





**STANDARD OPERATING PROCEDURE**

**Management of an Unwell Participant**

<b>AUTHOR.</b>	<b>AUTHORISED BY</b>	<b>DATE AUTH</b>	<b>RISK MANAGEMENT PROCEDURE NUMBER</b>
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<b>SIGNATURE</b>  	<b>SIGNATURE</b>  	<b>REVIEW DATE</b>  03/10/2016	

**RESEARCH AND DEVELOPMENT**



**BACKGROUND**

The Lancashire Clinical Research Facility (LCRF) provides a dedicated unit to support multidisciplinary clinical research. The facility provides a safe and quality environment for the delivery of clinical research. Participants attending the facility suffer from all disease areas and will be from all ages ranges, including children.

The management of an unwell patient is based on clinical assessment by appropriately qualified medical and nursing personnel.

The LCRF is served by the Lancashire Teaching Hospitals NHS Foundation Trust (LTH) emergency resuscitation teams and the main hospital buildings are assessed via a link corridor.

The LCRF staff includes a team of registered nurses and other allied health care professionals who receive regular training in managing emergencies. CRF nurses receive training and annual updates on CPR and the use of the Automated External Defibrillator (AED).

**PURPOSE/OBJECTIVE**

To describe the LCRF process for assessment of patients who arrive in the LCRF with new or worsening symptoms.

**SCOPE**

This SOP provides a framework for managing patients who complain of new or worsening symptoms. However, it is not a substitute for clinical judgement.

Procedure No. <b>LCRF-SOP-04</b>	Version. <b>1.1</b>	<b>Current Version is held on the Intranet. SOP's must not be copied or printed without signed authorisation.</b>	Date Authorised. <b>03/10/2016</b>
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This SOP applies to all qualified medical and nursing staff, Allied Health Professionals and Health Care Support Workers working at the LCRF.

This SOP does not apply to situations of emergency eg collapse and acutely unwell patients. Refer to LCRF SOP 02 for the management of medical emergencies.

## **PROCEDURE**

### **1. WHO?**

It is the responsibility of all LCRF clinical staff to:

1. Have read and understood this SOP.
2. Have read and understood documents related to the topic as specified in the SOP.
3. Follow the procedures in the SOP and use clinical judgement where applicable.
4. Maintain and update their knowledge and skills in the management of medical emergencies.

### **2. WHEN?**

This SOP must be followed prior to admitting participants onto the Lancashire CRF.

This SOP must be followed in the event a participant becomes unwell.

### **3. HOW?**

1. A medical emergency is any acute event which is or which has the potential to be life threatening. In the case of a medical emergency refer to LCRF SOP 02 for the management of medical emergencies.
2. If a patient attending the LCRF complains of a new or worsening symptom the treating nurse should obtain further details including a history of the symptoms, timescales and severity etc.
3. If the symptoms are felt due to the underlying disease or treatment for which they are attending the LCRF this should be documented within the appropriate research AE/SAE log.
4. The treating nurse should contact the PI or nominated deputy (if they are not already aware) to ensure no further action is required and/or safe to proceed with study interventions. Nurses should use clinical judgement and can escalate to senior nurses within the unit for advice.
5. If appropriate check full set of clinical observations. This must be documented on a Lancashire Teaching Hospitals NHS Foundation Trust observation chart. If the NEWS is 5 or more call the outreach team (Bleep 3388) and inform PI immediately for medical review.
6. If the patient requires a medical review it is the responsibility of the PI to review the patient and arrange further management. If the patient is stable to transfer out of the LCRF for assessment eg to outpatients or the cancer centre, this can proceed at the discretion of the PI/co-investigator.
7. The LCRF team should assist with investigations such as ECG, venepuncture and arrange any transfer for radiological investigations requested.

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8. It is the responsibility of the PI or delegated deputy to give advice on any medical queries to CRF staff. If patients require further assessment or admission to the hospital it is the responsibility of the PI to deputy to arrange transfer or further assessment.
9. If a patient requires transfer for admission/assessment in another area then this should be done in accordance with LTHTr RMP-C-116, Transfer of Patients Common Core Document, Version 1.3. LCRF staff should complete the LTHTr Adult Patient Transfer Information (Inter and intra Hospital/Department) form (MS118) and handover to nursing staff taking responsibility for the patient.
10. It is the PIs responsibility to ensure medial handover to the admitting clinician or ED consultant.
11. The Investigator is responsible for ensuring medical cover is available for the participants within the study at all times. Medical cover must be prearranged by the Principle Investigator and the name and contact information (bleep/pager) of the responsible clinician must be given to the nurse responsible for the study. The responsible clinician must be aware of the details of the study, the procedures to be performed and the nature of any anticipated clinical events. If medical cover is not in place the CRF can suspend research interventions until this is resolved.

#### 4. OTHER RELATED PROCEDURES;

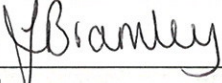
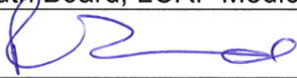
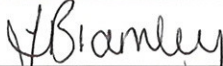
Lancashire Teaching Hospitals Adult Patient Transfer Information (Inter and intra Hospital/Department) form (MS118)

Lancashire Teaching Hospitals RMP-C-116, Transfer of Patients Common Core Document, Version 1.3.

#### CONSULTATION WITH STAFF AND PATIENTS

Name	Role
Louise Saynor	LTHTr Resuscitation Lead

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Sign Off Lancashire Teaching Hospitals			
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<b>Name and Position</b>	Jacqueline Bramley, LCRF Manager		
<b>Signature</b>		<b>Date</b>	03/10/16
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<b>Signature</b>		<b>Date</b>	3.10.16
<b>Authorised for release by:</b>			
<b>Name and Position</b>	Jacqueline Bramley, LCRF Manager		
<b>Signature</b>		<b>Date</b>	03/10/16

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