**Sponsor-Investigator**

**IND Annual Report Template**

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***Address for Drug Products regulated by CDER:***

Food and Drug Administration

Center for Drug Evaluation and Research

*Specify applicable CDER review division*

Central Document Room

5901-B Ammendale Road

Beltsville, MD 20705-1266

***Address for Biological Products regulated by CDER:***

Food and Drug Administration

Center for Drug Evaluation and Research

*Specify applicable CDER review division*

Therapeutic Biological Products Document Room

5901-B Ammendale Road

Beltsville, MD 20705-1266

***Address for Biological Products regulated by CBER:***

Food and Drug Administration

Center for Biologics Evaluation and Research

*Specify applicable CBER review division*

10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**Date:**

**Re:** **IND Annual Report – IND #**

To Whom It May Concern:

Enclosed please find three copies (the original and 2 photocopies) of a completed FDA [Form 1571](http://www.fda.gov/opacom/morechoices/fdaforms/1571es.pdf) and my Annual Report for IND Number       for the period between       and      .

Thank you for incorporating this Annual Report into the respective IND file.

Sincerely,

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**Signature of Sponsor- Investigator** **Printed Name of Sponsor- Investigator**

**Sponsor/Investigator IND Annual Report**

**IND Number:**

**IND Effective Date:**

**Annual Report Date:**

**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 during the previous year. The summary is required to include the following information for each study. For convenience, you may wish to complete a separate form for each study under this IND):*

* 1. **Title of study:**

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

* 1. **Purpose of study:**

* 1. **Research subject population:**

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

* 1. **Current status of study:**

*(Indicate whether the study is ongoing or completed.)*

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

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

*(Tabulate by age group, gender and race)*

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

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

* 1. **Brief description of final or interim study results:**

*(If the study has been completed, or if interim results are known, 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)*

1. **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. For studies using a cross-reference letter, add this sentence: "Additional IND safety reports are available under the original manufacturer’s IND.”).*

1. **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 during the previous year, state this.)*

1. **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 during the previous year, state this.)*

1. **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, during the past year, no new information was obtained that is pertinent to understanding the actions of the investigational drug, state this.)*

1. **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.)*

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

*(If there were no significant manufacturing or microbiological changes during the past year, state this.)*

* + 1. **General Investigational Plan**

*(Using the following format, describe the general investigational plan for the coming year [i.e., to replace the general investigational plan submitted the previous year].)*

1. **Rationale for the investigational drug or the research study (studies):**

1. **Indication(s) to be studied:**

1. **General approach to be followed in evaluating the investigational drug:**

1. **Types of clinical studies to be conducted in the following year:**

*(If plans have not been developed for the entire year, state this.)*

1. **Estimated number of patients or subjects who will be administered the investigational drug under these studies during the following year:**

1. **Anticipated significant risks of study participation:**

*(Describe any risks of particular severity or seriousness anticipated on the basis of preclinical toxicology studies or prior clinical studies of the investigational drug or related drugs. If no significant risks are anticipated, state this.)*

* + 1. **Investigator Brochure Revisions**

*(If the Investigator’s Brochure for the investigational drug has been revised during the past year, provide a description of the revisions and append a copy of the new brochure. If the Investigator’s Brochure for the investigational drug was not revised during the past year, state this. If there is no Investigator’s Brochure for the investigational drug [e.g., for an investigator-sponsored IND], state this and explain how each participating investigator is informed of new observations discovered by or reported to the sponsor on the drug, particularly with respect to adverse effects and safe use.*)

**E.****Phase 1 Protocol Modifications**

*(Describe any significant Phase 1 protocol modifications made during the past year that were not previously reported to the IND in the form of a Protocol Amendment. If there were no previously unreported, significant Phase I protocol modifications made during the past year, state this. If no Phase 1 protocols were ongoing during the past year, state this.)*

1. **Foreign Market Developments**

*(Summarize, if applicable, significant foreign marketing developments with the investigational drug during the past year, such as approval of marketing in any country or withdrawal or suspension from marketing in any country.*

*If there were no significant foreign developments with the investigational drug during the past year, state this. If there is no knowledge of foreign marketing of the investigational drug, state this.)*

1. **Outstanding FDA Business**

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