NIHR | King's Clinical Research Facility

Management of Medical Emergencies in the King's Clinical Research Facility

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Author	Noah Yogo, CRF Lead Research Nurse
Approved by	Elka Giemza, CRF Manager
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Supporting references	See Section 6.0

Change History		
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January 2014	1. Amend logos to update to current CRF letterhead template 2. Amend document number from CRF SOP012 to CRF-CL-SOP-6 to comply with Q-Pulse document numbering system 3. Amend name of Director to current Director 4. Amend typo in section 5.1 5. Addition of new section (6.0) which details procedure for medical emergency occurring in the MRI	E.Giemza
August 2016	1. Updated references and related documents 2. Revision of Section 5.0 to reflect current CRF practice and to adhere to current Resuscitation Council guidelines and local policies 3. Minor amendments to text for clarity	E.Giemza

September 2018	1. Change of author due to staff changes 2. Section 5.1: updated locations of the CRF resuscitation trolleys and the types of trolley available 3. Section 5.2: updated information on the checking of trolleys (weekly checks and daily checks) 4. Section 5.9: updated to include the training needs of the department 5. Section 5.15: addition of information relating to out-of-hours procedures for deteriorating patients 6. Section 5.16: addition of information relating to Do Not Resuscitate orders 7. Section 5.18: updated procedure to include collapsed patients as well as cardiac/respiratory arrest	E. Giemza
November 2020	1. Section 4.1 , 4.2: change to Research Practitioners 2. Section 5.7, 5.8: Clarification, addition of text 3. Section 6.8: Addition of KCH Immediate Life Support Training programme. Register on LEAP	E. Giemza

Review History		
Date	Review details	Approved by
January 2014	Review of version 1.0. Amended as detailed above in Change History and superseded by version 2.0. Reviewed by Maria Ines de Sousa de Abreu	E.Giemza
August 2016	Review of v2.0 conducted by Alexander Chan, CRF Research Nurse, as per the review date. Changes made as per 'Change History' and re-issued as v3.0	E.Giemza
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November 2020	Review of v4.0 conducted by John Lord Villajin, CRF Lead Clinical Trial Coordinator, as per the review date. Changes made as per 'Change History' and re-issued as v5.0	E.Giemza

1.0 Background

1.1 The King's Clinical Research Facility (CRF) supports a wide range of research projects involving both healthy volunteers and patients. These include both observational and interventional studies, including trials of new and existing medicinal products, treatments and devices. There is a risk of a medical emergency resulting from an adverse reaction to a medicinal product or treatment.

1.2 A medical emergency is an acute, unplanned event that has the potential for serious harm or death. This includes anaphylaxis and cardiorespiratory arrest.

2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe how medical emergencies are managed in the CRF.

3.0 Scope

3.1 The CRF encompasses the Clinical Trials Facility (CTF), the Experimental Medicine Facility (EMF) and the Cell Therapy Unit (CTU). CRF SOPs will apply to the CTF and EMF only and staff working in those areas should work to all relevant CRF SOPs. The CTU will continue to control and use its own policies and SOPs to ensure compliance with Good Manufacturing Practice (GMP).

3.2 This SOP applies to all core CRF staff (clinical and non-clinical) and all users of the CTF and EMF.

4.0 Responsibilities

4.1 Clinical staff, including nurses, doctors and research practitioners, are responsible for the identification of medical emergencies, mobilising the resuscitation team and providing initial treatment to address the emergency.

4.2 Research nurses and practitioners are responsible for ensuring that emergency equipment is available and is in good working order in accordance with the King's College Hospital (KCH) Cardiopulmonary Resuscitation Operational Policy.

4.3 Non-clinical staff are responsible for assisting in the management of emergencies, mobilising the resuscitation team when asked to do so and facilitating emergency procedures.

4.4 Clinical staff are responsible for ensuring that their ILS (Immediate Life Support) or BLS (Basic Life Support) training is up-to-date, as appropriate to their role.

4.5 The CRF Manager/Lead Research Nurse is responsible for arranging any additional training and for arranging regular emergency simulation training.

5.0 Procedure

Maintenance of equipment:

5.1 Resuscitation trolleys are located within the EMF on the 1st floor (adult and paediatric combined trolley), ground floor (adult and paediatric combined trolley) and an Airway trolley is located in the MRI suite. Within the CTF there are 2 resuscitation trolleys, one adult (chair-side) and one adult and paediatric combined trolley (ward-side).

5.2 Trolleys are checked by the core CRF clinical staff to ensure that all drugs and equipment are in-date and functional. The trolleys are checked weekly, but the items on top of the trolleys (the defibrillator, suction equipment and oxygen) are checked daily, as per the KCH policy and as indicated on the KCH checklists. Contents are checked against the KCH checklists, which are kept on each trolley.

5.3 Once checked, the trolley is sealed with a numbered tag.

5.4 Once a trolley has been sealed the seal should only be broken in the event of a clinical emergency or a subsequent check.

5.5 Trolleys must be restocked as soon as possible after use and resealed using a new tag.

5.6 A laminated card with details of how to contact the resuscitation team and how to communicate the location clearly is displayed near to all telephone points in the CRF.

Staff training:

5.7 All CRF clinical staff must be trained in BLS as a minimum standard. All nursing staff should be trained in ILS. An ILS certificate is valid for one year and attendance/ completion of the recall session up to 2 years from the date of your last ILS course.

5.8 Staff will arrange training in conjunction with the KCH Resuscitation Department. Refer to Section 6.8.

5.9 Cardiopulmonary resuscitation training must be updated annually and in accordance with the training needs of the department.

5.10 Emergency simulation training for all staff will be arranged periodically by the CRF Manager or delegate.

CRF staffing:

5.11 Whenever there are study participants in the EMF or CTF, two members of staff should usually be present to ensure that an emergency can be managed as safely as possible. At least one member of staff should be a member of the CRF clinical team.

5.12 Where the risk of an emergency is considered low, for example in an observational study of low risk patients, then the presence of a single staff member will be sufficient. In this situation, a risk assessment should be documented and agreed by the CRF Manager or Lead Research Nurse.

Procedure in the event of an emergency:

5.13 The study protocol may indicate a specific procedure that should be followed in the event of an emergency, for example, a reversal agent. Where it is possible to adhere to the protocol without jeopardising the safety or welfare of the participant, then this should be attempted.

5.14 In the event of an acute deterioration or collapse of any person in the CRF, CRF clinical staff will perform an ABCDE assessment in accordance with the current Resuscitation Council guidelines.

5.15 For deteriorating patients/study participants out-of-hours, please refer to CRF-CL-SOP-10 'Out-of-Hours and Weekend Medical Cover for Studies Conducted in the King's CRF'.

5.16 Check that the patient or participant has not signed a 'Do Not Attempt Resuscitation' order.

5.17 A member of staff should collect an appropriate arrest trolley, either combined paediatric/adult or adult only.

5.18 If a patient has collapsed, or a cardiac arrest has occurred, staff should initiate cardiopulmonary resuscitation and defibrillation in line with Resuscitation Council guidance and the KCH resuscitation policy.

5.19 Staff caring for the patient must activate the emergency alarm (the red triangular pull button/red pull cord in the EMF or red push button/red pull cord in the CTF).

5.20 On hearing the emergency alarm all available staff must attend immediately.

5.21 A member of clinical or non-clinical staff will contact the resuscitation team on 2222 stating 'adult cardiac arrest' or 'child cardiac arrest' as appropriate and give the location.

5.22 A member of staff should go to the nearest entrance to facilitate access for the resuscitation team.

5.23 Once the resuscitation team arrive, a member of CRF clinical staff will hand over to the resuscitation team using a structured handover technique, such as SBAR.

5.24 CRF staff should remain on hand to assist the resuscitation attempt. Staff should be aware that the resuscitation team may be unfamiliar with the layout of the CRF.

Procedure following a successful resuscitation attempt:

5.25 The resuscitation team will arrange for the transfer of the patient to a ward or appropriate critical care area in accordance with the KCH Cardiopulmonary Resuscitation Operational Policy.

5.26 CRF staff should inform the participant's emergency contact that the participant's condition has deteriorated, that he or she has been transferred and the place that the participant has been transferred to. It may be appropriate to give further details.

5.27 The resuscitation trolley should be restocked, checked and sealed.

5.28 The patient's clinical notes and study documentation should be updated with a full account of the emergency, action taken and outcome.

5.29 CRF staff should consider whether or not the emergency constitutes an adverse event (AE), serious adverse event (SAE) or important medical event (IME) and report in accordance with the study protocol and the CRF's Safety Reporting and Pharmacovigilance SOP (CRF-QA-SOP-5).

5.30 CRF staff should consider whether or not the emergency constitutes a clinical adverse incident. If so, a Datix report must be submitted in accordance with KCH policy.

5.31 CRF staff should inform the Principal Investigator of the event.

6.0 Related documents & References

6.1 CRF-QA-SOP-5: Safety Reporting and Pharmacovigilance in the King's CRF

6.2 KCH Policy for the Management, Reporting, & Investigation of Adverse Incidents (including Serious Incidents)

6.3 KCH Cardiopulmonary Resuscitation Operational Policy

6.4 KCH Adult Trolley Daily Checklist

6.5 KCH Adult and Paediatric Trolley Daily Checklist

6.6 All KCH documents: http://kingsdocs/Pages/Home.aspx

6.7 Resuscitation Council guidelines: https://www.resus.org.uk/resuscitation-guidelines/

6.8 **KCH Immediate Life Support Training Programme (ILS). Register on LEAP**

7.0 List of Appendices

N/A

8.0 Approval and sign off

Author:	
Name: Noah Yogo	
Position: CRF Lead Research Nurse	
Signature:	Date:
Approved by:	
Name: Elka Giemza	
Position: CRF Manager	
Signature:	Date:
Authorised by:	
Name: Professor Peter Goadsby	
Position: CRF Director	
Signature:	Date: