Icahn School of Medicine at Mount Sinai

Conduits
The Institutes for Translational Sciences

20XX Annual Report

IND

[PROTOCOL TITLE]

Serial [000X]

[DATE]

Confidential

Table of Contents

1 STUDY INFORMATION

Title of Study:

Study Design:

Purpose:

Patient Population:

Study Status:

1.1 Enrollment Update

Total enrollment goal:
Total currently enrolled:
[Are there external sites? What are those enrollment numbers?]

Table 1.2-1 Subject Enrollment by Site

Site	Total Enrolled	First Enrollment Date	Last Enrollment Date
Mt. Sinai			
Total US sites			
Total non-US sites			
Total subjects			

Table 1.2-2 Subject Demographics

	Female		Male		Both Genders	
Ethnic Category	**N**	**%**	**N**	**%**	**Total**	**%**
Hispanic or Latino						
Not Hispanic or Latino						
Total						100%
Racial Category (single category per participant)	**N**	**%**	**N**	**%**	**Total**	**%**
White			-	-	-	-
Black or African American	-	-	-	-	-	-
Multiracial	-	-	-	-	-	-
Other	-	-	-	-	-	-

Total		**%**	**-**	**-**	**-**	-
Age at Enrollment Category	**N**	**%**	**N**	**%**	**Total**	**%**
18 – 21 years						
22 – 29 years						
30 – 39 years						
40 – 49 years						
50 – 59 years						
60 years and older						
Total						100%

Table 1.2-3 Status of Enrolled Participants

Total Enrollment	
Total Completed Treatment	
On Study	
On treatment	
Completed treatment	
Off treatment early	
Terminated Study Early	
Completed treatment	
Off treatment early	
Completed Protocol Follow−up	
Completed treatment	
Off treatment early	
Termination associated with an adverse experience	

1.2 Brief Description of Study Results

2 Summary Information

2.1 Adverse Events: Frequent and Serious

N=

Event	Grade (n)				Total
	1-2	3	4	5	

2.2 Summary of IND Safety Reports

A summary list of all IND safety reports submitted during the past year is as follows:

Protocol: PI:				
Report#	**Report (initial, f/u)**	**Event**	**ReportDate**	**Relationship to study drug**

2.3 Study Subject Deaths

2.4 Study Subject Dropouts Resulting from Adverse Drug Experiences

2.5 Understanding of the Drug's Action

2.6 List of Preclinical Studies

2.7 Summary of Manufacturing or Microbiological Changes

3 GENERAL INVESTIGATIONAL PLAN

3.1 Brief Description of the Overall Investigational Plan

3.1.1 Rationale

3.1.2 Indication(s) to be Studied

Primary Study Endpoints

Secondary Study Endpoints

3.1.3 Planned Clinical Trials

3.1.4 Estimated Number of Subjects

3.1.5 Anticipated Risks

4 Protocol Modifications

Changes that were made to the protocol during past year that were reported to FDA and approved by IRB, and changes not yet reported.

5 Foreign Marketing Developments

6 Outstanding business with respect to IND