NIHR | Lancashire Clinical Research Facility

STANDARD OPERATING PROCEDURE

Out of Hours Cover for Clinical Trials

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RESEARCH AND DEVELOPMENT

LCRF

BACKGROUND

The National Institute of Health & Care Research (NIHR) Lancashire Clinical Research Facility (LCRF) is a purpose-built unit within Lancashire Teaching Hospitals NHS Foundation Trust (LTHTr), providing access to Early Phase Experimental Medicine research trials to the population of Lancashire and South Cumbria.

The Principal Investigator (PI) has ultimate responsibility for all aspects of a trial conducted through the LCRF. Some of these tasks may be delegated to appropriately trained and experienced staff and this is documented in the study delegation log. For Clinical Trials of an Investigational Medicinal Product (CTIMP) the PI must have received appropriate training on the investigational medical product (IMP) and the current approved protocol and Investigator Brochure.

The MHRA definition of an Adverse Event (AE) is any untoward medical occurrence in a trial which does not necessarily have a causal relationship with the treatment. In such events it is important that the PI or appropriately delegated medically qualified individual is available to give advice where required.

PURPOSE/OBJECTIVE

The purpose of this Standard Operating procedure (SOP) is to provide guidance to PIs and research study teams to ensure that the PI or an appropriate medically qualified individual is available (specifically outside of working hours) to give advice on any untoward medical occurrence in a trial.

SCOPE

This SOP applies to all members of research teams (and specifically Principal Investigators/Co-Investigators) conducting CTIMPs within the LCRF, for which it is reasonably expected that out-of-hours (OOH) clinical advice (including unblinding) may be required.

PROCEDURE

1. WHO?

- The PI is ultimately responsible for all aspects of a trial therefore they must have read and understood this SOP. As likely the most senior member of the study team involved in the trial and with an in-depth knowledge of the investigational medicinal product, and disease area, they bear responsibility for safeguarding participants including assessment and management of all adverse events.
- This SOP must also be read by Sub/Co-Investigators and other team members who may be involved in OOH cover for a trial.
- The Lead nurse of the trial must have read and understood this SOP.

2. WHEN?

- This SOP must be referred to during the setup of any clinical trial involving the LCRF for which it is reasonably expected that OOH clinical advice may be required from the PI or appropriately delegated individual.

3. HOW?

OOH advice for participants.

For First in human (FIH) and Phase 1 trials, participants must be provided with 24-hour emergency contact number.[1,2] This number will connect to hospital teams who will then contact the Principal Investigator or appropriate Sub-Investigators.

There are a number of methods by which participants are provided with the contact details of the research team. This may be via an office number, ward/switchboard number, oncology helpline or trial-specific personal mobile telephones.[1] This may also include a list of appropriately delegated study staff. The LCRF will facilitate PIs and Sub-Is to have remote access to trial specific documentation including the protocol via the EDGE system. This procedure must be agreed as part of the feasibility process.

All methods of contact must be formally tested prior to recruiting participants onto the trial. Testing of the emergency contacts must be documented and retained.[1]

The LCRF must also hold the contact numbers for participants to ensure that they are able to be contacted outside the unit should the need arise.[1]

Should OOH cover not be provided by the CRF for a trial (i.e. it is an investigator team providing OOH cover) then study documentation must specify how this is tested.[2]

Appropriate arrangements must also be in place to ensure that there is cover for those staff who are travelling and for staff who are on holiday or on sick leave.[1] This must ensure that agreed OOH contact methods are available on a permanent basis regardless of individual availability.

OOH advice for investigators.

For Phase 1 trials best practice is that delegated staff must have access to the sponsor's medical monitor or defined delegates whom they can contact by telephone at any time. A cascade of contactable personnel on the sponsor's side must be available to the investigator site – ideally this can be added to the study protocol or, failing this, be detailed in a separate document.[3]

This documentation should be readily accessible via the EVOLVE electronic health record (EHR) or other EHR system as appropriate (e.g. iQEMO for oncology trials, and on the EDGE system). Responsibility for this lies with the Research nursing team/Clinical Fellow.

For later phase trials provision of OOH medical advice for investigators provided by the sponsor can be determined by the sponsor using a risk-based approach, depending on the trial specifics and population under investigation.[1]

4. References:

1. MHRA Good Clinical Practice Guide 2012
2. UKCRF Framework for Conducting Highest Risk Phase I and Experimental Medicine Studies within NIHR Clinical Research Facilities and wider NHS acute Trusts Version 1.0 – November 2020
3. ABPI Guidelines for Phase I clinical trials 2018 edition

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