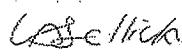
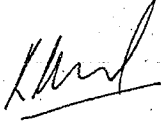


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SOP Out of Hours Patient Visits to CIRU

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Version	Date	Reason for Change
2.0	11 th January 2016	Change in content

1. Purpose

The purpose of this document is to detail the procedure for ensuring adequate medical cover is in place when a research participant attends the Clinical Investigation and Research Unit, (CIRU) for an appointment outside of the unit's regular working hours, 9am -5pm Monday to Friday.

2. Introduction

The Clinical Investigation and Research Unit (CIRU), supports the conduct of a broad range of clinical research studies involving patients and healthy volunteers.

During it's opening hours, the unit is staffed by a team of administrators, Research Practitioners, Registered Nurses and a Doctor is either in the unit or contactable by bleep at any time to assist with an unwell patient, where the need arises.

The unit has resuscitation equipment, an anaphylaxis kit and a 'Management of an acutely unwell patient SOP- SOP/CIRU/003).

CIRU SOP on Management of an Acutely Unwell Patient (SOP/CIRU/003) outlines in detail, the steps that must be followed in the eventuality that a patient becomes unwell on the unit. All staff that work on the unit are trained on this SOP.

Many research participants lead busy lives and increasingly, the research teams need to accommodate requests from participants to have their appointments either before or after the unit's regular working day.

Many protocols include study visits with a long duration such as visits that involve the collection of pre and post dosing pharmacokinetic samples. These visits may result in research participant being on the unit for many hours out of the units usual opening time.

3.0 Responsibilities

In order to protect the safety and welfare of all patients/healthy volunteers at all times, The CIRU Clinical Director, CIRU Lead Research Nurse, and Trial Principle Investigator are responsible for ensuring that the CIRU Emergency Procedures could be implemented, should the need arise, at any time when a research participant is on the unit.

4.0 Procedure

When the trial feasibility proforma is completed, the need for 'out of business hours' visits will be identified and documented.

The Principal Investigator will determine whether s/he deems it to be a low or high risk visit with the support of the defined criteria below.

This level of risk will be documented on the trial feasibility.

Staffing will be allocated accordingly.

Where an 'out of business hours' trial visit is conducted, the visit will fall in to one of the following two categories.

In both categories, the trained clinical staff will be BSUH NHS Trust employed staff who are trained in BSUH emergency procedures and familiar with the CIRU Emergency Procedures.

Category 1-a low risk visit

A routine appointment that does not involve a 'high risk' procedure or intervention. In this situation, three staff must be in the unit with the patient, two of which are clinically trained.

Category 2-a high risk visit

In this situation, there should be a total of 4 staff on the unit, three of which are clinically trained.

A high-risk procedure or intervention is:

- The administration of a drug that is likely to cause an adverse reaction.
- The administration of any phase 1 trial drug.

- Conducting a skin prick test procedure
- Conducting a clinical procedure with known risks e.g. a lumbar puncture
- Administration of a drug as part of a desensitisation programme
- A research participant whose condition or clinical situation requires close monitoring.
- Any other reason outlined by the trial Principal Investigator

5.0 Training

This is a 'read and understand' SOP. The R&D department discourages the retention of hard copies of SOPs and can only guarantee that the most up to date version is on the CIRU shared drive.

6.0 Cross Referenced SOPs

CIRU Management of Acutely Unwell Patient SOP (SOP036)

7.0 References N/A

