**University of Arizona**

**IND FINAL REPORT TEMPLATE**

1. **Instructions to User:**
	1. **Sections and text that are in regular font and that have not been highlighted in grey** represent standard language. In general, these sections should be present in your final report and the language should not be changed. However, every IND is unique, and changes to standard sections and language may be necessary to meet the needs of your report. Please review the language carefully to make sure that it is accurate for your study.
	2. Sections that are highlighted in grey represent sections or information to be **customized as applicable** to your study.
	3. Highlighted text in regular font is generally considered to be standard if that section (or procedure) applies to your study and **may be left unchanged or modified as needed**. Remove highlighting after you have customized the text or have verified that it is appropriate as-is for your study’s final report.
	4. *Highlighted and italicized text represents instructions and/or example text.* ***All require complete customization*** *for your study.* Remove highlighting and restore the font to regular *(from italics)* after you have customized the text
	5. As you customize each section of the protocol, **remove the highlighting and restore the font to regular (from italics)** to denote that section as having been completed.
	6. Double-click inside the header and footer, to customize IND number, Sponsor name, Date.
	7. Table of Contents (TOC) and (optional) List of Table & Figures:
	8. To manually update the TOC or List of Tables & Figures, select/highlight the entries, then press Ctrl/Shift/F9 (Windows) or Cmd/Shift/F9 (Mac) to unlink the field code.
	9. For advanced Word users: to auto-update the TOC, be sure all new or revised text has been formatted with appropriate styles (headings and normal text).
		1. To automatically **Refresh/update** the TOC
			1. Select/highlight the entries.
			2. (Windows) from the References tab, click “Update Table”, or (Mac) from the Document Elements tab, choose Table-of-Contents ✓.
			3. Select the option to “Update entire table” if the headings have changed; otherwise select “Update page numbers only.”
			4. To refresh the List of Tables and Figures, select/highlight the entries.
				1. In MS Word 2010, from the “References” tab, select “Insert List of Figures”.
				2. In Word for Mac 2011, follow the instructions for TOC above. The program will recognize the selection as a list of Tables/Figures.
	10. **Review** the document to ensure that all highlighting and italics have been removed, and that headings and the table of contents are correctly formatted.
	11. **Delete** this instructional page and update the Table of Contents again (page numbers only).

**IND *XX,XXX***

**FINAL REPORT**

***DRUG TRADE NAME (GENERIC NAME, NAME OF ANTIBODY)***

**Reporting Period Covered in this Report: *MM DD, YY to MM DD, YY***

Date of Final Report: *MM DD, YY*

*Sponsor Name*

*Institution Name*

*Mailing Address*

*Mailing Address*

*Telephone*

**CONFIDENTIAL**

**TABLE OF CONTENTS**

**1** **STUDY INFORMATION**

1.1 Study Summary

1.2 Brief Description of Study Results

**2** **SUMMARY INFORMATION**

2.1 Adverse Events: Frequent and Serious

*2.1.1* *Adverse Events:*

2.2 Serious Adverse Events:

2.3 Summary of IND Safety Reports

2.4 Study Subject Deaths

2.5 Study Subject Dropouts Resulting from Adverse Drug Experiences

2.5 Understanding of the Drug’s Action

2.6 List of Preclinical Studies

2.7 Summary of Manufacturing or Microbiological Changes

**3** **GENERAL INVESTIGATIONAL PLAN**

3.1 Brief Description of the Overall Investigational Plan

*3.1.1* *Rationale*

*3.1.2* *Indication(s) to be Studied*

*3.1.3* *Planned Clinical Trials*

*3.1.4* *Estimated Number of Subjects*

*3.1.5* *Anticipated Risks*

**4** **INVESTIGATOR BROCHURE**

**5** **PROTOCOL MODIFICATIONS**

**6** **FOREIGN MARKETING DEVELOPMENTS**

**7** **OUTSTANDING BUSINESS WITH RESPECT TO IND**

**8** **APPENDICES**

# TABLES AND FIGURES

Table 1. Clinical Studies Conducted with *DRUG*

Table 2. Subject Enrollment by Site

Table 3. Subject Demographics

Table 4. Status of Enrolled Participants

Table 5. Adverse events by time of dose administration

Table 6. Summary of Serious Adverse Events (other than death).

Table 7. Summary of Deaths

Table 8. Summary of Drop-Outs

# STUDY INFORMATION

The original *IND XX,XXX* was submitted to the FDA on *Date*. This final report summarizes data for all studies conducted under the IND from *Date to Date*. Table 1 presents an overview of all studies, completed and ongoing.

*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:*

*Note-use table below for multiple studies under one IND. If only one study under IND, then list that and no table is needed.*

**Table 1. Clinical Studies Conducted with *DRUG***

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol Number** | **Objective** | **Study Status** | **Final Report Location** |
| *AB0001* | *To test the safety and efficacy of oral DRUG in children and adults with disease who have condition* | *Complete* | *Serial No. 009* |
| *AB0002* | *To characterize the long-term use, safety, and efficacy of DRUG in children and adults with disease or condition in an observational study of AB0001 participants* | *Complete* | *Serial No. 0018* |
| *XXXXXX* | *To investigate the safety and efficacy of oral DRUG in children and adolescents with disease or condition X-Y years of age* | *Complete* | *N/A* |

## Study Summary

**Title of Study:** *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:*

*XXXXXX: Multi-center, Multi-national, Randomized, Placebo-Controlled Trial of DRUG in Subjects with Disease or Condition X-Y Years Old*

**Study Design:** *Multicenter double-blind randomized clinical trial*

**Purpose:** *To investigate the safety and efficacy of oral DRUG in patient population with disease who have condition*

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

*Male and female subjects X years and ≤ Y years of age with a diagnosis of disease*

**Treatment Regimen:** *Trade Name® (generic name) 250mg of DRUG orally three times a day*

**Study Duration:** *Total duration of the treatment period for each subject is XX weeks*

**Study Status:** *Enrollment: Completed in XX/XXXX*

*Completion of data collection and analysis: XX/XXXX*

**Study Sites:** *If applicable please use table below:*

**Table 2. Subject Enrollment by Site**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Institution**  | **Contract** **Finalized** | **Enrollment** **Start date** | **Number****Enrolled** | **Number****Per month** |
| ***UA - Tucson*** |  | *12/2/13* | *9* | *0.81* |
| ***Institution*** | *Nov 2013* | *12/30/013* | *9* | *0.90* |

**Table 3. Subject Demographics**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Female** | **Male** | **Both Genders** |
| **Ethnic Category**  | **N** | **%** | **N** | **%** | **Total** | **%** |
| Hispanic or Latino  |  |  |  |  |  |  |
| Not Hispanic or Latino  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |
| **Racial Category (single category per participant)**  | **N** | **%** | **N** | **%** | **Total** | **%** |
| White  |  |  |  |  |  |  |
| Black or African American  |  |  |  |  |  |  |
| Asian |  |  |  |  |  |  |
| Other  |  |  |  |  |  |  |
| **Total**  |  |  |  |  |  |  |
| **Age at Enrollment Category**  | **N** | **%** | **N** | **%** | **Total** | **%** |
| 18 − 21 years  |  |  |  |  |  |  |
| 22 − 29 years  |  |  |  |  |  |  |
| 30 − 39 years  |  |  |  |  |  |  |
| 40 − 49 years  |  |  |  |  |  |  |
| 50 − 59 years  |  |  |  |  |  |  |
| **Total**  |  |  |  |  |  |  |

**Table 4. Status of Enrolled Participants**

|  |  |
| --- | --- |
| Total Enrollment  |  |
| Total Completed Treatment  |  |
| On Study |  |
|  On treatment  |  |
|  Completed treatment  |  |
|  Off treatment early  |  |
| Terminated Study Early  |  |
|  Completed treatment  |  |
|  Off treatment early  |  |
| Completed Protocol Follow−up  |  |
|  Completed *12 month* follow up |  |
|  Lost to follow up  |  |
| Termination associated with an adverse experience  |  |

## Brief Description of Study Results

*Provide a brief description of those results as in the following examples:*

*We completed enrollment of all xx subjects on (date).*

*A comprehensive DSMB review was conducted after the first 17 subjects were enrolled; no concerns were raised, and the DSMB recommended that we continue the study.*

*The DSMB placed the study on temporary hold for 2 days, after a third subject was reported to have a deep venous thrombosis. Of note, one of these 3 subjects was subsequently found to have been erroneously diagnosed with a thrombosis. The DSMB performed an unblinded review, and then recommended that enrollment resume.*

*A second comprehensive DSMB report was submitted on March 31, 2015.*

*Due to a family crisis, our biostatistician had to reduce her workload, and subsequently had to resign from the study. We therefore obtained approval to work with a new biostatistical group.*

*Our results thus far are summarized in the following abstracts that have been accepted for presentation at the xxxxx Society meeting, in xx/xxxx.*

# Summary Information

## Adverse Events: Frequent and Serious

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

### Adverse Events:

**Adverse events by time of dose administration-** *Information may be provided using a narrative or tabular format*

**Table 5. Adverse events by time of dose administration**

|  |  |  |  |
| --- | --- | --- | --- |
| **Event** | **Pre-Dose 1** | **Post-Dose 1** | **Any Time** |
| Cardiac arrhythmia |  |  |  |
| Disseminated intravascular coagulation |  |  |  |
| Hypertension |  |  |  |
| Hypotension |  |  |  |
| Elevated liver enzyme (ALT >100 IU/L) |  |  |  |
| Meningitis |  |  |  |
| Persistent pulmonary hypertension requiring NO and FiO2 > 50% |  |  |  |
| Platelet count < 100000 per microL |  |  |  |
| Renal dysfunction (serum creatinine >1.5) |  |  |  |
| Sepsis |  |  |  |
| Sinovenous thrombosis (SVT) |  |  |  |
| Polycythemia |  |  |  |
| Cardiopulmonary decompensation |  |  |  |
| Other |  |  |  |
| Total adverse events (A) |  |  |  |
| Total patients with adverse events (n) |  |  |  |
| Total patients (N) |  |  |  |
| Rate of adverse events (A/N) |  |  |  |
| % of patients with Adverse events (n/N x 100) |  |  |  |

## Serious Adverse Events:

*There were 11 total SAEs that occurred in 9 subjects:*

*SAE N*

*Deaths 7*

*Renal vein thrombosis 1*

*Multiple venous thromboses 1 (brachiocephalic veins and portal vein thromboses)*

*Sinovenous thrombosis 1 (Later found to be erroneous diagnosis)*

*Cardiopulmonary arrest 1 (within 2 hours of study drug administration)*

*The DSMB placed the study on temporary hold after 3 patients developed venous thromboses. The DSMB reviewed these cases in an unblinded fashion, receiving treatment allocation data from the biostatistician. The DSMB also received information from…….After this careful DSMB review, we were allowed to resume study enrollment.*

**Table 6. Summary of Serious Adverse Events (other than death).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SID** | **Site** | **SAE Age** | **Category** | **Description** | **Related to study drug** | **Outcome** | **Ongoing** |
| *1015* | *Institution* | *4 days* | *Venous* *thrombosis* | ***Sinovenous thrombosis*** *initially suspected by site neuroradiologist. On subsequent review, the study neuroradiologist did not find MRI evidence of SVT. Doppler studies revealed normal flow.* | *Possibly* | *Resolved* | *No* |
| *2007* | *Institution* | *1 day* | *Cardiopulm**arrest* | *A****pnea and bradycardia requiring PPV and cardiac compressions****, within 2 hours of study drug. Patient deeply sedated (phenobarbital and morphine drip), and went on to become intubated 8 hours after this event.*  | *Unlikely* | *Resolved* | *No* |
| *2007* | *Institution* | *6 days* | *Venous thrombosis* | *R****enal vein thrombosis*** *seen via ……...* | *Possibly*  | *Resolved* | *No* |

## Summary of IND Safety Reports

*During this reporting period, no serious adverse experiences resulted in the submission of an IND Safety Report in the XXXXXX study.*

**OR:**

*During this reporting period, a total of # SAEs resulted in the submission of an IND Safety Report. # follow-up Safety Reports (Serial No. ###;mm/dd/yy) was/were also submitted.*

## Study Subject Deaths

*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.*

*No patient deaths were reported for the XXXXXX study during this reporting period.*

**OR:**

*A summary of patient deaths for the XXXXXX study during this reporting period is presented in Table X.*

**Table 7. Summary of Deaths**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **ID** | **Site** | **Severity**  | **Withdrew****Support** | **Brief Summary** | **Related to** **study drug** |
| *2003* | *Institution* | *Moderate* | *Yes* | *HIE, presumed sepsis, meconium aspiration and PPHN, DIC and pulmonary hemorrhage. Decision to withdraw support due to critical medical condition.* | *Unrelated* |
| *2004* | *Institution* | *Moderate* | *Yes* | *HIE, placental abruption, meconium aspiration and PPHN. Course complicated by severe anemia, DIC, pulmonary hemorrhage. Decision to withdraw support due to critical medical condition.* | *Unrelated* |
| *4005* | *Institution* | *Severe* | *Yes* | *HIE, EEG with severely attenuated background, MRI showed diffuse brain injury involving both hemispheres and brainstem. Multi-organ failure. Decision to withdraw support due to critical condition and poor neurologic prognosis.*  | *Unrelated* |

## Study Subject Dropouts Resulting from Adverse Drug Experiences

*No subjects were discontinued prematurely from the XXXXXX study due to an adverse event during this reporting period.*

**OR:**

*A summary of subjects who were discontinued prematurely from the XXXXXX study due to an adverse event is presented in Table X.*

**Table 8. Summary of Drop-Outs**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Patient ID** | **Dose Level/Regimen** | **Date of Randomization** | **Date of First Dose** | **Date of Discontinuation** | **Cause of Discontinuation** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

## Understanding of the Drug’s Action

No new information regarding the action of *DRUG* *name* has been obtained during this reporting period.

**OR (if applicable):**

*Sponsor-Investigator is authorized by DRUG manufacturer to reference the following NDAs and IND for information related to the mechanism of action of the drug products referred to in IND XX,XXX:*

*NDA YY-YYY, DRUG Trade Name® (generic name) 250 mg Tablets*

*IND ZZ,ZZZ – Antibiotic Oral*

## List of Preclinical Studies

No preclinical studies were completed or in progress with *DRUG name* under the IND during this reporting period.

**OR (if applicable):**

*[Number] preclinical studies were completed/are ongoing with DRUG name during this reporting period. They are summarized in Table X.*

## Summary of Manufacturing or Microbiological Changes

*No Changes OR Sponsor-Investigator is authorized by DRUG manufacturer to reference the following NDAs and IND for information related to the manufacturing of the drug products referred to in IND XX,XXX:*

*NDA YY-YYY, DRUG Trade Name® (generic name) 250 mg Tablets*

*IND ZZ,ZZZ – Antibiotic Oral*

# General Investigational Plan

## Brief Description of the Overall Investigational Plan

*Enrollment was closed at all X active study sites as of Date. All study visits were completed on Date. We plan to lock the database by Date “or” The database was locked on xx/xxxx. Our goal is to complete the manuscript by xx/xxxx.*

### Rationale

The rationale for studying *(study description here)* is:

1. *Pre-clinical studies of hypoxic-ischemic brain injury suggest that (drug) is an effective neuroprotective agent that is safe, and improves histologic and neurologic outcomes.*
2. *There are 2 clinical trials that have been published suggesting ………. Both studies were small and performed outside of the United States.*
3. *xxxxx is a safe drug that is used routinely to treat xxxxxxx*

### Indication(s) to be Studied

*Description here*

### Planned Clinical Trials

No additional clinical trials are planned under this IND

### Estimated Number of Subjects

We have enrolled a total of *xxx* subjects with *xxxxxx* in this *phase II* trial.

### Anticipated Risks

*NONE*

# Investigator Brochure

*No changes (see appendix for Package Insert)*

***OR***

*The prescribing information for DRUG name is serving the function of an Investigator Brochure for the XXXXXX study. The prescribing information was most recently revised in Month 201X*

# Protocol Modifications

There have been no modifications to the protocol version that was approved by the FDA on date

***OR***

*The original IND xxx,xxx was approved on xx/xx/xxxx, to perform a phase x study. Following successful completion of the phase I trial, we submitted FDA amendments to perform the current phase II study called “xxxxxx” x. The xxxxx study protocol was approved by the FDA in August 2013, and we began patient enrollment in December 2013. On January 23, 2014, we informed the FDA that patient enrollment had begun and that we would continue to submit our annual IND report each year on August 1st.*

# Foreign Marketing Developments

*Not Applicable.*

# Outstanding Business with Respect to IND

*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.*

**OR**

There is no outstanding business for which the FDA expects a reply, comment, or meeting.

# Appendices