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