**Drug Use Form**

|  |
| --- |
| Research Study Title …………………………………………….. |
| PI …………………………………………….. |
| Phone …………………………………………….. |
|  |
| Address ………………………….…………………….. |

*[Please respond to the following statements]*

1. Identify the drug(s) or biological products:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Trade name of Drug or Biological Product | Generic or Biological name | Manufacturer of the product | Recommended storage temperature |
| 1 | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 2 |  |  |  |  |

If the Drug or Biological Product are to be stored at refrigerator or freezer temperature

*[Please respond to the following questions(1-3)]*

1. Is there a back-up power source in the event of power outage?

[ ] Yes [ ] No

1. Is the refrigerator or freezer alarmed to alert staff in the event of power outage?

[ ] Yes [ ] No

1. Confirm Drug or Biological Product will be stored in a dedicated medication storage refrigerator or freezer:

[ ] Yes [ ] No

1. Is the Drug or biological product currently approved by SFDA?

[ ] Yes [ ] No

-If ‘yes’, please provide the package insert

 Click or tap here to enter text.

-If ‘No’, please provide the following:

Chemical Structure Click or tap here to enter text.

Pharmacology Click or tap here to enter text.

Form of Administration Click or tap here to enter text.

Maximum Tolerated Dose in Humans Click or tap here to enter text.

Toxicity Observed Click or tap here to enter text.

Pharmacokinetics Data Click or tap here to enter text.

Procedures for minimizing adverse events in humans Click or tap here to enter text.

1. If the Drug or Biological Product used in this research are not dispensed by a pharmacist, they can only be dispensed by a physician, or a personnel in agreement with the physician. Examples of this personnel are: physician’s assistant and nurse. Only persons with legal authority to dispense the Drug or Biological Product, and those under their direct supervision, can have access to the Drug or Biological Product storage area.

List the person(s) and their degree, responsible for dispensing the drug or biological product to the project’s subjects, and having access to the storage area.

|  |  |  |
| --- | --- | --- |
| No. | Person | Degree |
| 1 | Click or tap here to enter text. | Click or tap here to enter text. |
| 2 |  |  |

1. Emergency unblinding:

*[Please respond to the following questions(1-3)]*

1. Please explain how the contents of a drug container will be identified in case of emergency. The names and contact information of the persons who will be responsible for the unblinding, and who are expected to be available 24 hours a day/7 days a week, in a timely manner should be listed.

Click or tap here to enter text.

1. Please confirm that the following information are on the labeling of the medication container dispensed to the study subjects.

|  |  |
| --- | --- |
| 1. Name, address, and telephone number of clinic of physician’s office
 | [ ] Yes [ ] No |
| 1. Prescribing physician’s name
 | [ ] Yes [ ] No |
| 1. Subject’s name or subject number
 | [ ] Yes [ ] No |
| 1. Date of dispensing
 | [ ] Yes [ ] No |
| 1. Direction for use
 | [ ] Yes [ ] No |
| 1. Drug name, protocol name or number
 | [ ] Yes [ ] No |
| 1. Manufacturer’s name
 | [ ] Yes [ ] No |

1. If the study is registered as Clinical Trial, please indicate the Clinical Trial Identifier:

Click or tap here to enter text.