brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

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Serious Incidents in Research

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Version	Date	Reason for Change
2.0	**21st April 2016**	Quality Assurance and Safety Committee changed to Research Governance &Quality Assurance Committee Trial.monitors@bsuh.nhs.uk added and gemma.earl@bsuh.nhs.uk removed

1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for receiving, reviewing and actioning serious incidents in research at Brighton and Sussex University Hospital NHS Trust (BSUH).

2.0 Introduction

The R&D department should be made aware of serious incidents occurring in all research studies conducted at BSUH. This includes research hosted and sponsored by BSUH. A Serious Incident Reporting Form is used to notify the R&D department of the incident. This standard reporting mechanism allows R&D to receive notification of serious incidents centrally and ensure that the appropriate action has been taken by the research team, themes are identified and training needs can be recognized & addressed.

3.0 Responsibilities

All Staff

Members of staff at BSUH are responsible for reporting any serious incidents in research to the R&D department in a timely manner.

R&D Department

The R&D department is responsible for reviewing serious incidents in research that are reported by members of staff and for ensuring that immediate appropriate action has been taken.
The department is also responsible for presenting these reports and any themes identified to the Research Governance & Quality Assurance Committee.

Research Governance & Quality Assurance Committee

The Research Governance & Quality Assurance Committee is responsible for ensuring appropriate actions have been taken in relation to the serious incidents reported to the R&D department. The Committee is responsible for identifying any further action required.

4.0 Procedure

Serious incidents will be reported to the R&D department using the Serious Incident Reporting Form (see appendix 1). The form will be completed by BSUH researchers and sent to R&D (trial.monitors@bsuh.nhs.uk & caroline.humphreys@bsuh.nhs.uk).

Examples of serious incidents include a study being suspended due to safety issues at BSUH. Serious adverse events (SAEs) should be reported in line with the study's safety reporting procedures. For BSUH sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs), please refer to SOP/RD/006 Managing AEs in CTIMPs. SAEs should only be reported as serious incidences if they result in implications to the conduct of the study.

4.1 Receipt of Serious Incident Form

Upon receipt of a Serious Incident Form, the Quality Assurance Manager will contact the person reporting the incident to confirm receipt and ensure the information reported is complete.

The serious incident will then be recorded on the Serious Incidents in Research spread-sheet, saved on the R&D shared drive.

4.2 Review of Serious Incident

The incident will be reviewed initially by the Quality Assurance Manager and Head Research Nurse. Any other relevant members of the R&D team will be alerted of the incident if applicable. The R&D department will ensure any immediate corrective actions have been implemented by the research team and consider whether preventative actions can be put in place to stop the incident occurring again. A list of serious incidences and themes identified by the R&D department will be tabled for discussion at each Research Governance & Quality Assurance Committee. This Committee will review all serious incidences, ensure all actions have been implemented satisfactorily and suggest further actions where necessary. If further escalation is required, the Research Governance &Quality Assurance Committee will flag these issues to the R&D Management Committee.

5.0 Training

This is a 'read and understand' SOP. 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

SOP/RD/006 Managing AEs in Clinical Trials of Investigational Medicinal Products

7.0 References

No references

Appendix 1

Serious Incident Reporting Form

This form should be completed & emailed to R&D if a serious incident has been identified relating to a research study e.g. study suspended due to safety issues at BSUH

N.B Serious adverse events (SAEs) should be reported in line with your study's safety reporting procedures. SAEs should only be reported as serious incidences if they result in implications to the conduct of the study. If you have any queries, please contact to your line manager

Study Title:
IRAS Number:
Principal Investigator:
Sponsor:
Brief Summary of Serious Incident & Actions Taken:
Has this incident been reported to the Sponsor? Yes / No
Reported Completed by: **Date:** **Contact Telephone Number:**

Please email this form to trial.monitors@bsuh.nhs.uk and caroline.humphreys@bsuh.nhs.uk