Institutional Review Board (IRB)
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Form-1 IND

This form is required to be submitted with a Form-1 Research Study Proposal when the protocol involves the study of a drug and no current IND has been filed with the FDA for this protocol.

Study Title:

Drug Name:

1. Is an IND required for this study?
   ○ NO ○ YES

   If YES, provide the IND# and stop here:

2. If the answer to Question #1 is "no," then answer the following:

   a. Is the investigation intended to be reported to the FDA as a well-controlled study in the support of a new indication for use?
      ○ NO ○ YES

   b. Is the investigation intended to be used to support any other significant change in the labeling of the drug?
      ○ NO ○ YES

   c. If the drug is undergoing investigation is lawfully marketed as a prescription drug product, is the investigation intended to support a significant change in the advertising for the product?
      ○ NO ○ YES

   d. Does the investigation involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product?
      ○ NO ○ YES

   e. If this investigation studies drugs in combination, has each drug in the combination been approved by the FDA for marketing in the United States?
      ○ NO ○ YES ○ N/A

Note: It is the responsibility of the investigator to determine whether an IND is required for a study. All of the answers to Questions #2(a) through (d) must be "no" and the answer to Question #2(e) must be "yes" or "n/a" for a study to be exempt from obtaining an IND. Consultation with the FDA may be needed at the discretion of the IRB, for example, if the IRB has questions or concerns regarding the investigator's determinations under Question #2 above. In the event that the IRB has such questions or concerns, the investigator may respond by a letter from the FDA stating that an IND for that study is not required.

Signature of Principal Investigator Date