University of Cape Town **Clinical Research Centre**	**Standard Operating Procedures**

Title	**General preparation for the conduct of Trials**
Number	4
Version	1

	Name	Title	Signature	Date
Reviewer	Brenda Wright	Project Manager		28 Apr 2015
Authoriser	Delva Shamley	CRC Director		28/4/15
			Effective date	28 Apr 2015
			Review date	28 Apr 2018

1. Purpose/scope

To describe the procedure for ensuring that stock, equipment, template documentation, staff and venue for all trials conducted by the Clinical Research Centre are adequately prepared.

2. Templates/forms

4.1 Stock check-list

4.2 Bed plan

4.3 Equipment servicing schedule

4.4 Timelines

4.5 Assessment schedules

All templates/forms are available electronically and can be modified to be trial specific.

3. Glossary/definitions

None

4. Responsibilities and procedure

a. Medical stock and equipment

A suitably trained member of the trial team should be delegated responsibility for facilitating the checking, ordering and labelling of medical stock and equipment.

i. Stock check-lists (AD01.1) are developed for general medical consumables and equipment (including items for out-patient visits and in-patient days), based on the

protocol's requirements. NB these lists may be combined with ward set up check lists found in AD05.

ii. Any existing stock (from previous trials) is checked, and expired items destroyed as appropriate. In-date stock is placed in a trial-specific secure storage area.

iii. New stock and any identified additional trial-specific supplies/equipment are ordered through the appropriate purchasing method. On receipt, stocks and requisition forms are checked for protocol compliance before securely stored in appropriate storage space.

iv. Participant-specific packs, if required, are prepared from the general medical consumables stock, and placed in a trial-specific secure storage area. Packs and their contents are labelled according to trial requirements, and a quality control check conducted by designated members of the trial team (or contract employees) as documented in a note to file. Unless otherwise specified in the protocol or elsewhere, sample containers will be labelled with the trial number, participant number, trial period and sample time-point. NB very small items (such as cryovials and eppendorfs) may only include participant information, as long as the boxes they are stored in indicate the trial.

v. If required, participant-specific identity bands (or equivalent) are sourced and prepared, together with the bed plan and associated bed labels (AD01.2).

vi. Equipment is serviced according to manufacturers' recommendations throughout the trial. All records relating to stock and equipment (including check lists, quality control, calibration records and servicing documentation) will be filed in the Investigator Site File throughout the trial (or a note to file indicating where they are stored). It is recommended that a trial-specific equipment servicing schedule be developed (AD01.3).

vii. Drugs other than the Investigational Medicinal Product (IMP) are sourced according to the protocol or Principal Investigator (PI) requirements (e.g. for symptomatic relief of subjects' minor ailments and anti-retroviral for HIV post-exposure prophylaxis). These may be stored in the pharmacy or a ward medicine trolley depending on a particular trial's requirements. There should be controlled access to such other drugs while participants are in the facility.

viii. Expiry dates for all stock are checked regularly during the pre-trial phase to ensure the integrity of stock at the study start, as documented on the stock check-lists.

ix. During the trial general medical stocks are checked regularly against the stock lists for general consumables with expired stocks removed and re-ordered as above. Any stock that has been re-packaged into subject-specific boxes is also checked and replaced as above.

x. Stock-takes of the resuscitation equipment are made according to Clinical Research Centre requirements. However, these should be such that there is enough time to re-stock if required before trial participants are expected. During admission periods, the top of the trolley and equipment (including the suction and AED) will be checked twice daily (at the start of each shift) and daily at the start of screening/follow-up days. When no trial activity takes place in the ward, the trolley will be checked at least once a week. The sealed part of the trolley will be checked once a month by 2 x allocated staff members.

xi. Ultimate responsibility for adequate function and stock of the resuscitation equipment remains with the senior investigator on site. The suitably appointed staff members checking the trolley once a month will alert the investigator regarding expired stock and obtain prescriptions to replace emergency trolley medicine to expire.

b. Staff

i. The PI should ensure the allocation, or recruitment, of suitably qualified staff to make up the trial team. Trial timelines and schedules will be arranged to ensure the trial is conducted according to the protocol (AD01.4 and 5).

ii. All relevant staff should attend relevant meetings and training as necessary prior to their start with the trial, documenting qualifications and training as per regulatory and SOP requirements.

c. Venue, including catering and entertainment

i. If utilising the ward, prior to and during the trial a member of the trial team will be tasked with liaising with the ward management for it to be cleaned and organised as per the enrolment schedule.

ii. By the time of trial start a member of the trial team will be tasked with planning for and source on-going catering supplies as per protocol requirements for trial participants, and also for the trial team, according to the schedule of clinical conduct. A stock list specific to such consumables may be used as above.

iii. Adequate entertainment will be planned.

d. Template documentation

i. A member of the trial team will be tasked with coordinating the production of adequate template documentation including, but not limited to, participant folders including source documents, SOP forms/templates and trial-specific instructions. See relevant SOPs for details.

5. Document history:

Version No.	Date	Reviewer	Details of changes
1.0	31 Mar 15	B. Wright	NA - first version of SOP

	University of Cape Town **Clinical Research Centre**				**CRC 4.1 Stock check list**
Trial number				**Sponsor**	
***Stock type**	Med cons. = MC	Emergency trolley = ET	Ward gen. + WG	Catering = C	Other (detail) = O

Details of stock take:

***Stock type:**	**Description** *(Examples)*	**No**	**Expiry**	**Order**	**Comment**
	22G Black Needles				
	Alcohol swabs				
	Applicator sticks				
	Barrels				
	Baumenometer				
	Beige cups				
	Black ballpoint pens				
	Blank labels				
	Caffeinated Tea/Coffee				
	Ceres juices				
	Clipboards				
	Cotton gauze				
	Cotton wool balls				
	Decaff tea and coffee				
	Demarcated glasses				
	FlexiGrid				
	G20 Cannulas				
	Gauze swabs				
	Hibiscrub				
	Hypodermic needles				
	Juice				
	Kettle (x 2)				
	Latex gloves - large				
	Latex gloves - medium				

	Latex gloves - small				
	Leuer Adaptors				
	Linen savers				
	Lunch boxes				
	Mandrin holders				
	Mandrins				
	Masking tape				
	Micropore				
	Milk (Breakfast and tea)				
	Mugs				
	Oscilloscope				
	Paper plates				
	Permanent markers				
	Plastic bags				
	Plastic cups				
	Prestik				
	Purple top tubes – 4.5 ml				
	Reflex hammer				
	Rusks				
	Sabax Saline – 20 ml				
	Safe-lock Eppendorfs				
	Sampling barrels				
	Stethoscope				
	Stop watch				
	Syringes – 10 ml				
	Syringes – 5 ml				
	Thermometers				
	Tongue depressors				
	Tourniquets				
	Urine jars 50 ml				
	Vials for 70% ethanol				
	Webcols				

	Clocks x				
	Intercom x				
	Bed sheets				
	Duvets				
	Pillows				
	Pillow cases				
	Towels				
	Soap				
	Toilet paper				
	Detergents				
	Paper				
	Electrode paste				
	Ambubag				
	Mask				
	O_2 connection tube				
	E-T tube connector				
	Bandages				
	Dressing pads: 100 x 100				
	Dressing pads: 100 x 200				
	Adhesive tape				
	Stethoscope				
	Functioning Baumenometer				
	Tourniquet				
	Scissors				
	Securing tape				
	Magills Forceps				
	Mosquito Forceps				
	Functioning Manual suction pump				
	Manual suction pump collection vial				
	Manual suction pump catheter				
	Laryngoscope (4 blades) in working order				

	Spare Laryngoscope bulb				
	Spare 1.5V batteries				
	Sterile burn dressings: 100 x 100 mm				
	Sterile burn dressings: 200 x 200 mm				
	Hypodermic needles (box)				
	Alcohol Prep Swabs (box)				
	IV Cannula: 14				
	IV Cannula: 16				
	IV Cannula: 18				
	IV Cannula: 20				
	IV fluid delivery set				
	Blood Administration Set				
	10 ml syringe				
	20 ml syringe				
	Endotracheal tubes: 7.5				
	Endotracheal tubes: 7.0				
	Endotracheal tubes: 6.5				
	Yankhauer Suction Catheter (Adult)				
	Suction Catheter (Control FG 12)				
	Suction Catheter (Control FG 14)				
	Feeding tube (Ryles FG14)				
	Urine Drainage Bag				
	Introducer 5.0 mm				
	Airways (various sizes)				
	Mouth to mouth non-return valve				
	0.9% NaCl (200 ml)				
	1 litre Ringers Lactate				
	8.5% Na Bicarb (50 ml)				
	10% CaCl injection				
	50% Dextrose (20 ml) injection				

	Water for injection (10 ml)				
	Atropine (1 ml) injection				
	100 mg Hydrocortisone injection				
	Adrenaline (1 mg/ml) injection				
	50 mg Mepyramine injection				
	K-Y jelly tube				

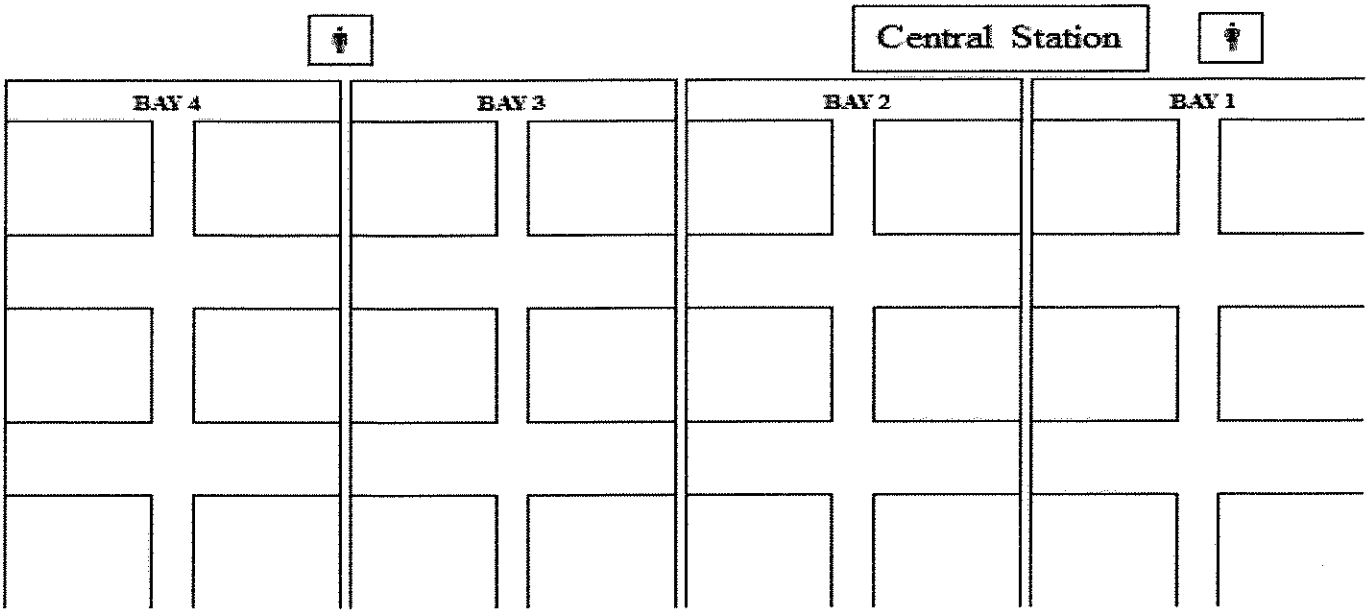
Completed by	**Designation**	**Signature**	**Date**

University of Cape Town
Clinical Research Centre

Protocol:
Cohort:
Date:

Ward J51 Bed Plan

Signed:



	University of Cape Town Clinical Research Centre		**CRC 4.3 Equipment servicing schedule**
Trial number		**Sponsor**	
Equipment	**Model/manufacturer**	**Service/calibration date**	**Comment/next date**

CRC 4.4 Timelines

		Participant 1	Participant 2	Participant 3
25-Mar-15	Wed			
26-Mar-15	Thu			
27-Mar-15	Fri			
28-Mar-15	Sat			
29-Mar-15	Sun			
30-Mar-15	Mon			
31-Mar-15	Tue			
01-Apr-15	Wed			
02-Apr-15	Thu			
03-Apr-15	Fri			
04-Apr-15	Sat			
05-Apr-15	Sun			
06-Apr-15	Mon			
07-Apr-15	Tue			
08-Apr-15	Wed			
09-Apr-15	Thu			
10-Apr-15	Fri			
11-Apr-15	Sat			
12-Apr-15	Sun			
13-Apr-15	Mon			
14-Apr-15	Tue			
15-Apr-15	Wed			
16-Apr-15	Thu			
17-Apr-15	Fri			
18-Apr-15	Sat			

CRC 4.5 Assessment Schedules:

Date - Day 1 (Dosing)		
	1	2
Med hx		
Physical (abrev)		
Temp		
Physical		
Start rest		
BP/HR		
ECG 1		
ECG 2		
ECG 3		
Start holter		
Hand warmer		
Cannulate		
Pathcare bloods (glucose)		
PG sample		
PK 1 (pre-dose)		
ELIGIBILITY		
Dose (supine?)	**8:00**	
Hand warmer		
PK 2 (0.5hr)	**8:30**	
Temp		
Start rest		
BP/HR		
ECG 1		
ECG 2		
ECG 3		
Hand warmer		
PK 3 (1 hr)	**9:00**	
Start rest		
BP/HR		
ECG 1		
ECG 2		
ECG 3		
Hand warmer		
PK 4 (2 hr)	**10:00**	
Start rest		
BP/HR		
ECG 1		
ECG 2		

Training Log for General preparation for Clinical Conduct		
Name:	**Initial:**	**Date:**
