



Icahn
School of
Medicine at
Mount
Sinai

Conduits

The Institutes for Translational Sciences

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 Annual Report

Dear XX :

Per 21 CFR 312.33, we are submitting this annual report for the above-referenced IND XX,XXX for use of DRUG in the treatment of disease. This report summarizes the progress of our investigations during the time interval Date to Date.

If you have any questions regarding this submission, please contact me at 212-XXXX

Thank-you for incorporating these documents into the IND file.

Three copies (original and 2 copies) of the following documents are enclosed:

- FDA Form 1571
- IND Annual Report
- FDA Form 1572 [if there are key personnel changes]
- FDA Form 3674 [if one was never submitted, if there are updates to the protocols, if protocol has been closed, if there are results]

Sincerely,

Sponsor Name, MD

Title

Institution

Phone number

Email address