Washington University in St. Louis
SCHOOL OF MEDICINE

IND Annual Report Template

A Sponsor or Sponsor-Investigator is required to submit a report on the progress of the investigation within 60 days of the anniversary date that the IND went into effect.

The following template provides guidance for preparing this annual report. FDA requires a response to every question outlined at 21 CFR 312.33, which are outlined below. For more information, these regulations can be reviewed at:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.33

Note:

- *The regulations do not specify a format for these responses, and you may modify or delete the tables below as necessary.*
- *This form may be used to report on multiple studies investigating one IND, but each question Section A will need to be answered individually for each study.*
- *Do not skip any questions. If a question is not applicable for any reason, describe why it is not applicable.*

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Washington University in St. Louis
School of Medicine

Address for Drug/Biologic 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 CBER:
Food and Drug Administration
Center for Biologics Evaluation and Research
Specify applicable CBER review division
HFM-99, Room 200N
1401 Rockville Pike
Rockville, MD 20852-1448

Date:

IND Annual Report – IND # XXXXXX

Enclosed please find three copies (the original and 2 photocopies) of a completed FDA Form 1571 and my Annual Report for IND # XXXXXX, which was approved on mm/dd/yyyy. This report refers to the conduct of the investigation from MM/YY to MM/YY.

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

Sincerely,

_____ _____

Signature of Sponsor-Investigator Printed Name of Sponsor-Investigator

A. Individual Study Information

1. **Title of Study:** (*Include the protocol number or other identifiers if applicable)*

2. **Purpose of Study:**

3. **Patient Population:** *(Briefly describe the disease, condition, age range, and gender of the research subject population.)*

4. **Study Status:** *(Open, Enrolling, Closed to Enrollment, Completed, etc…)*

5. **Total Number of Subjects Initially Planned for Enrollment:**

6. **Total Number of Subject Enrolled To Date:** *(For multi-site studies, use the below table and add/delete rows as necessary.)*

Site	Total Enrolled	First Enrollment Date	Last Enrollment Date
Washington University in St. Louis			
Site 1			
Site 2			
Site 3			
Site 4:			
All Sites			

7. **Total Number of Subjects Enrolled Tabulated by Demographics:** *(For studies with a fairly uniform patient population, the below tables may not be necessary.)*

	Female		Male		Both Genders	
Race/Ethnicity	**N**	**%**	**N**	**%**	**Total**	**%**
White						
Black or African American						
Hispanic or Latino						
Other (Specify)						
Total						

Age at Enrollment	N	%	N	%	Total	%
18 - 21 years						
22 - 29 years						
30 - 39 years						
40 - 49 years						
50 - 59 years						
60 - 69 years						
Total						

8. **Number of Subjects Who Completed the Study As Planned:**

9. **Number of Subjects Who Dropped Out of the Study For Any Reason:**

10. **Brief Summary of Final or Interim Study Results:** *(If a study has closed or an interim analysis has been completed, summarize any findings.)*

B. Summary of Investigational Drug Findings (Information obtained during the previous year's clinical & nonclinical investigations)

1. **Summary showing the most frequent and most serious adverse experiences by body system:** *(This summary can be in narrative or tabular form.)*

2. **Summary of all IND Safety Reports submitted in previous year:**

3. **List of subjects who have died during participation in the study:** *(Specify the cause of death for each subject, even if not study related.)*

4. **List of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be investigational drug related:** *(Specify nature of adverse event for each subject.)*

5. **Description of any new information that is pertinent to understanding the action of the investigational drug:** *(Include information about dose response, bioavailability, or relevant measures of effectiveness. Include any information identified in relevant clinical trials.)*

6. **List of preclinical studies related to the investigational drug completed or in progress during the previous year and a summary of any major preclinical findings:** *(Include any animal or in-vitro studies.)*

7. **Summary of any significant manufacturing or microbiological changes to the investigational drug made during the previous year:**

C. General Investigational Plan

1. **Rationale for the study drug or the research study:**

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

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

4. **Kinds of clinical trials to be conducted in the coming year:**

5. **Estimated number of patients to be given the drug in all studies using the investigational drug in the coming year:**

6. **Significant risks of anticipated on the basis of currently available data:**

D. Revisions to the Investigational Brochure

(Include a description of any revisions to the IB and include a copy of the most recent brochure. If you do not have an IB for the investigational drug, state this in response.)

E. Revisions to the Phase 1 Protocol

(Include a description of any significant Phase 1 protocol modifications made during the previous year that have not already been reported to the FDA in an protocol amendment to the IND.

F. Foreign Marketing Developments

(Include a summary of any significant developments in foreign marketing for the investigational drug, such as approvals, suspensions, or withdrawals in any country.)

G. Outstanding Regulatory Issues

(Include a summary of any outstanding issues with respect to the IND, such as an expected response or comment from the FDA that has not yet been received.)