STANDARD OPERATING PROCEDURE

Risk Assessment and Mitigation

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RESEARCH AND DEVELOPMENT

LCRF

BACKGROUND

The NIHR Lancashire Clinical Research Facility (LCRF) s set up to deliver clinical research studies. All clinical studies, regardless of their phase, bring an element of risk to the organisation that must be assessed and mitigated to ensure participant safety.

PURPOSE/OBJECTIVE

The purpose of this procedure is to describe the responsibilities held by LCRF staff and clinical study teams for assessing and mitigating risk for participants' visits held in the LCRF.

SCOPE

This SOP applies to all staff involved in the setting up of clinical studies in the LCRF and in participants' visits held in the NIHR Lancashire Clinical Research Facility.

PROCEDURE

1. WHO?

It is the responsibility of all LCRF clinical staff involved in the care of participants to

- Have read and understood this SOP.
- Follow the procedures in the SOP and use clinical judgement where applicable.
- Have read and understood documents related to the topic as specified in the SOP.

2. WHEN?

This SOP must be followed when setting up any clinical study within the LCRF. All clinical studies supported by the LCRF are reviewed for support which includes assessment of staff resource, clinical equipment and identification of training needs. Pharmacy clinical trials staff will independently assess supply, storage, stability and dispensing instructions.

3. HOW?

3.1 Risk Assessments

3.1.1 A comprehensive risk assessment must be completed for all studies being delivered in the LCRF. The study risk assessment form is part of the LCRF assessment and approval process. This must be completed at the planning and set up stage by the LCRF team.

3.1.2 The risk assessment template used will depend upon the intensity and phase and the organisation delivering the trial, of the clinical study requiring LCRF support. For phase III and observational/epidemiology clinical studies the LCRF will accept the individual organisations internal risk assessment form. If no risk assessment has been provided the UK CRF Network Risk Assessment template will be used. Early phase (First in Human/phase I/phase II) clinical studies require the LCRF EPRC Risk Assessment must be thoroughly completed, reviewed and approved by the Early Phase Study Review Committee.

3.1.3 Clinical staff (PI, delivery team) will assess the study risk and complete the required risk assessment and submit to the LCRF Lead as part of the LCRF study approval process. This will ensure that the risk of harm to research participants, LCRF staff and visitors to the facility is minimised as practicably possible. Each study submitted will be given a risk score generating an overall estimate of risk significance. Significant risks will be identified as part of this process which may require further review and/or action(s).

3.1.4 The risk score is calculated using the likelihood and impact/consequence of an adverse event occurring (Table 1)

Hazard	Something (e.g. an object, a property of a substance, a phenomenon or an activity) that can cause adverse effects
Likelihood	The likelihood of a hazard resulting in an incident (1= rare; 2= unlikely, 3=possible, 4=likely; 5=highly likely)
Consequence/Impact	The severity of the incident if it were to occur (1=insignific ant; 2=minor, 3=moderate; 4=severe, 5=catastrophic)
Risk Score/Significance	The likelihood of a hazard resulting in an incident set against the severity of that incident if it does occur. The risk score is calculated by multiplying: Consequence (C) x Likelihood (L) = Risk Score/Significance (R)

3.2 Risk Mitigation for Clinical Visits

The documents and processes required to mitigate risk will depend upon the risk level identified in the risk assessment. In addition to the quality system SOP's, mandatory training and study specific training, additional steps will be implemented depending on the risk of the study and the procedures required to deliver the study protocol. Study protocols and Sponsor contract will dictate any specialist knowledge and expertise which may require additional steps to those outlined in **table 2**.

Table 2

High	• Protocol trained medic present in the LCRF for all patient visits where the intervention is being administered. • During intervention, two ILS trained research nurses (if a children's study 2 paediatric research nurses PILS trained) on duty and a senior clinical lead. • Communication procedure with critical care, resus team and on call anaesthetists completed as per the communication flowchart. • Complete NEWS2/PEWS (Neuro NEWS2). • IMP delivery/procedure must be delivered in core working times Monday to Friday.
Medium	• Study medic/LCRF medic on site. • Minimum two ILS (or PILS if a children's study) trained research nurses. • IMP delivery/procedure within core working hours Monday to Friday. • Communication procedure with critical care, resus team and on call anaesthetists completed as per the communication flowchart.
Low	• Study team up to date contact details readily available. • Two AIMS/BLS trained research nurses (PBLS for children's' studies).

The LCRF Lead and Medical Director will review the risk score and mitigation/management strategies to ensure there are sufficient procedures and processes identified to manage the risk safely. If the study is FiH or phase I the risk assessment and mitigation strategies will be reviewed by the Early Phase Study Review Committee as part of their approval process.

4. OTHER RELATED PROCEDURES;

CONSULTATION WITH STAFF AND PATIENTS

Name	Role
NIHR Operational Group	Ratification
Jacqueline Bramley	LCRF Lead
Rebecca Wilby	Research Access Project Manager / Quality Assurance Lead

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