Royal Papworth Hospital
NHS Foundation Trust

Research and Development, Heart and Lung Research Institute, Clinical Research Facility (R&D HLRI CRF) Medical Cover for Research Studies

Document Number: R&D SOP099

Staff involved in development: *Job titles only*	Senior R&D Manager, HLRI CRF Operations Manager, HLRI CRF Clinical Director, RPH Medical Director, HLRI CRF Research Nurse Team Leader
Document author/owner:	HLRI CRF Operations Manager
Directorate:	Research and Development
Department:	Research and Development / HLRI CRF
For use by:	Staff working at the HLRI CRF
Review due:	June 2026

Summary of Amendments

Version Number	Modification:
Version 2	**General review to include relevant RPH policies. SOP number changed from SOP098 to SOP099**

Key Points of this Document

To document the procedure and requirements for providing medical cover for clinical trials in the HLRI CRF

1 Purpose and Contents

To ensure clearly identified, accessible, and appropriate medical cover for all patients and healthy volunteers participating in research in the HLRI CRF.

Definitions

Medical Cover	Qualified medical doctors providing care for study participants
Research Link Nurse	HLRI CRF Named nurse for the clinical research study/trial
Study Flow Sheet	Aide memoire to the study protocol
RESPECT	Recommended Summary Plan for Emergency Care and Treatment
PI	Principal Investigator
HLRI	Heart and Lung Research Institute
CRF	Clinical Research Facility
SAB	Scientific Advisory Board
ALERT Team	Emergency Response Team (
IMP	Investigational Medicinal Product
RGM	Patient Royal Papworth Hospital Number

2 Roles & Responsibilities

This SOP applies to investigators and other staff using the HLRI CRF.

It is the responsibility of the Principal Investigator (PI) to ensure that:

- arrangements are made for appropriate medical staff cover, familiar with the trial protocol to be in place at any time that a research participant is present on the HLRI CRF.
- HLRI CRF staff are provided with up-to-date details including contact numbers of identified medical cover.

It is the responsibility of the Research Link Nurse to ensure that contact information is recorded on the Study Flow Sheet (HLRI CRF 090) and is kept up to date.

It is the responsibility of the nurse allocated to look after a research participant to ensure that medical cover is in place prior to commencing any research interventions.

3 Policy

This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

4 Procedure

The following sections provide a description of the processes to be followed when implementing this document's procedures:

4.1 Level of medical Cover required

Every research participant attending the HLRI CRF requires medical cover, regardless of the nature of the study or whether they are a healthy volunteer or a patient.
The nature of the medical cover required will be determined in advance by the Scientific Advisory Board (SAB) through the study risk assessment process.

The level of medical cover required is confirmed in the SAB approval letter.

There will be a minimum provision of:

- Specialist telephone advice by a medically qualified person familiar with the study protocol.
- The presence on site (Cambridge Biomedical Campus, unless stated otherwise) of a nominated and agreed medically qualified person who is familiar with the study protocol and is able to attend the HLRI CRF in an emergency situation. This will include agreement upfront on whether the nominated medically-qualified person is required to be within the HLRI or accessible on the biomedical campus.

  The HLRI CRF studies will require participants to be registered on Lorenzo. For these studies, it is the responsibility of the study team to ensure that the medical cover has appropriate Lorenzo access and training in place. The CRF will facilitate training for those who require this.

4.2 Agreement of medical Cover

The Research Link Nurse for the study is responsible for confirming details of the medical cover at the study set-up meeting with the PI or their designate.

HLRI CRF Study Set-up Checklist (HLRI CRF FRM 088) must be completed to indicate:

- Names and contact numbers of medical staff providing medical cover.
- Details of the agreed nature of the medical cover

The study-specific flowsheet (HLRI CRF FRM 090) must be completed to include the contact details and nature of the medical cover on the front page (ref HLRI CRF Study flowsheet).

As part of the visit preparation: ALERT Team must be informed the day before of any IMP Dosing date, giving RGM of research patient, exact location (Inpatients/Outpatients and bed/room number) and time of the visit.

The following RPH policies are considered relevant for the management of this SOP

- DN538 – Management of deteriorating patient procedure
- DN749 - Recognition of the Deteriorating Patient at Night Policy
- DN309 – Resuscitation Procedure
- DN134 – CPR Scoop Run guidelines for ward arrests.
- DN771 – Self presenters or deteriorating outpatients at Royal Papworth Hospital Guidelines
- DN765 – Inter Hospital Transfer Guideline for Patients between Cambridge University Hospitals & Royal Papworth Hospital
- DN495 -Oxygen emergency prescribing and administration in adults trust wide

7.3. Confirmation of Medical Cover

On the day of study attendance, the nurse looking after the research participant will contact the medical cover contact (telephone or bleep) to verify that appropriate medical cover is still available. If no cover is clearly identified, the CRF team will escalate to the CRF Operations Manager to find alternative medical cover, escalate or take the appropriate action, including cancelling the appointment if deemed necessary.

7.4 Patient Transfer from HLRI to RPH (reference DN765)

DN765 describes the patient transfer from HLRI to RPH. To note:

- The link corridor, which is access controlled, is to be used for the transfer of appropriate patients between HLRI and RPH and between RPH and Cambridge University Hospitals.
- Patients who are assessed as not being appropriate for transfer using the link corridor should be transferred by ambulance.
- The arrangements for transfer HLRI to RPH are described in DN765, section 7.3 . Latest version of the DN policy should be followed.
    - This includes the need of a medical referral to appropriate area and to be accepted. HLRI team would contact RPH bed managers in hours or Operational Night Matrons (out of hours).
    - Transfer and expected timeframes communicated to ward team.
    - All elective transfers requiring nurse escort to be made with a member of the HLRI clinical team. All non-elective transfers to be made with an appropriate clinical escort as identified by member of the ALERT team.
    - HLRI contacts OCS service desk to arrange portering (OCS Services begin at RPH corridor side)
    - Clinical team ensure all documentation is up to date prior to transfer (EMR transfer letter (nursing) . Appropriate discharge summary (medical). ReSPECT Form if applicable Patient property form)
    - Nurse in charge informs next of kin of transfer plan and ensure patient's property packed documented for transfer.
    - Nursing team checks patient is safe and ready for transfer,
    - Participant is escorted through link corridor to receiving ward/ unit in RPH and will be clinically handed over to RPH receiving ward/unit.

Facilities and Equipment (between HLRI and RPH)

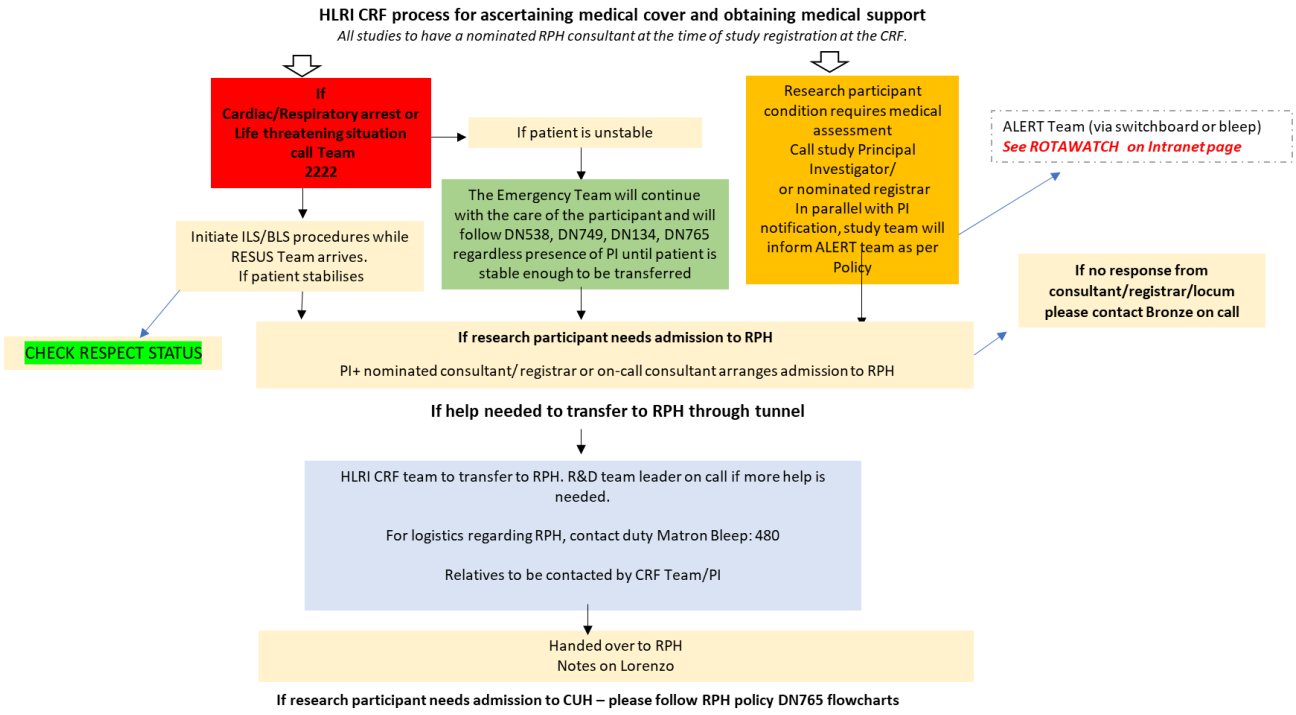
At HLRI there are two resuscitation trolleys within the CRF

There is a patient transfer bag located at the HLRI with equipment next to the lifts.

This is to be used for transfers of all patients from HLRI to RPH and returned to the HLRI location after transfer. (This transfer bag is the responsibility of the HLRI CRF staff for transfers).

There is signage within the link corridor to assist with directions.

There is a telephone located in the link corridor.



If no response from PI or nominated consultant/registrar, this will be investigated and reported to the CRF Management Committee and RPH QRMG (Quality and Risk Management Group). Also, a Datix report will be carried out ASAP.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g., Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(This version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2018)
Key related documents:	Trust Research Policy Trust Policy DN001 Document Control Procedures HLRI CRF FRM 090 Study flowsheet HLRI CRF FRM 088 Study Set-up Checklist DN538 – Management of deteriorating patient procedure DN749 - Recognition of the Deteriorating Patient at Night Policy DN309 – Resuscitation Procedure DN134 – CPR Scoop Run guidelines for ward arrests. DN771 – Self presenters or deteriorating outpatients at Royal Papworth Hospital Guidelines DN765 – Inter Hospital Transfer Guideline for Patients between Cambridge University Hospitals & Royal Papworth Hospital DN495 -Oxygen emergency prescribing and administration in adults trust wide

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	DATE June 2026

I certify the contents of this SOP has been reviewed and ratified.

DocuSigned by:
Patrick Calvert
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05-Sep-2023

Signed by Dr Patrick Calvert, Clinical Director of R&D

Date

SOP Release Date: …….