*Investigator-Sponsor’s Name*

*Academic Department of Investigator-Sponsor*

Address

Date:

Re: **IND Annual Report – IND #** *Specify IND number*

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 ; covering the time frame of MM/YY to MM/YY.

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

Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Investigator-Sponsor Printed Name of Investigator-Sponsor

Table of Contents

[1. STUDY INFORMATION 3](#_Toc472944984)

[1.1 Title of Study 3](#_Toc472944985)

[1.2 Enrollment Update 3](#_Toc472944986)

[1.3 Brief Description of Study Results 4](#_Toc472944987)

[2. SUMMARY INFORMATION 5](#_Toc472944988)

[2.1 Adverse Events: Frequent and Serious 5](#_Toc472944989)

[2.2 Summary of IND Safety Reports 5](#_Toc472944990)

[2.3 Study Subject Deaths 5](#_Toc472944991)

[2.4 Study Subject Dropouts due to Adverse Experience 5](#_Toc472944992)

[2.5 Understanding of the Drug’s Actions 5](#_Toc472944993)

[2.6 List of Preclinical Studies 6](#_Toc472944994)

[2.7 Summary of Manufacturing or Microbiological Changes 6](#_Toc472944995)

[3. GENERAL INVESTIGATIONAL PLAN 7](#_Toc472944996)

[3.1 Brief Description of the Overall Investigation Plan 7](#_Toc472944997)

[3.1.2 Indications to be Studied 7](#_Toc472944998)

[3.1.3 Estimated Number of Subjects 7](#_Toc472944999)

[3.1.4 Anticipated Risks 7](#_Toc472945000)

[4. INVESTIGATOR BROCHURE 8](#_Toc472945001)

[5. PROTOCOL MODIFICATIONS 9](#_Toc472945003)

[6. FOREIGN MARKETING DEVELOPMENTS 10](#_Toc472945005)

[7. OUTSTANDING BUSINESS WITH RESPECT TO IND 11](#_Toc472945007)

# 1. STUDY INFORMATION

*Brief summary of studies undergone in the previous year and their current status.*

## 1.1 Title of Study

*Include the following information…*

**Title of Study:** study title as appears on cover page

**Study Design:** case-controlled, randomized, systematic review etc.

**Purpose:** what the study is designed to achieve

**Patient Population:** age, condition, symptomatic/asymptomatic etc.

**Treatment Regimen:** dosage, times per day/week

**Study Status:** open, closed, currently enrolling, completed etc.

**Study Duration:** time period that of treatment and/or follow-ups

## 1.2 Enrollment Update

*Tabulation of subjects categorized by initial estimate, currently enrolled, current phase of study, gender, race, study site etc.*

*Below are sample example tables that may or may not be used based on your study’s needs. Tables may be altered to best fit your study.*

**Table 1.2-1**

|  |  |  |  |
| --- | --- | --- | --- |
| **Site** | **Total Enrolled** | **First Enrollment Date** | **Last Enrollment Date** |
| University of () |  |  |  |
| Other |  |  |  |
| Other |  |  |  |
| Total US Sites |  |  |  |
| Total non-US Sites |  |  |  |
| **Total Subjects** |  |  |  |

**Table 1.2-2 Subject Demographics**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Male** | | **Female** | | **Both** | |
| **Ethnicity** | **Number** | **%** | **Number** | **%** | **Number** | **%** |
| Hispanic or Latino |  |  |  |  |  |  |
| Not Hispanic or Latino |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |
| **Race** | **Number** | **%** | **Number** | **%** | **Number** | **%** |
| White |  |  |  |  |  |  |
| Black or African American |  |  |  |  |  |  |
| Multiracial |  |  |  |  |  |  |
| Other |  |  |  |  |  |  |
| Not reported/Unknown |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |

**Table 1.2-3 Status of Enrolled Participants**

|  |  |
| --- | --- |
|  | **Number** |
| Total Enrolled |  |
| Completed Treatment |  |
| Ongoing Study |  |
| On treatment |  |
| Completed treatment |  |
| Off treatment early |  |
| Terminated Study Early |  |
| Completed treatment |  |
| Off treatment early |  |
| Completed Follow-Up |  |
| Completed Treatment |  |
| Off treatment early |  |
| Terminated due to Adverse Experience |  |

## 1.3 Brief Description of Study Results

*A brief description of the study if it has been completed. If incomplete/ongoing, describe the progress of the research, including any preliminary observations and any information about study results or trends.*

# 2. SUMMARY INFORMATION

*Current information available from the study in its present state.*

## 2.1 Adverse Events: Frequent and Serious

*Describe the most frequent and most serious adverse events that have occurred during the trial. Events may be tabulated or described, including the prevalence (%) of the adverse event by body system. Below is a sample table that may be used or altered to best fit your study.*

|  |  |  |
| --- | --- | --- |
| **Body System** | **Number of Instances** | **Prevalence** |
|  | X | % |
|  | X | % |
|  | X | % |

## 2.2 Summary of IND Safety Reports

*Summarize all IND Safety Reports that pertain to the study during the reporting period.*

## 2.3 Study Subject Deaths

*List any subjects that have died during the study, including their cause of death and if it is connected to the study.*

## 2.4 Study Subject Dropouts due to Adverse Experience

*Provide a list of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be drug related.*

## 2.5 Understanding of the Drug’s Actions

*Brief describe what, if anything, was obtained that is pertinent to an understanding of the drug's actions, including, for example, information about dose response, information from controlled trials, and information about bioavailability.*

*If not applicable, state here.*

## 2.6 List of Preclinical Studies

*Provide a list of the preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major preclinical findings.*

*If not applicable, state here.*

## 2.7 Summary of Manufacturing or Microbiological Changes

*Summarize any significant manufacturing or microbiological changes made during the past year.*

*If not applicable, state here.*

## 

# 3. GENERAL INVESTIGATIONAL PLAN

*Describe the general investigational plan and include any amendments or changes to the plan that has taken place in the last year.*

## 3.1 Brief Description of the Overall Investigation Plan

*Brief description of investigational plan that includes 3.1.1-5.*

**3.1.1 Rationale**

### 3.1.2 Indications to be Studied

### 3.1.3 Estimated Number of Subjects

### 3.1.4 Anticipated Risks

# 4. INVESTIGATOR BROCHURE

# *Describe any changes to the investigator brochure and provide a copy of the new investigator brochure*

*Alternatively, refer to Letter of Cross-Reference Authorization here, if applicable.*

# 5. PROTOCOL MODIFICATIONS

# *Describe any significant Phase 1 protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment.*

*If not applicable, state here.*

# 6. FOREIGN MARKETING DEVELOPMENTS

# *Summarize any major foreign marketing developments during the reporting period, including both acceptance and withdrawal of marketing in any foreign country*

*If not applicable, state here.*

# 7. OUTSTANDING BUSINESS WITH RESPECT TO IND

# *Reporting of any outstanding business that pertains to the IND to which the sponsor requests a reply, comment, or meeting.*

*If not applicable, state here.*

**General Help:**

*Remember to delete all instructional text (italicized).*

*Charts and tables are inserted for guidance, and do not represent the only way in which information may be presented.*

*Make sure to restructure the Table of Contents based on your report, adding in page numbers that correspond with the different sections.*

*Sections on the cover page and in the headers on each page that are within brackets ([]) will autofill.*