



**Icahn
School of
Medicine at
Mount
Sinai**

Conduits
The Institutes for Translational Sciences

[Investigator/Sponsor – Name, Title]

Icahn School of Medicine at Mount Sinai
One Gustave L. Levy Place
New York, NY 10029

[date]

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Application for an Investigational Device Exemption (IDE) for an investigator-initiated trial entitled: [study title]

To Office of Device Evaluation:

We are pleased to submit this investigator-initiated IDE application for a [brief description – including for example]:

Trial type – [retrospective, prospective – single centered, multi-centered – non-randomized, randomized – pilot study, pivotal study, continuation study]

Study Goal

Patient diagnosis

Patient Inclusion Criteria

Study Strategy

Number of patients

Number of sites/centers

1. Certification

We certify that this is an original IDE application

2. Device Information

[manufacturer name and name of device]

3. Sponsor Contact Information

Icahn School of Medicine at Mount Sinai

One Gustave Levy Place
New York, NY 10029 USA
Contact: [name]
Phone:
Email:

4. Manufacturers Information

This is not a manufacturer submission.

5. Applicant Information

See above under sponsor

6. Pre-IDE meetings

None

7. Waiver requests

None

8. Referenced files

The device manufacturer, [manufacturer name] has provided a ***Rights of Reference Letter***, granting the FDA permission to reference applicable device files in its review of the current application.

We thank you for your consideration of this IDE application.

Sincerely,

[PI/Sponsor Name, Title]
Icahn School of Medicine at Mount Sinai