating to this IND.

Sincerely,

Sponsor Name, MD

Title

Institution

Phone number

Email address

cc: file

submitted in triplicate: *Form FDA 3500A*