[Sponsor Name], MD

[Title, Department]

Icahn School of Medicine at Mount Sinai

One Gustave L. Levy Place, Box [XXXX]

New York, NY 10029

[Date]

Food and Drug Administration

Center for Drug Evaluation and Research

Division of [Therapeutic Area]

Central Document Room

5901-B Ammendale Rd.

Beltsville, MD 20705-1266

**Request for Pre-IND Meeting**

Dear Dr. [Division Director]:

In response to our conversation on [DATE], I am formally requesting a Type B meeting to discuss the proposed study [study title].

A proposed outline for discussion is provided below:

* **Product Name**
* **Chemical Name and Structure**
* **Proposed Indication(s)**
* **Type of Meeting Requested**Pre-IND, Type B meeting. We would prefer a teleconference as an alternative to a face-to-face meeting.
* **Statement of Purpose**To discuss [choose the possible following topics]
* the intended product formulation
* testing and data requirements
* scientific issues that may need to be resolved
* safety profile
* chemistry
* adequacy of manufacturing and control standards
* clinical trial design
* identification of potential clinical hold issues
* **Specific Objectives of Meeting**Obtain answers to submitted questions
* **Proposed Agenda**General Introductions
Brief Review of Protocol
Discussion of FDA Responses to Questions
* **Names of Participants from Name of Institution**
* **Proposed Date and Time for Teleconference**

We would ask that the meeting be held Example: at any time other than Monday or Thursday mornings (PST) as the members of our research group have administrative responsibilities during those times*.* We propose the following dates in 201X:

* **The approximate date on which supporting documentation will be sent to the review division**

Supporting documents will be submitted to FDA 30-days prior to the meeting date.

**PRELIMINARY LIST OF QUESTIONS FOR FDA**

**Regulatory:**

**Preclinical:**

**Chemistry, Manufacturing and Control:**

**Clinical Questions:**

If you require additional information, please contact me at the phone number or email address provided below.

Sincerely,

[Sponsor Name], MD

Title

Institution

Phone number

Email address