Icahn School of Medicine at Mount Sinai

*Conduits*
The Institutes for Translational Sciences

**Pre-IND Briefing Packet**
**[Compound X]**
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## 1. INTRODUCTION

***1.1.*** Clinical Background
*[*Describe clinical situation that exists and rationale for proposed therapy*]*

***1.2.*** Regulatory Background
[Provide any information related to approval of existing approved products that have bearing on this program*]*

***1.3.*** Pharmacological Class

***1.4.*** Mode of Action

***1.5.*** Proposed Clinical Indication

## 2. PHARMACOLOGY

***2.1.*** In Vivo Pharmacology
[Describe what effect the therapeutic has on the body]

***2.2.*** In Vitro Pharmacology
[If applicable]

***2.3.*** Pharmacokinetics
[This should include any data on the timing of effect or clearance of the product]

## 3. CLINICAL PLAN

***3.1.*** Summary

***3.2.*** Title of Study

***3.3.*** Investigators/Study Center

***3.4.*** Phase of Development

***3.5.*** Objectives

***3.6.*** Design of Study

***3.7.*** Diagnosis and Key Subject Selection Criteria (Exclusion and Inclusion)

***3.8.*** Treatments

***3.9.*** Dose Justification

***3.10.*** Main Parameters of Efficacy

***3.11.*** Main Parameters of Safety

## 4. TOXICOLOGY

***4.1.*** In Vivo Toxicology

[Summarize any literature on effects in animals. Safety data from published studies should be summarized under In Vivo Pharmacology]

## 5. CHEMISTRY, MANUFACTURING AND CONTROLS

***5.1.*** Drug Substance

[This is a description of what the investigational product will be (i.e. 7% saline). In addition, there should be a short description of how the drug substance is prepared including any excipients that are added for long-term stability. Information on the stability program should be provided here or reference the drug manufacturers Drug Master File].

***5.2.*** Drug Product

[Here you should describe how the product will be prepared, the form that will be given to subjects, and any information on the instructions that subjects will be given for administration.]

***5.3.*** Anticipated Process Changes for Manufacture of Investigational Product

[As an example, if you anticipate that a 7% solution will eventually be prepared and manufactured, this would be the place to describe that.]

## 6. DEVELOPMENT PLANS

***6.1.*** Summary of Proposed Development

[Here you can discuss proposals for publishing and developing consensus treatment regimens.]

## 7. FDA QUESTIONS

[This section is usually the most difficult because you need to carefully consider your questions and how you ask them.]

***7.1.*** Preclinical

[Here you are asking whether the existing animal and human safety data are sufficient to support initiating this clinical study. It is good to restate briefly the information that exists and ask whether FDA concurs that additional animal toxicology studies are not required].

***7.2.*** Clinical

[Any questions you have related to the protocol design,

inclusion/exclusion criteria, safety monitoring, etc. can be asked here.]

***7.3.*** Chemistry, Manufacturing, and Controls

[Here you will be briefly describing the drug product you intend to use and asking whether the plan as described about is acceptable. You may want to consider questions about stability. Does the manufacturer have long-term stability data that will support your study? Are you going to compound this in the pharmacies for the subjects? Need to clarify any issues about this process here.]

***7.4.*** Regulatory

[Here you would typically ask about issues related to referencing the manufacturers IND, anything related to the devices that you are using for outcome measures (particularly if they are not approved devices).

## 8. REFERENCES

[Include copies of all references used in the package and list them here.]