STANDARD OPERATING PROCEDURE

S66 – Managing Medical Emergencies and Incidents for research teams based outside the main hospital template.

Version	2
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Controlled document

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DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
1.0	12/12/2015		to establish a procedure for managing medical emergencies within Research, outside of the main Hospital template
2	18/01/2021	Samantha Keenan	to amalgamate two separate SOPs for the above to encompass all buildings outside of the main Hospital template including RDE NHS sites.

Associated Trust Policies/ Procedural documents:	*NEWS 2 observation chart* *Safety Reporting SOP 22*
Key Words:	*Emergency Transfer* *Deteriorating patient* *Immediate Life Support* *Transfer to ED/AMU*
In consultation with: CRF Operations Manager, (RD&E Version 1 creator)	

Contents

1 INTRODUCTION

Within the Royal Devon and Exeter NHS Foundation Trust (RD&E), research participant visits are conducted in a number of locations. Many are located on the main Wonford site in satellite buildings e.g. the Child Health Building (CHB), Macleod Diabetes & Endocrine Centre (MDEC), Mireille Gillings Neuroimaging Centre (MGNC) and the Research Innovation Learning and Development (RILD) building. Therefore, research staff will need specific instructions for dealing with medical emergencies or incidents when working in these areas. Clinical emergencies are dealt with by calling (9) 999 and an ambulance team will respond.

2 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the process to be followed when dealing with medical emergencies or incidents for research staff who conduct research participant visits.

3 SCOPE

This SOP applies to all research staff conducting research visits outside of the main hospital template.

4 DEFINITIONS

Medical Emergency
For the purpose of this process, a medical emergency may be defined as: 'An acute/urgent illness or injury which poses an immediate risk to a person's life or long term health, requiring immediate medical attention' e.g. cardiac arrest, stroke and anaphylaxis.

Medical Incident
For the purpose of this process, a non-medical emergency may be defined as: 'Someone who whilst requiring treatment or support, does not require an urgent response and the presenting condition is non-life threatening' e.g. fall with laceration or peripheral fracture.

Minor illness or injury
For the purpose of this process a minor illness or medical occurrence may be defined as: 'An untoward medical illness or injury which can be dealt with through Minor Injuries or General Practice Services' e.g. sprain, rash, raised blood pressure, recurrent cough.

Outside main hospital template
For the purpose of this process outside the main hospital template may be defined as 'any clinical area where research participants are seen in a Trust satellite building such as the Child Health building, RILD, MDEC or MGNC.

AE	Adverse Event
AED	Automated External Defibrillators
AMU	Acute Medical Unit
BLS	Basic Life Support
CTU	Clinical Trials Unit
DATIX	Trust incident reporting system
ED	Emergency Department

GOG	R&D Governance Oversight Group
ILS	Immediate Life Support
IMP	Investigational Medicinal Product
MDEC	Macleod Diabetes & Endocrine Centre
MGNC	Mireille Gillings Neuroimaging Centre
NEWS2	National Early Warning Score system
PI	Principal Investigator
PRC	Patient Recruitment Centre
R&D	Research & Development
RILD	Research Innovation Learning and Development
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate

5 DUTIES AND RESPONSIBILITIES OF STAFF

It is the responsibility of the relevant research team to have carried out a risk assessment before seeing study participants in a building outside of the main hospital template. This will protect the safety and welfare of subjects and ensure that the setting is suitable for the nature of the study visits to be carried out.

Research staff are expected to provide care to study participants suitable to their level of competence, A more detailed description of responsibilities can be found in the Procedures Section 6 below.

Delivery Team Leads are responsible for ensuring their research nurses receive appropriate training which includes annual training and updates incorporating Basic Life Support (BLS), Immediate Life Support (ILS), anaphylaxis, the use of Automated External Defibrillators (AED) and emergency scenario training.

It is the responsibility of the research staff undertaking study visits in a building outside of the hospital template to be familiar with and work to this procedure. Research staff should be familiar with the facilities, exits and emergency equipment. They are also responsible for documenting any medical emergencies or incidents in the clinical notes and raising a Datix report if appropriate.

It is the responsibility of staff caring for research participants to know the location of ED and AMU. Transportation of a deteriorating or unwell research participant must be performed by a Registered Nurse with appropriate support whether that be with an ambulance crew, medical Doctor or other Healthcare professional.

6 PROCEDURES

6.1. Dealing with a medical emergency outside the main hospital template

Seek assistance from the delegated medical cover available and summon additional support from colleagues, either verbally or by use of the emergency call bell system.

If required, an ambulance can be called by dialling (9) 999 from the nearest telephone.

Clinical staff are expected to provide emergency care suitable to their level of competence, e.g. Basic Life Support or Intermediate Life Support.

Full assessment of vital signs must be undertaken and documented using available resources.

Non clinical staff are expected to assist with calling for an ambulance and direct ambulance staff to the correct location. This may require if possible for a clinically trained member of the team to stand outside of the appropriate building and making themselves known to the emergency crew, then directing them accordingly. If a clinically trained member of the team is not able to do this, a non-clinical member of the team (e.g Administrator or porter) with appropriate instruction can go outside and make themselves known to the emergency crew then directing them accordingly.

6.1.2 Prior to transfer

If the decision is made to transfer the research participant out of the external Facility using the ambulance service, the following procedures are to be followed;

- Dial (9)999 to summon the ambulance crew
- A staff member should be outside the building to greet the ambulance crew. The ambulance crew would then be taken to the patient where the clinical team can hand over the condition of the patient.
- Designated medical doctor will liaise with ED/ AMU and the ambulance crew. This handover should include research participant personal details, details of the study, the IMP (if relevant), symptoms, intervention, any infection control issues, and the most recent vital signs and NEWS2. They should also confirm the estimated time of arrival. The responsible nurse may also liaise with the nurse in charge of the receiving area.

A pack containing transfer related documentation is located above the resuscitation trolley and should be used when transferring by ambulance or wheelchair. The pack contains;

- Transfer checklist (see app 1)
- Handover sheet (see app 2)
- Observation chart
- Outpatient prescription chart
- Cannula care plan

A minimum of 2 packs should be available at all times. It is the responsibility of the nurse leading the transfer to replace the used pack (as soon as practically possible).

The nurse leading the transfer will inform the next of kin and provide these details to the receiving area.
Collect any equipment required for transfer that is not available via the ambulance crew.

Ensure that any existing medication accompanies the research participant.
Ensure that a copy of the Participant Information Leaflet and Consent is in the notes and the incident is fully documented.

6.1.3 On arrival and after transfer

Give a comprehensive verbal handover to the receiving area including the study and IMP details.
Ensure any equipment is cleaned (and an ‘I am clean’ label attached) and returned to the appropriate area.
The leading nurse will inform the PI of the incident and report the SAE to the sponsor and R&D.
Datix this event.
Establish whether this requires a formal debrief and act as a learning opportunity.

6.2. Dealing with a medical incident outside the main hospital template

For a non-life threatening incident which requires medical assessment contact the Principal Investigator or a study Doctor in the first instance.

Clinical staff are expected to provide clinical assessment, treatment and advice in order to deal with

the medical incident suitable to their level of competence.

If the PI or study Dr are not available within a reasonable timeframe and assessment is required before allowing the research participant to leave the Trust, transfer research participant to the Emergency Department (ED). Also see above 6.1.2 and 6.1.3 for a safe transfer.

If necessary, there is an outdoor wheelchair available in the RILD building (within the CRF) and one wheelchair is located under the stairs in the PRC within the Child Health Building. These can be used to move research participants from outbuildings to the main hospital template as long as 2 members of staff are available to transport the research participant, taking a mobile phone in case of emergency. 1 member of staff must be clinical (Nurse, AHP, Medic) the other can be non-clinical (administrator, porter, security). You will need an ID badge with access to RILD or the Child Health Building to access these wheelchairs or ask at reception.

Call ED on x2303 (Minors) or x2319 (Majors) in advance to warn them of transfer.

For research participants who are not able to be transferred via wheelchair, the ambulance service must be contacted via (9) 999.

After research participant transfer to ED ensure the outdoor wheelchair is returned to the RILD/ Child Health Building.

Staff involved in the transfer must ensure that the PI is informed of the event if the PI was not present at the time of transfer. In addition the event should be reported as a serious adverse event to the study Sponsor and recorded on Datix.

6.3 Dealing with a minor illness or injury outside the main hospital template
For minor illness or medical occurrences that are identified during a research participant visit, alert the PI or Study Doctor and ask the research participant to visit the GP or minor injuries unit. Report adverse event or serious adverse event according to the individual study protocol and the Safety Reporting SOP 22.

Research participants can be sent unaccompanied to Minor Injuries or their GP.

6.4 Useful numbers:

Porters:	x2016
Security:	x6450 or mobile telephone 9/ 07799 342 821
ED Minors pt flow coordinator:	x2303
ED Majors pt flow coordinator:	x2319
Site Practitioner:	fast bleep 772 2172 followed by the extension number.
Emergency Ambulance:	(9) 999

7 DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the RDE Research website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

7.3 If applicable, a training log within the Investigator Site File/ Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.

8 MONITORING COMPLIANCE AND EFFECTIVESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	A risk assessment should be carried out to assess the suitability of the setting for seeing research participants.	Documented risk assessment in ISF.
2.	Delivery Team Leads are responsible for ensuring their research nurses receive annual training and updates in Immediate Life Support (ILS) including anaphylaxis and the use of Automated External Defibrillators (AED).	Relevant training evidenced in staff training records.
3.	It is the responsibility of the research staff undertaking study visits in a building outside of the hospital template to report any medical emergencies or incidents which occur.	Any medical emergencies or incidents should be recorded in the clinical notes, Datix report if appropriate and AEs or SAEs reported to R&D where appropriate.
4.	Issues arising from compliance with or confusion over the contents of the policy may be raised as general questions to the Quality Assurance Team. If large numbers are received this would prompt a review of the policy.	Discussion at GOG meetings, documented in meeting minutes

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9 ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the RDE Research website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10 REFERENCES

Appendix one: **Research Transfer Checklist**

When transporting an unwell or deteriorating participant to the ED or AMU please ensure that the following have been completed: **Page 1 of 2**

Before Transfer	**Yes / No**	**Comments**
Inform Senior Nurse on Duty	Y / N	
Give a clear, concise verbal telephone handover as detailed in ILS training	Y / N	
Complete set of physiological vital signs and record on observation chart	Y / N	
Ensure all transfer documents and medical notes accompany participant	Y / N	
Complete Handover sheet	Y / N	
PIS available for receiving area	Y / N	
Collect Equipment required for transfer (if not provided by ambulance crew)	Y / N	
Ensure adequate supply of I.V. fluids / infusions or medication required to treat clinical condition during transfer and handover period.	Y / N	
Ensure attending clinicians have documented current presenting problems, reasons for transfer and interventions taken	Y / N	
Ensure NOK aware of need to transfer and location given	Y / N	
Identify and assess risks that may occur during transfer period	Y / N	
Call receiving area immediately prior to leaving the clinical area to inform them that participant is en-route	Y / N	
Utilise admin team member (or others) if needed to hold doors open ready for transfer	Y / N	
Send clinical staff (if possible) to ensure ambulance is not blocked in by other vehicles and to provide a handover of participants current condition	Y / N	
Intravenous containers must be hung away from participants head and the integrity and functions of infusions checked prior to transfer	Y / N	

Research Transfer Checklist

When transporting an unwell or deteriorating participant to the Emergency Department, please ensure that the following have been completed: **Page 2 of 2**

On Return to Research area	**Yes / No**	
Ensure all equipment returned to the Research area is cleaned / decontaminated as per Trust policy	Y / N	
Inform study PI (if they are not already aware)	Y / N	
Inform study lead nurse (if not already aware	Y / N	
Complete DATIX incident report	Y / N	
Ensure 2 x complete transfer documentation packs are ready for use as per 6.2.2 of SOP	Y / N	

Appendix 2:

Patient Handover Sheet

Patient Name:
NHS number:
Date of Birth:

Time left Research area: _____

Receiving Area (location): _____

NEWS 2 score on leaving Research area: ☐

Please be aware that this person is participating in the following research study

Study Title:	
Study No:	
Principal Investigator: Contact Number:	
Research Nurse Contact Number:	
24hr Emergency Study Contact Number:	
Reason for Transfer:	

MRSA Status: +ve / -ve / unknown

Known Infection Risk (give details):

Significant Clinical Information:

Details of clinical Intervention / Study procedures / diagnostic tests prior to transfer:

I.V Cannula:	I.V fluids:
Blood samples:	Other Interventions:

NOK aware of transfer: Yes / No

NOK details: