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Brighton and Sussex University Hospitals NHS Trust

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Notification of Serious Breaches of Good Clinical Practice or the Study Protocol

SOP Reference:	**SOP/RD/003**
Version Number	**Version v6.0** GE 10.Jan 17
Date:	**05th January 2018~~7~~**
Effective Date:	30th Jan 2017
Review by:	30th Jan 2020

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Version	Date	Reason for Change	Author
1 & 2	N/A	Versions 1 and 2 were not published	N/A
3.0	30th November 2009	Change in MHRA definitions and reporting procedure	Gemma Earl
4.0	04th June 2013	Addition of protocol deviation log, reporting serious breaches to REC, updated examples of serious breach (appendix 2), GAS committee & cross referencing relevant SOPs	Gemma Earl
5.0	28th May 2015	Research Governance Manager and R&D Manager referred to, now QA Manager and Head of R&D. MHRA form & guidance has changed & MHRA notification address has changed	Hannah Butler
6.0	21st Sep 2016	Removed reference to CTIMPs as all BSUH sponsored CTIMPs will be run through BSCTU	Gemma Earl

1.0 Purpose

This Standard Operating procedure (SOP) describes the process for notification of serious breaches of GCP (Good Clinical Practice) or the approved study protocol to the Sponsor and the Research Ethics Committee (REC) for BSUH NHS Trust sponsored studies that are not run through the Brighton & Sussex Clinical Trials Unit.

2.0 Introduction

Deviations from study protocols and GCP principles are relatively common occurrences in research studies. Most of these instances will be technical deviations that do not result in harm to the participants or significantly affect the scientific value of the reported results of the study. These cases should be documented in either the Case Report Form (CRF) or on the protocol deviation log in order for these deviations to be reviewed by the Sponsor and appropriate corrective and preventative actions to be taken. In addition, these deviations should be included and considered when the clinical study report is produced, as they may

have an impact on the analysis of the data. Some deviations are more significant and can be defined as a serious breach.

A serious breach is defined as any serious breach of:

(a) the conditions and principles of GCP (or equivalent standards for conduct of non-CTIMPs) in connection with the study or

(b) the protocol relating to that study

that effects to a significant degree the safety or physical or mental integrity of the participants in the study and/or the scientific value of the study (Reference 1).

The Sponsor and the REC that gave a favourable opinion of the study should be informed of serious breaches relating to that study to ensure appropriate action is taken in relation to participant safety and data quality. This SOP details the process.

3.0 Responsibilities

Sponsor

The sponsor has the responsibility to ensure the REC are notified within 7 days of becoming aware of the serious breach.

The sponsor is responsible for ensuring appropriate corrective and preventative actions are taken in response to the serious breach and to ensure these actions are documented.

Chief Investigator (CI)

The CI is responsible for reporting all potential serious breaches to the sponsor.

4.0 Procedure

4.1 Identifying and notifying the sponsor of a serious breach

It is the responsibility of the Chief Investigator (CI) to continually monitor the conduct of the study and report suspect serious breaches to the Sponsor.

Anyone who is unsure whether a breach has occurred can contact the Research and Development department to discuss the situation and clarify whether a breach is classed as serious or not. Please also refer to SOP/RD/015 Research Misconduct and Fraud.

Any breaches suspected either through monitoring, audit, or by any other means must be reported to the Research & Development department (sponsor) immediately.

Initial Reporting to the sponsor should be carried out by email to **sponsorship.approvals@bsuh.nhs.uk** and should inform of:

- Name of CI and Principal Investigator (PI) at the site where the breach occurred
- Full title of the study
- When and where the breach occurred
- An explanation of how the breach was identified
- Details of the breach, including the outcome
- Who was involved in the breach
- Details of any initial corrective actions, including any information given to the participants
- Assessment of the impact the breach will have on the trial participants and/or scientific integrity

4.2 Assessment of a Serious Breach

Upon receiving an initial report of a breach the Head of Research & Development (HRD) and Head of Quality Assurance (HQA) will discuss the issue with the CI to identify which section of GCP or the protocol has been breached and how the breach impacts on participant safety and/or the scientific integrity of the trial.

The HRD and HQA will meet with the CI and study team to discuss the breach and compile evidence to support notification to the REC.

The HRD and HQQ will work with the CI to identify the extent of the breach and to initiate any urgent safety measures or temporary halt of the study that may be required (see SOP/RD/016 Amendments, USM and Temporary Halt of Trial). Any other immediate corrective and preventive actions will be discussed and initiated.

4.3 Initial Notification of a Serious Breach

The HRD or HQA will collate all available information and submit notification to the REC that gave a favourable opinion for the study. If the study has closed or it is no longer appropriate to inform the REC, the Health Research Authority should be informed (breaches.nres@nhs.net).

The REC can advise the sponsor of any ethical considerations and if required a substantial amendment can be submitted if, for example, new information is to be given to participants as a result of the breach.

If all the information is not available at the time of the initial notification of the serious breach to the REC, then it is acceptable to send updates.

Copies of all documentation relating to a breach must be retained in the Trial Master File for that study.

4.4 Circulation of Serious Breach Notification

In addition to those who need to be informed of the breach internally and externally as per this procedure, the Trust's Research Governance & Quality Assurance Committee will also be informed of the serious breach to maintain oversight and ensure appropriate corrective and preventative action plans have been implemented.

5.0 Training

This is a 'read and understand' SOP. To evidence that you have read and understood this SOP, please complete 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 Reference SOPs

SOP/RD/015 Research Misconduct and Fraud
SOP/RD/016 Amendments, USM and Temporary Halt of Trial

7.0 References

Reference 1- Standard Operating Procedures for Research Ethics Committees, version 7 September 2016, pg 173-175 'Serious Breaches of the protocol or GCP'