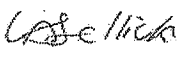





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**SOP CIRU Management of Acutely Unwell Patients**

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2.0	Jan 2016	Change in content
3.0	24 <sup>th</sup> Mar 2016	Change in content

**1. Purpose**

The purpose of this document is to detail the procedure for dealing with acute anaphylaxis or sudden deterioration in patient/volunteer's medical condition within CIRU.

## 2. Introduction

The Clinical Investigation and Research Unit (CIRU), supports the conduct of a broad range of clinical research studies involving patients and healthy volunteers. The CIRU team includes Registered Nurses and Research Registrars. The unit is situated within The Royal Alexandra Children's Hospital (RACH) and is served by the hospital emergency response team.

CIRU Research Nurses receive training and annual updates in adult resuscitation skills and the use of the Automated and/or Advisory External Defibrillator (AED) in accordance with BSUH NHS Trust policy. Research registrars are all trained in Advanced Life Support skills.

In the event of a medical emergency occurring in CIRU, the appropriate BSUH NHS Trust policy and procedure for dealing with the situation will be implemented, i.e. resuscitation or anaphylaxis.

The unit has resuscitation equipment and an anaphylaxis kit.

### 3.0 Responsibilities

The CIRU Clinical Director, CIRU Lead Research Nurse, and trial Principle Investigator (PI) are responsible for ensuring that appropriate procedures are in place to protect the safety and welfare of subjects, staff and visitors in CIRU. They are also responsible for ensuring that all CIRU nurses and Research Registrars have the opportunity to be trained and updated annually in cardiopulmonary resuscitation (CPR) and use of the Automated and/or Advisory External Defibrillator (AED).

The CIRU Lead Nurse is responsible for checking that the CIRU emergency equipment is checked as per BSUH NHS Trust policy.

The Research Nurses and Research Registrars are responsible for attending mandatory study days provided by the trust and are therefore considered to be trained appropriately to initiate emergency procedures when required. These staff members are also responsible for documenting all emergency treatment in the medical records, as well as reporting incidents as per trial protocol i.e. SAE reports. Care of the critically ill patient is the responsibility of the PI and research staff, until such time as the patient has stabilised or the care has been handed over to the emergency team or other Trust medical staff. This must also be documented in the medical records.

### 4.0 Procedure

On identifying an unwell or collapsed patient in CIRU, the staff member will assess the response of the patient, shout for assistance and activate the nearest CIRU emergency buzzer. The member of staff will then assess the patient's airway, and breathing (and circulation if trained to take a major pulse).

If the patient is unresponsive with no signs of life (no breathing and/or circulation):

- The staff member should make a 2222 call stating adult cardiac arrest. CPR should be commenced immediately following the BSUH resuscitation policy.

If the patient is breathing normally and has signs of life and a pulse, they may require a different intervention:

- If the patient requires assistance from CIRU Research Registrars, the CIRU medical bleep should be fast bleeped on 8805 and one of the CIRU doctors will attend within 3-5 minutes
- If CIRU staff require the advice and support of the Critical Care Outreach Team, they can be bleeped on 8495
- If a rapid response is required for a patient who becomes ill causing staff concern then a 2222 call should be made and the medical emergency team (MET) should be called

But if the patient's condition deteriorates and they become unconscious or have a respiratory or cardiac arrest, the CIRU member of staff should call 2222 and ask for the adult cardiac arrest team.

When contacting the switchboard to summon the assistance of the BSUH NHS Trust Emergency team, the CIRU staff member must state clearly the exact location of the incident within the unit (i.e. which room) and state that it is an ADULT.

*NB – when a 2222 call or the outreach team are bleeped the CIRU medical bleep holder must also be contacted*

A member of CIRU team will stand by the entrance to the unit in order to direct the emergency response team to the appropriate ROOM.

The Principal Investigator (or Co Investigator in the absence of the Principle Investigator) and CIRU Clinical Director must be informed of the event by the CIRU Research Nurse responsible for the patient.

All events and actions related to the event must be clearly documented in the patient's medical notes and the Principle Investigator or Co Investigator and Research nurse responsible for the patient's care must provide a comprehensive handover to the doctor or resuscitation team leader. This will include all information relating to the research study in which the patient is participating. The most senior doctor present will complete the cardiac arrest form unless delegated to another member of the team.

Any materials relating to or potentially relating to the cardiac arrest e.g. drugs, equipment etc must be retained securely for examination and incident reporting purposes.

The Principal Investigator or Co Investigator and Research Nurse responsible for the patient will remain with the resuscitation team until the patient is stabilised and transferred to an appropriate hospital department. If no bed is immediately available, the patient will be stabilised and monitored on CIRU until a bed becomes available.

The Research Nurse or Principle / Co Investigator will be responsible for contacting the patient's next of kin to inform them of the patient's condition.

The Research Nurse will ensure that a Serious Adverse Event (SAE) report is completed and submitted to the sponsor immediately.

If the medical emergency is considered to be the result of a critical incident, the CIRU Lead Research Nurse will ensure that the incident is reported on the BSUH NHS Trust DATIX system.

## **5.0 Training**

This is a 'read and understand' SOP. The R&D department discourages the retention of hard copies of SOPs and can only guarantee that the most up to date version is on the CIRU shared drive.

## **6.0 Cross Referenced SOPs – N/A**

## **7.0 References**

Resuscitation Council (UK) Anaphylaxis algorithm  
Resuscitation council (UK) Adult Advanced Life Support

BSUH In hospital Resuscitation guidelines

All available of BSUH Intranet resuscitation page:

<http://www.bsuh.nhs.uk/clinical/teams-and-departments/trust-wide-teams/resuscitation/>