



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: **Initial Investigator New Drug Application
Serial Number 0000**

Dear Dr. [Division Director]:

We are submitting this initial application for a Sponsor-Investigator IND. We propose to evaluate [Drug generic name (Trade Name[®])] under this IND for safety and efficacy for the treatment of [disease or condition].

This submission also contains the initial study protocol [Study Number] Protocol v. 1.0] entitled, "[XXX]." Approximately [XX] patients will be enrolled in this study.

[A brief description of the protocol]

[If applicable, Pharmaceutical Company] has agreed to provide study drug [XXX] for the duration of the above referenced research study at no charge to the study participants or to their insurance providers. In addition, they have provided a letter authorizing the FDA to refer to all relevant data included in their IND #[XXX].

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.

Per 21 CFR 312.20, please find three copies (1 original and 2 photocopies) of

- Investigational New Drug Application for [title of the study].
- Form FDA 1571

Serial #0000

- Form FDA 1572
- Form FDA 3674

Sincerely,

[Sponsor Name], MD

Title

Institution

Phone number

Email address