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Out of Hours Contact Information

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Version	Date	Reason for Change	Author
2.0	05th Jan 2017	Completion of SOP Training Matrix added	Gemma Earl

1.0 Purpose

To describe the process that should be followed to provide appropriate medical care and advice on trial related matters outside of normal working hours for research conducted at BSUH. This SOP also applies to research sponsored by BSUH that is conducted elsewhere.

2.0 Introduction

When deemed appropriate by the sponsor, trial participants should be provided with out of hours contact details. This information allows the participant to contact site staff in the event of adverse events or any other issues where access to additional

information about the trial is required. It is therefore imperative that systems are in place to facilitate this out of hours contact.

Commonly used methods include:

1) Investigators office number with arrangements in place to forward the call out of hours to an additional number or provide additional contact details on a voicemail.

2) Ward number being given to the trial participant. Although this is a preferable method as it is a permanently manned phone line, it is important to ensure staff receiving calls out of hours from participants are appropriately informed about the trial and able to access relevant information or hold trial team personal contact details if necessary.

3) Switchboard number being given to the trial participant. Although this is a preferable method as it is a permanently manned phone line, it is important to ensure staff receiving calls out of hours from participants are able to access relevant information and that appropriate back up is in place when staff are on annual leave, for example.

4) Trial specific mobile number is given to the participant. If this system is used, it must be ensured that an appropriate voicemail is left for the participant if the phone isn't answered immediately and that the phone is frequently checked with adequate cover (holiday, sickness etc) must be considered.

Whichever system is used, it should be tested at the beginning of the trial to ensure it functions as intended. Evidence of this testing should be kept to demonstrate this.

3.0 Responsibilities

Sponsor
The sponsor is responsible for determining the level of out of hours contact information that is required for each Clinical Trial of Investigational Medicinal Product (CTIMP)

Chief Investigator (CI)
For BSUH sponsored trials, the CI is responsible for ensuring all participating sites have adequate out of hours cover as determined by the sponsor.

Principal Investigator (PI)
PI's at BSUH are responsible for arranging adequate out of hours contact for trial participants when applicable. This should be tested prior to the site initiation and re-tested if any changes are made.

For multi-centred CTIMPs, the PI at each site is responsible for ensuring that the out of hours contact details provided to patients are suitable, correct and in compliance with their own Trust policies and procedures

4.0 Procedure

For each CTIMP run at BSUH, the out of hours contact information should be considered at feasibility stage.
Trial participants should be provided with appropriate out of hours contact information once they have consented to take part in a trial. The out of hours contact should be in place and tested prior to being given to the trial participant. If the out of hours contact information changes, this should be re-tested successfully before being given to the participant. The out of hours contact information should be provided on the participant documents as well as being discussed with the participant. It is recommended that the information is included on the patient information sheet and a contact card (see Appendix 1).
For BSUH sponsored CTIMPs the sponsorship committee, in collaboration with the CI, will determine what level of out of hours cover is required for each trial.

Testing Out of Hours Contact
The out of hours contact information should be tested successfully before the first patient is recruited.
Test calls should be made out of hours e.g. between 5.30pm – 9am week days or any time on a weekend/bank holiday. The test caller will use the information provided to participants to make the test.
The call is considered successful if the tester is able to make contact with the appropriate staff who are able to access the appropriate information and provide relevant advice.
The call is considered unsuccessful if the telephone number is incorrect or rings continuously with no answer or appropriate voicemail message; or the staff member is unable to provide the expected information.
All test calls and correspondence should be evidenced in writing and held in the site file. A copy of this documentation should be sent to the sponsor so it can be stored in the trial master file.

5.0 Training

This is a 'read and understand' SOP. When applicable, research staff involved in research at BSUH should read and understand this SOP. Evidence of this training should be provided by completion of your SOP Training Matrix.

Please note that 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 Trust website.

6.0 Cross Referenced SOPs

N/A

7.0 References

MHRA, Good Clinical Practice Guide, chapter 11, page 382-383, The Stationary Office, 2012

Appendix 1

Dear Patient

You have been given this card because you are taking part in a clinical trial.

Please carry the card with you at all times

- This is for your safety, in case you need medical attention – it will help doctors to give you the best and safest treatment
- If you go to your GP or any other doctor while you are in the trial, please show the doctor this card
- If you have a medical emergency it is very important to show the doctor or nurse this card

Numbers to Call

- If you, or your family, have any concerns about the trial, or about the effects of the medicine you are taking please call the number on the **BLUE** side of the card during normal office hours. For emergency out of hours contact, please call the number on the **RED** side of the card
- If you have any questions about the card, the medicine or anything else about the trial, please ask the trial doctor or nurse.

This Patient is in a clinical trial conducted at (*insert local information*). If you have any queries during office hours call (*inset local information*). Tel no:.....

Trial Name

Patient Trial No.

Clinical Trial Doctor

Research Nurse