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 Protocol Amendment: New Investigator(s)**

Dear Dr. [Division Director]:

Per 21 CFR 312.3 we are submitting this protocol amendment for the above-referenced IND XX,XXX for use of DRUG in the treatment of disease.

This submission notifies you ofa new investigator for Protocol Number and Name. Please find enclosed a copy of the *Form FDA 1572* for Jane K. Doe, MD, University of Virginia.

Curriculum Vitae and medical licensure for all Protocol Number investigators are on file at Name of Sponsor-Investigator’s institution.

If you have any questions regarding this submission, please contact myself or Name of Sub-Investigator, MD at phone number or email address. Dr. Name of Sub-Investigator 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 1571*

Protocol Number and Name