NIHR | Lancashire Clinical Research Facility

STANDARD OPERATING PROCEDURE

MANAGEMENT OF MEDICAL COVER REQUIREMENTS

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RESEARCH AND DEVELOPMENT

LCRF

BACKGROUND

The NIHR Lancashire Clinical Research Facility (LCRF) at Lancashire Teaching Hospitals provides a supportive, participant-focused environment to host quality research of the highest scientific excellence from study design to completion.

The LCRF supports both inpatient and outpatient clinical research studies from a wide range of disciplines, led by investigators in both adult and paediatric specialities.

Where studies require an appropriately qualified doctor, who is trained in the study protocol and study procedures, this is usually provided by the research team. However, the LCRF employs a Senior Research Fellow (SRF) to provide medical cover when requested upon application.

PURPOSE/OBJECTIVE

The purpose of this SOP is to:

1. To describe the procedures for identifying and delegating medical cover provision for clinical trials/ research studies within the LCRF
2. To define individual roles and responsibilities of those involved in the medical management of participants on clinical trials/ research studies within the LCRF.
3. To provide a clear plan for the medical management of any clinical concerns for the participant and associated referral pathways.

SCOPE

This SOP sets out the medical cover requirements and referral pathways in acute medical emergencies for high and low risk studies carried out at LCRF:

High risk studies are defined as studies where the clinical condition of the target population, or the intervention/ treatment being investigated, can affect participant safety.

Low risk studies are defined as studies where there is minimal intervention and therefore minimal risk to participant's safety.

This SOP applies to all members of staff who are directly or indirectly involved in the medical care of participants in the LCRF.

PROCEDURE

1. WHO?

1.1. It is the responsibility of staff who are directly or indirectly involved in the medical care of participants at the LCRF to:

1.1.1. Have read and understood this SOP.

1.1.2. Ensure they are adequately trained to carry out procedures required within specific study protocols.

1.1.3. Undertake this procedure according to the SOP.

2. WHEN?

2.1. This SOP must be followed when:

2.1.1. Setting up a clinical research study in the NIHR Lancashire Clinical Research Facility.

2.1.2. Prior to admitting patients (inpatient, outpatient, and day visits) to the LCRF.

3. HOW?

3.1. Identification of medical cover requirements

3.1.1. If LCRF medical cover provision is required, it should be clearly outlined in the LCRF application form and agreed by the Study Review Group.

3.1.2. Studies requiring medical cover provision by LCRF staff must be fully costed by the Industry Lead and LCRF Manager, or their delegate, at the earliest opportunity.

3.1.3. The Lead Nurse must carry out a feasibility assessment on all studies at the set-up stage. Any patient safety issues in relation to medical cover requirements must be identified, with actions to protect participants agreed by the Study Review Group meeting and Early Phase Study Review Committee (EPSRC) as required (all phase I/II interventional experimental medicine trials).

3.2. Delegation of medical cover

3.2.1. The Principal Investigator (PI) maintains overall responsibility for the provision of medical cover, but the LCRF Senior Research Fellow can be delegated to perform specific tasks, including but not limited to:

- Obtaining informed consent.
- Obtaining medical history and performing physical examinations.
- The documentation of Adverse Events (AE's), Adverse Reactions (ARs), Serious Adverse Events (AE's) and Suspected Unexpected Serious Adverse Reactions (SUSAR's) and the determination of their relationship to the study protocol.
- Any specialist assessments, examinations and procedures required by the protocol.
- Signing prescriptions required for study treatments.
- Provision of continuous monitoring e.g., during an infusion or after drug exposure, as defined in the trial protocol.
- Acting as the emergency contact for Clinical Trials of Investigational Medicinal Product (CTIMP) studies

3.2.2. The Study Lead must prepare a delegation of duties log for the study, which must include clearly identified responsibilities for the provision of all aspects of medical cover. This must be signed by the Principal Investigator.

3.2.3. Each individual must sign the delegation log for those responsibilities assigned to them and must only accept delegated responsibility for providing medical cover if they are medically competent and are familiar with the specific study protocol and procedures. Delegation of medical cover responsibility must also be as per Sponsor requirements for the study.

3.3. Acute medical emergencies and referral pathways

All LCRF studies are risk assessed in accordance with LCRF-SOP-19 Risk Assessment and Mitigation SOP.

3.3.1. High risk studies (in hours)

- The PI or sub-investigator must always be contactable during study visits to assess the participant should any medical emergency, or new acute medical condition occur, and if physically present at the LCRF should act as first responder in an emergency.
- If the PI is not physically present at the LCRF, the person with delegated responsibilities must act as first responder and assess the participant's condition.
- If the PI of the study is a consultant at Lancashire Teaching Hospitals (LTHTr) and the change in the participant's condition is related to their specialty area, the person with delegated responsibilities must request an urgent consultation from the PI or his/her designee to assess the participant.
- If the PI of the study is not a consultant at LTHTr or if the change is not related to their specialty area, the person with delegated responsibilities must request a consultation from the on-call general medicine, critical care, or surgical registrar, depending on the nature of the acute medical problem. Discussion of which speciality to contact in an emergency must have taken place in the set-up phase and written approval given.

3.3.2. High Risk studies (out of hours)

- If the PI is not physically present at the LCRF, the person with delegated responsibilities must act as first responder in an emergency and assess the participant's condition.
- The first responder must inform the PI and the Senior Research Fellow about any acute changes in the participant's condition immediately.
- The first responder must next request a consultation from the on-call General Medicine, Surgery Registrar or Speciality Registrar, depending on the nature of the clinical problem. The process of making contact must be discussed before the participants are recruited.
- Depending on the findings of the consultation, the participant should be transferred to an appropriate acute ward for clinical care, if required. The PI must discuss and confirm the admission pathway in the study set up phase. If a ward bed is not available, there may be

circumstances under which a patient must be transferred to the ED department for further assessment and onward care. If the PI of the study is a consultant at LTHTr and the change in participant's condition is related to their specialty area, the participant should be admitted to the ward under the care of the PI.

- If the PI of the study is not a consultant at LCRF, or if the change is not related to their specialty area, the participant should be admitted to the ward under the care of the on-call Medical or Surgical Consultant. If a ward bed is not available, there may be circumstances under which a patient must be transferred to the ED department for further assessment and onward care.

- The nurse looking after the participant must follow the participant transfer and follow-up procedures documented in the Management of Medical Emergencies SOP (LCRF-SOP-02) and use the LCRF Study Procedure Manual for handing over the patient's care.

3.3.3. Low risk studies

- The physical presence of the PI is not required during study visits to assess the participant should any medical emergency occur.

- The Nurse Lead must inform the PI and/ or the person with delegated responsibilities about any acute change in participant's condition immediately.

- According to the advice given by the PI and/or by the person with delegated responsibilities and if the PI is unable to attend, the PI must next request a consultation from the on-call general medicine or surgery registrar by bleeping.

- Depending on the findings of the consultation, the participant should be transferred to an appropriate acute ward for clinical care, if required. The Study Procedure Manual should be available to the acute ward staff in order to safely hand over the participant. If a ward bed is not available, there may be circumstances under which a patient must be transferred to the ED department for further assessment and onward care.

- If the PI of the study is a consultant at LCRF and the change in participant's condition is related to their specialty area, the participant should be admitted to the ward under the care of the PI.

- If the PI of the study is not a consultant at LCRF, or if the change is not related to their specialty area, the participant should be admitted to the ward under the care of the on-call Medical or Surgical Consultant. If a ward bed is not available, there may be

circumstances under which a patient must be transferred to the ED department for further assessment and onward care.

- The nurse looking after the participant must follow the participant transfer and follow-up procedures documented in the Management of Medical Emergencies SOP (LCRF-SOP-02).

3.3.4. In all cases of acute emergency, the LCRF Resuscitation Team should be contacted as per LTHTr resuscitation policy and the LCRF SOP for Managing Medical Emergencies (LCRF-SOP-02).

3.4. **Out of Hours Medical Cover**

3.4.1. As per ICH Good Clinical Practice the Principal Investigator (PI) has full responsibility of the clinical trial at site, this includes providing medical cover out of hours.

3.4.2. It is the responsibility of the PI to ensure there is adequate medical cover throughout the duration of the trial, which includes making provisions outside of normal working hours (Monday – Friday 8-6pm).

3.4.3. In case of acute medical issue outside of core working hours, please refer to trial specific SOP for management and escalation guidelines where applicable.

4. OTHER RELATED PROCEDURES;

Management of Medical Emergencies SOP (LCRF-SOP-02).
Study Procedure Manual
LCRF-SOP-19 Risk Assessment and Mitigation

CONSULTATION WITH STAFF AND PATIENTS

Name	Role
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LCRF Operational Group	Review and Approval

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