



Icahn
School of
Medicine at
Mount
Sinai

Conduits
The Institutes for Translational Sciences

201x IDE Annual Progress Report

IDE Gxxxxx

IDE Title (if title being used)

Name of Sponsor Investigator, MD
X Professor, Department
Icahn School of Medicine at Mount Sinai

Date of Submission

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1 GENERAL INFORMATION

If you chose to use Cover Sheet-Form FDA 3514, most of the information that should be presented in this section is already captured in the form.

If you chose not to use the form, please state your:

- 1) IDE number
- 2) Device name and indication(s) for use
- 3) Sponsor's name address, phone numbers and fax
- 4) Contact person

2 STUDY PROGRESS

(Data from the beginning of the study should not be reported, unless otherwise indicated)

2.1.1 Brief Summary of the Study Progress

2.1.2 Number of investigators/Investigational Sites

2.1.3 Number of Subject Enrolled

2.1.4 Number of Device Shipped

2.1.5 Brief Summary of the Results

2.1.6 Summary of Anticipated and Unanticipated Adverse Effects

2.1.7 Deviations from the Investigational Plan

Please, describe all the deviations from the investigational plan since the last progress report.

3 RISK ANALISYS

Summary of any new adverse information (since the last progress report) that may affect the risk analysis. This include preclinical data, animal studies, foreign data, clinical studies etc.

Also, please attach the reprints of any articles published from data collection from this study.

Present the new risk analysis if necessary, based on the new information that have been collected and on study progress

4 OTHER CHANGES

Summary of any changes in the manufacturing process and quality control, including the changes that has not be submitted as a supplemental application.

Summary of all changes in the investigational plan not required to be submitted in a supplemental application.

5 FUTURE PLANS

Progress towards product approval with projected data from the 510(k) or PMA submission.

If there are any plans to change the investigation, e.g., to expand the study size or indications, to discontinue portions of the investigation or to change manufacturing practices, please state in this section. (NOTE: Actual proposals for these changes should be made in a separate supplemental application where some of them would require prior approval).