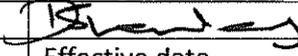


THIS SOP REMAINS THE PROPERTY OF THE UCT CLINICAL RESEARCH CENTRE

 University of Cape Town Clinical Research Centre		Standard Operating Procedure
Title	Evacuation from the Clinical Research Ward of participant/staff member in the event of a Medical Emergency	
Number	02	
Version	1	

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

1. Purpose/scope

To describe the procedure for safely evacuating a trial participant or staff member due to a medical emergency from the Clinical Research ward (trial facility) during a clinical trial conducted by the Clinical Research Centre.

2. Templates/forms/check lists

- CRC 2.1 Trial-specific emergency contact details form (updated before each trial, and continually reviewed)
- CRC 2.2 Trial-specific terminology (when making telephone contact about a medical emergency)
- CRC 2.3 Agreements between UCT and the various emergency service providers, e.g. ambulance service, emergency department group, and receiving hospital (reviewed, and updated if needed, at least 28 days before dosing starts)

3. Glossary/definitions

None

4. Responsibilities and procedure

- 4.1** Throughout the admission period for any trial, there will be at least two health professionals (Investigator/trained paramedic/s and or an experienced nurse) in the trial facility 24 hours per day, 7 days per week (24/7).
- 4.2** During a First into Human trial a minimum of one of the abovementioned health professionals will be advanced cardiac life support (ACLS)-trained and one will be basic life support (BLS) trained.

THIS SOP REMAINS THE PROPERTY OF THE UCT CLINICAL RESEARCH CENTRE

- 4.3** There will also be at least one ACLS-trained medical doctor remaining in the ward from 07h00 to 18h00 throughout the admission period, with an ACLS-trained medical doctor remaining in the ward 24/7 from the time of dosing until 12 hours after the predicted time of maximum concentration (Tmax) during a First into Human Trial
- 4.4** All clinically qualified trial team members must be able to deal with emergency medical situations. Non-clinicians should be trained in BLS while clinicians should be trained in ACLS. Emergency procedures (including transfer of a stretcher to the ambulance) should be regularly trained (e.g. every 3 months) as documented in the training records.
- 4.5** The emergency trolley will be checked as follows:
- Once a month 2 x staff members will check all the contents of the trolley as per the emergency trolley check list. The drawers will be sealed, initialled and dated by the staff members.
 - Any contents nearing expiration date will be replaced and the checklist updated with new expiry dates.
 - During the admission period night staff will check the unsealed part of the trolley in the morning and day staff will check the same in the afternoon.
 - During non-admission times this check will be done on the morning of the study visit.
 - When there are no study visits, this check will be performed at least once a week.
- 4.6** The patient should be rapidly assessed and stabilised by the clinical staff on duty, with the most senior clinical staff member(s) taking the lead. In case of resuscitation, if a paramedic is on duty, he/she should take the lead, assisted by the nurse and the investigator/Investigator-on-call.
- 4.7** If the patient's condition is deemed **unstable** by the investigator/investigator-on-call, the following procedure should be followed by available support staff (See form CRC 2.1 for contact details and CRC2.2 for script):
- 4.7.1** The paramedic/nurse/investigator to remain with the patient while the other contacts the ambulance call centre to dispatch an ambulance, and provide the following information
- Brief description of the condition of the patient
 - Directions to enter the Old Main building from Palm Court entrance 5 to J-floor
 - That referral of the participant to the receiving hospital has been arranged
- 4.7.2** A suitably trained staff member to contact security at GSH to arrange for ambulance crew entry through Palm Court entrance to Old Main Building.

THIS SOP REMAINS THE PROPERTY OF THE UCT CLINICAL RESEARCH CENTRE

4.7.3 A sub-investigator/nurse to Contact the Principal/Lead investigator (if not already involved) to inform them of the nature of the medical emergency and actions taken.

4.7.4 The Principal/Lead investigator/sub-investigator to contact the emergency department group/emergency physician-on-call to inform them of the nature of the medical emergency, actions taken and that the volunteer is expected to arrive at the hospital in 10-15 minutes.

4.7.5 The emergency department group/emergency physician-on-call to contact the hospital Intensive Care Unit Physician-on-call to arrange an ICU bed.

4.7.6 Resuscitation by trial staff should be continued until hand over to the ambulance service.

4.7.7 For trial participants, all relevant source documents should be completed and the relevant authorities (Sponsor, regulatory authority, ethics committee) notified of the event according to trial-specific safety procedures and SOP 04

4.8 If the patient’s condition is deemed **stable**, the investigator/investigator-on-call should decide on further management and referral to clinical care or consult with a relevant medical specialist if indicated.

4.8.1 If transfer is required, a nurse must contact the ambulance call centre to request an ambulance (as per 4.7.1 above) and notify security at GSH to expect and facilitate entry for ambulance crew via the Old Main building from Palm Court entrance 5 to J-floor (as per 4.7.2 above).

4.8.2 For trial subjects, all relevant source documents should be completed and the relevant authorities (Sponsor, regulatory authority, ethics committee) notified of the event according to trial-specific safety procedures and SOP 04.

5. Document history:

Version No.	Date	Reviewer	Details of changes

THIS SOP REMAINS THE PROPERTY OF THE UCT CLINICAL RESEARCH CENTRE

	University of Cape Town Clinical Research Centre		CRC 2.1 Trial-specific emergency contact details form
Trial number		Sponsor	
Name		Contact details	
Investigators			
Emergency Services Group Consultant on call			
Ambulance services (To be contacted in this order)			
GSH OMB E-floor security OMB E-floor security Boom gates entrance to Palm court Main entrance (bottom of the hill)			
Private Hospital Emergency Unit contact numbers			

THIS SOP REMAINS THE PROPERTY OF THE UCT CLINICAL RESEARCH CENTRE

	University of Cape Town Clinical Research Centre		CRC 2.2 Trial-specific terminology Form
Trial number		Sponsor	
<p>For ambulance services</p> <p>Dial: [add number]</p> <p>“My name is [name of the caller] from the UCT (name disease) Clinical trial. I need assistance with a medical emergency. I am located in ward J51 Old Main Building at Groote Schuur Hospital. The entrance to the building is entrance 5, opposite Palm court in the Old Main Building. I have a patient [describe age and gender] who has [briefly describe the medical emergency].</p> <p>My contact telephone number is 021 406 6641 (ward) and my mobile number is [provide mobile number].“</p> <p>Ensure telephone line is available until the ambulance arrives.</p>			
<p>For GSH OMB security guards</p> <p>Dial: [add number]</p> <p>“My name is [name of the caller] I need assistance with a medical emergency. I am calling from upstairs in ward J51 Old Main Building at Groote Schuur Hospital. I have a patient that urgently needs to be taken by ambulance to [hospital] on a stretcher. I am expecting an ambulance from [ambulance service provider]. Can you make sure that they can get to ward J51 in the Old Main Building as soon as they arrive at the main entrance? Please make sure that the doors are ready for the entry and exit to save time.”</p> <p>How to get to our ward on J51</p> <ol style="list-style-type: none"> 1. Turn left into the passage and walk past the displays (on your right hand side) and the lifts 2. Continue all the way down the passage until you see the ‘Exit’ and ‘Management Suite’ signs to your left 3. Keep to your right, turn left into an open area with large wooden “GSH Donation” boards displayed on all the walls 4. YOU ARE NOW ON E FLOOR 5. Up ahead you will see the GSH curio shop, and to your right you should catch a glimpse of the Big Barn Café 6. Continue down the passage, directly above, you should see a white “UCT Clinical Research Centre” sign 7. Turn right at the corner into another short passage and pass the UCT Skills Laboratory. Up ahead you will see another white “UCT CRC” sign 8. Turn left below the 2nd “UCT CRC” sign, to your left is a bank of elevators. Take the elevator up to J floor 9. Once you alight on J floor, please turn right and ring the bell for assistance if the door is not open <p>My contact telephone number is 021 406 6641 (ward)</p>			
<p>For [hospital] referral</p> <p>Dial: [add number] for specialist physician on call.</p> <p>“My name is Dr [name of the caller] from the UCT (name disease) clinical trial. I need assistance with a medical emergency. I have a patient [describe age and gender] enrolled in the UCT (name disease) trial. He/she has developed [briefly describe the patient’s condition and outline what has been done so far]. There is a briefing summary in [hospital Emergency Unit] describing the trial, and the agreement with the [Emergency department group], [hospital] and Dr [specialist physician] to manage any medical emergency in this study. I will be sending a referral letter and the investigations done so far.</p> <p>My contact telephone number is 021 406 6641 (ward) / or my mobile phone is [provide mobile number]</p>			

THIS SOP REMAINS THE PROPERTY OF THE UCT CLINICAL RESEARCH CENTRE

MEMORANDUM OF UNDERSTANDING

MADE AND ENTERED INTO BY AND BETWEEN

THE UNIVERSITY OF CAPE TOWN

A university incorporated in terms of the Higher Education Act, 1997, and the statute of the University of Cape Town, promulgated under Government Notice No. 1199 of 20 September 2002
(hereinafter referred to as “UCT”)

and

A company incorporated in terms of the laws of South Africa under company registration number
.....

(Hereinafter referred to as “”)

(collectively hereinafter referred to as the “Parties”)

THIS SOP REMAINS THE PROPERTY OF THE UCT CLINICAL RESEARCH CENTRE**PREAMBLE**

WHEREAS UCT shall be conducting a [trial title], under the leadership of [PI name] as Principal Investigator (“the Study”);

AND WHEREAS UCT wishes to make provision for hospital admission and treatment of any subjects of the study (“Study Subjects”) who exhibit symptoms in reaction to the administration of [trial drug] which, in the view of the UCT clinical researchers, requires the Study Subject to be monitored and treated in hospital; **AND WHEREAS** [hospital] is willing to admit and treat such study subjects at the in its Intensive Care Unit or general wards;

NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1. ADMISSION OF STUDY SUBJECTS AS PATIENTS

- 1.1. [hospital] agrees to admit any Study subjects, who are identified by a Study clinician as exhibiting symptoms requiring hospitalisation in reaction to the administration of the Study drug, as patients to [hospital].
- 1.2. [hospital] further agrees to monitor and treat such patients until they have recovered sufficiently for discharge.

2. COSTS OF HOSPITALISATION AND TREATMENT

- 2.1. UCT agrees to cover the costs of hospitalising and treating the admitted Study subjects incurred by [hospital].
- 2.2. [hospital] shall charge UCT for such costs at the standard rates of hospitalisation and treatment as set out in Annexure A annexed hereto.
- 2.3. For each Study subject admitted [hospital] shall invoice UCT, which invoice shall itemise the costs claimed.
- 2.4. Invoices shall be sent to UCT at (insert address) and marked for the attention of (insert).
- 2.5. UCT shall pay such invoices within 30 (thirty) days of receipt.

3. CONFIDENTIALITY

- 3.1. Each party and its employees, agents and subcontractors shall hold in confidence and shall not disclose, distribute, sell, copy, share or otherwise use any information obtained by the other Party while performing this MoU, which relates to the other Party’s patients, employees, research, development, business affairs, records, processes, techniques or types of equipment, whether past, present or future that have been disclosed to the other party as being confidential, except as may be contemplated by this MoU or authorised by the other Party in writing. Upon completion of its work under this MoU, each party and its employees, agents, and subcontractors shall return to the other party all confidential information and all records or documents received from the other party, including without being limited to, any and all copies thereof which may have been made.
- 3.2. Neither Party shall incur any obligation under this Clause 3 (three) with respect to information which:
 - 3.2.1. is already known to the receiving Party, and not impressed already with any obligation of confidentiality to the disclosing Party; or
 - 3.2.2. is or becomes publicly known without the fault of the receiving Party; or

THIS SOP REMAINS THE PROPERTY OF THE UCT CLINICAL RESEARCH CENTRE

- 3.2.3. is obtained by the receiving Party from a third party in circumstances where the receiving Party has no reason to believe that there has been a breach of an obligation of confidentiality owed to the disclosing Party; or
- 3.2.4. is independently developed by the receiving Party; or
- 3.2.5. is approved for release in writing by an authorised representative of the disclosing Party; or
- 3.2.6. the receiving Party is specifically required to disclose in order to fulfil an order of any Court of competent jurisdiction or to comply with an Act of law.

4. BREACH AND TERMINATION

- 4.1. Should either Party fail to fulfil any of the obligations undertaken by it and fail to remedy the breach within a period of 30 (Thirty) calendar days after receiving written notification from the other Party demanding that the breach be rectified, either Party shall be entitled, without further notice, to cancel this MoU.
- 4.2. Either Party may unilaterally cancel this MOU by giving 90 (ninety) days written notice.

5. SERVICE OF REQUIRED NOTICES

- 5.1. Any notice required to be given under this MoU shall be deemed made if given by registered or certified mail, postage prepaid, and addressed either to the stipulated *domicilium citandi et executandi* given below or to such other address as may hereafter be specified in writing by the parties:

- 5.1.1. If to [hospital]:

(insert)

- 5.1.2. If to UCT:

Attention: The Director
Research Contracts & IP Services
University of Cape Town
Allan Cormack House
2 Rhodes Ave
Mowbray, 7700

6. GENERAL

- 6.1. No alteration, variation, addition or agreed cancellation of this MoU shall be of any force or effect unless reduced to writing as an addendum to this MoU and signed by the Parties or their duly authorized signatories.
- 6.2. No failure or delay on the part of either Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege preclude any other or further exercise thereof, or the exercise of any other right, power or privilege. The rights and remedies herein expressly provided are cumulative and not exclusive of any rights or remedies, which the Parties would otherwise have.
- 6.3. No indulgence, leniency or extension of time which any Party ('the grantor') may grant or show to the other shall in any way prejudice the grantor or preclude the grantor from exercising any of its rights in the future.

THIS SOP REMAINS THE PROPERTY OF THE UCT CLINICAL RESEARCH CENTRE

6.4. If any clause or term of this MoU should be invalid, unenforceable or illegal, then the remaining terms and provisions of this MoU shall be deemed to be severable therefrom and shall continue in full force and effect unless such invalidity, unenforceability or illegality goes to the root of this MoU.

SIGNED AT _____ THIS THE _____ DAY OF _____ 2014 for and on behalf of **the University of Cape Town**

Signed: _____

Name: _____

Title: _____

SIGNED AT _____ THIS THE _____ DAY OF _____ 2014 for and on behalf of [hospital]

Signed: _____

Name: _____

Title: _____

