**IND Final Report**

IND Number: Specify IND number

Date: Specify date of submission

A. Individual Clinical Study Information

*Include a brief summary of the status of each clinical study (i.e., being conducted under this IND) in progress and each study completed. The summary is required to include the following information for each study:*

1. Title of study:

*Provide, in addition to the title of the study, any applicable study identifier(s), such as a protocol number.*

2. Purpose of study:

3. Research subject population:

*Provide a brief statement identifying (i.e., by disease or condition, age range, and gender) the research subject population.*

4. Total number of subjects initially planned for inclusion in the study:

5. Total number of subjects entered into the study to date:

*Tabulate by age group, gender and race*

6. Number of subjects whose participation in the study was completed as planned:

7. Number of subjects who dropped out of the study early for any reason:

8. Brief description of final study results:

*If the study has been completed, provide a brief description of those results.*

B. Summary Investigational Drug Information

*Provide a summary of information (i.e., using the following format) about the investigational drug obtained during the previous year’s clinical and non-clinical investigations.*

1. Summary of the most frequent and most serious adverse experiences by body system:

*Information may be provided using a narrative or tabular format*

2. Summary of all IND Safety Reports submitted during the previous year:

*If no IND Safety Reports were submitted for the investigational drug during the previous year, state this.*

3. List of research subjects who died during participation in clinical studies of the investigational drug (i.e, inclusive of all clinical studies conducted under the IND)

*List all research subjects (by study title, subject initials and corresponding subject code number) who died while participating in the clinical study (studies) of the investigational drug; i.e., whether or not the death was thought to be related to the investigational drug. Indicate the cause of death for each listed research subject.*

*If no research subjects died while participating in clinical studies of the investigational drug, state this.*

4. List of research subjects whose participation in clinical studies of the investigational drug was terminated in association with an adverse experience (i.e., inclusive of all clinical studies conducted under the IND):

*List all subjects (by study title, subject initials and corresponding study code number) whose participation in the clinical study (studies) of the investigational drug was terminated (i.e., by the research subject or the investigator) in association with an adverse experience; i.e., whether or not the adverse experience was thought to be related to the investigational drug. For each listed subject, specify the nature of the adverse experience associated with study termination.*

*If no research subjects were terminated (i.e., in association with an adverse experience) from participation in a clinical study of the investigational drug, state this.*

5. Description of new information pertinent to understanding the actions of the investigational drug:

*Provide a brief description of newly obtained information pertinent to understanding the actions of the investigational drug; including, for example, information about the dose response of the investigational drug, its bioavailability, and effectiveness.*

*If no new information was obtained that is pertinent to understanding the actions of the investigational drug, state this.*

6. List of preclinical studies (including in-vitro and animal studies) completed or in progress during the past year, and a summary of major preclinical findings:

*If there were no preclinical studies completed or in progress during the past year, state this.*

7. Summary of any significant manufacturing or microbiological changes made during the past year:

*If there were no significant manufacturing or microbiological changes, state this*

C. Outstanding FDA Business

*If desired, include a log of any outstanding business with respect to the IND for which the investigator-sponsor requests or expects a reply or comment from, or a meeting with, the FDA.*