



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

IND Transfer

Serial Number XXXX

Dear Dr. [Division Director]:

This letter is to inform you that the [name of the institution transferring the IND] has transferred/will be transferring ownership of the IND #[XXXXXXX] for [name of drug product] to the Mount Sinai School of Medicine as of [date]. Included in this submission is a letter from [the transferring institution] confirming the transfer of ownership, all rights to the application, and all sponsor obligations under 21 CFR 312. Per 21 CFR 314.72 I accept the commitment to agreements, promises, and conditions made by the former IND owner and contained in the IND application.

A complete copy of the IND records will be provided to me by [the transferring institution]. I agree to amend the IND within 60 days to cover any and all changes in the IND that result from the change in ownership, and to provide subsequent changes by amendments in accordance with FDA regulations.

All future correspondence for the above referenced IND should be sent to me. If you have any questions regarding this submission, please contact myself at [phone number] or [email address].

Please find three copies (1 original and 2 photocopies) of:

- Form FDA 1571
- Form FDA 1572
- Letter from the former IND owner

- CVs for the new investigators
- Letter of support from the study drug manufacturer
- IRB approval letter and approved ICF
- Updated protocol with references to previous owner deleted and replaced with new owner.

Sincerely,

[Sponsor Name], MD

Title

Institution

Phone number

Email address