Supplementary Information Sheet for Phase 1 Study

A phase I clinical trial means a clinical trial which fulfils any of the following criteria:

(a) A clinical trial which is designated a phase 1 clinical trial on its protocol.
(b) A clinical trial on an Investigational Medicinal Product (IMP) which is tested in humans for the first time.
(c) A clinical trial aiming primarily at assessing the human pharmacology and/or safety of an IMP and does not have efficacy as a primary objective.
(d) A clinical trial which is reasonably deemed by the relevant research ethics committee (REC) a phase 1 clinical trial or equivalent to a phase 1 clinical trial from the perspective of clinical risk.

I. Background Information:

Study title	

CREC no.		Protocol no.	
Principal investigator		No. of Subjects	

Type of Subject(s)

☐ Healthy Adult
☐ Adult patients with targeted diseases of the study drug
☐ Vulnerable subjects, specify:_____
☐ Others, specify:_____

II. Study Design (please describe the nature of study and study procedure)

III. Please fill in the details of the following items and justify the related safety measures

1. Location of the study (e.g. administration of medicine):

☐ **1.1 Phase 1 Clinical Trial Centre, Special Block 11 EF, PWH**

☐ **1.2 In-patient ward:**

Hospital:_____ Building:_____

Department:_____ Ward:_____

How long will the subject(s) stay in the study site:_____

Site Emergency contact person and number:_____

☐ **1.3 Non in-patient ward:**

Study site: _____

How long will the subject(s) stay in the study site:_____

Site Emergency contact person and number:_____

2. Expertise and Experience of Study Site Personnel (include Physician(s), Pharmacist(s), Laboratories technician(s), Nurse(s), supporting staff(s) etc.):

Name	Qualification & Department	Roles and Responsibilities	Valid BLS Certificate
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

3. Describe the Study Medication (The person who manages the study medication is responsible for keeping drug related documents, formulation record, dispensing record, accountability record and storage record and recall record etc.)

Person who manage the study medication:_____

Dosage:_____

Dosage Form and Route Administration:_____

Manufacture:_____

Storage method:_____

Storage location:_____

Describe starting dose and dose escalation:

Describe known and potential risks and harms of study medication (include the toxicity, the seriousness of possible adverse reactions and the probability of them happening)

4. Equipment & Drugs for Resuscitation:

4.1 Resuscitation Drugs: (Please put a "√" if available)

☐ Adrenaline Inj. 1 in 10000
☐ Lignocaine Inj. 1%
☐ Atropine Sulphate Inj. 0.6 mg/ml
☐ Naloxone HCL Inj. 0.4mg/ml
☐ Dextrose Inj. 50%
☐ Sodium Bicarbonate Inj. 8.4%
☐ Vecuronium Bromide Inj. 4mg/ml
☐ Amiodarone Inj. 50mg/ml
☐ Calcium Chloride Inj. 10%
☐ Adenosine Triphosphate Disodium Inj. 10mg/ml

Other relevant drugs. Please list: _____

Person trained on Basic Life Support and holds a valid BLS certificate :_____

4.2 Resuscitation Equipment: (Please put a "√" if available)

☐ BVM unit ☐ Nasopharyngeal & Oropharyngeal Airway ☐ PPE
☐ Defibrillator ☐ ECG electrodes ☐ Defib-pads ☐ Suction Catheter
☐ Heparin block ☐ IV fluid ☐ IV drips sets ☐ IV extension tubes
☐ O2 Mask ☐ Angiocaths ☐ Syringes ☐ Alcohol Prep
☐ Tourniquet ☐ Tegaderm ☐ Micropore ☐ 3-way
☐ Kidney dish ☐ Magill forcep ☐ ET tubes ☐ Stylet
☐ Yankauer ☐ K-Y jelly ☐ Blenderm/cotton tie ☐ Incontinence pads
☐ Others, please list:_____

5. Describe any other measures in place to ensure the safety of subjects:

6. Describe qualified medical doctor(s) (who are responsible for monitoring the safety of subjects, making medical decisions, and dealing with medical emergencies):

7. Describe data protection (keeping documents, specimen storage, how to protect subject's privacy etc.)

Reported by:

Name of PI	Signature of PI	Date