



Icahn
School of
Medicine at
Mount
Sinai

Conduits
The Institutes for Translational Sciences

IND Exemption Application

ISMMS;ORS

Date

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3.0 INTRODUCTORY STATEMENT AND GENERAL INVESTIGATIONAL PLAN

3.1 Drug and Broad Objectives

3.2 Previous Human Experience

[CITE research papers]

3.3 Drug Withdrawal from Investigation or Marketing

3.4 Overall Investigational Plan

4.0 STATEMENT OF REQUEST FOR IND EXEMPTION BASED ON 21 CFR 312.2(B)

Please see attached Statement of Request for IND Exemption

5.0 INVESTIGATOR'S BROCHURE [OR PACKAGE INSERT]

Please see attached Investigator's Brochure [or package insert]

6.0 PROTOCOL

Attached please find the complete clinical protocol for this phase [phase of study] study. An FDA Form 1572, Statement of the Investigator as well as Curriculum vitae of the investigator is also included.

The research will be carried out at the Mount Sinai Medical Center, One Gustave L. Levy Place, New York, NY 10029. The Program for the Protection of Human Subjects of the Mount Sinai School of Medicine, 1 Gustave L. Levy Place, Box 1081, New York, NY 10029-6754, will be responsible for the initial and continuing review and approval of the study.

7.0 CHEMISTRY, MANUFACTURING, AND CONTROL INFORMATION

7.1 Drug substance

This drug has the following chemical structure: [chemical structure]

Study drug will be supplied by the manufacturer, [pharmaceutical company].

7.1 Drug product

[drug/agent name] will be provided to research subjects for the duration of their participation in this trial at no charge to them or their insurance providers.

The study drug/agent will be shipped to [address of pharmacy, if applicable: Department of Pharmacy, The Mount Sinai Medical Center, One Gustave L. Levy Place, Annenberg B-2, Room 206, NY, NY, 10029].

It will be stored [INSERT conditions under which it will be stored, ie freezer at temperature -80]

7.2 Placebo [INSERT description of placebo, who will supply, etc. If not applicable, say that]

7.3 Labeling

The labels for the study drug will include the following: "Store at", "Keep Out of Reach of Children", "For Clinical Trial Use Only", "Caution: New Drug: Limited by Federal (USA) Law to Investigational Use Only". In addition, a black box warning will read:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS
2. Etc. as appropriate

7.4 Environmental analysis requirements

We are claiming a categorical exclusion under 21 CFR 25.31 (e).

8.0 PHARMACOLOGY AND TOXICOLOGY INFORMATION

[Non-clinical animal studies]

9.0 PREVIOUS HUMAN EXPERIENCE WITH THE INVESTIGATIONAL DRUG

[clinical studies]

Pharmacokinetics

Mechanism of Action:

Absorption:

Distribution:

Metabolism and Excretion:

Safety Information:

[Summary of Safety Analysis]

Efficacy Information:

[Summary of Efficacy Analysis]

10. ADDITIONAL INFORMATION

[If applicable]: Pharmaceutical company's Certificate of Analysis

[If available]: Published articles to support your argument

11. REFERENCES

12. ATTACHMENTS