brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

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SOP Amendments, Urgent Safety Measures (USM) and Temporary Halt of a Study for BSUH Sponsored Research

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	Signature	**Date**
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Version History

Version	Date	Reason for Change	Author
1	27-Nov-2013	Gemma Earl's email address changed to sponsorship.approvals@bsuh.nhs.uk References to Sponsorship Committee removed and changed to sponsor Amendment categories A,B,C added to 4.1.4	Hannah Butler
2.0	19/Oct/2016	Removal of references to CTIMPs and addition of latest HRA guidance	Gemma Earl

1. Purpose

The purpose of this document is to detail the process for making amendments to BSUH (Brighton and Sussex University Hospital NHS Trust) sponsored research studies. The process for implementing urgent safety measures (USM) and temporarily halting research studies sponsored by BSUH is also outlined.

2. Introduction

An amendment is any change to the protocol or associated documents that were initially given a favourable ethical opinion by the REC (Research Ethics Committee). There are two types of changes that can be made to a study; substantial amendments or non-substantial amendments. It is the sponsor's decision as to which category the amendment falls under and therefore the sponsor must be notified of proposed changes to ensure they are categorised appropriately and relevant approvals are sought prior to implementing the change. This document details the process of making amendments to a research study. Urgent Safety Measures (USMs) may be taken in order to protect research participants against immediate hazard to health or safety, however, the sponsor must be immediately informed to ensure appropriate action is taken and the relevant regulatory bodies are informed. This SOP also covers temporarily halting the study for any reason.

3. Responsibilities

Sponsor

The sponsor is responsible for determining whether a proposed amendment to a research study is substantial or non-substantial.

The sponsor is responsible for ensuring USMs and any temporary halts of the study are reported to the REC and any other relevant parties within the required time frames.

Chief Investigator (CI)

The CI is responsible for submitting proposed amendments to the sponsor. Once it has been determined by the sponsor whether the amendment is substantial or non-substantial, the CI is responsible for submitting the amendment to the relevant parties.

The CI is responsible for ensuring that the research team at each participating research site has the amendment information and any associated trial documents that have been updated.

In the event of an USM and/or temporarily halting the study, the CI is responsible for informing the sponsor immediately (sponsorship.approvals@bsuh.nhs.uk) and notifying REC within the required time frames.

Principal Investigator (PI)

The PI is responsible for implementing amendments at their local research site.

If the PI is instigating an USM, they are responsible for notifying the CI of the study immediately of this.

4. Procedure

4.1 Amendments

4.1.1 Amendments to BSUH Sponsored Research Studies

Any proposed amendment to a research study that is sponsored by BSUH must first be submitted for approval to sponsorship.approvals@bsuh.nhs.uk. The sponsor will then determine whether the amendment is substantial or non-substantial..

4.1.2 Substantial Amendments

A substantial amendment is a change that is likely to have a significant impact on the safety or physical/mental integrity of the research participants, or the scientific value of the research study. The decision as to whether the amendment is substantial lies with the sponsor. Even if it is clear that an amendment is substantial or non-substantial), approval must still be sought from the sponsor to ensure that there will be adequate management and monitoring of the study given the proposed changes.

For further information on submitting a substantial amendment to REC, please contact BSUH Sponsorship Approvals (sponsorship.approvals@bsuh.nhs.uk) or refer to the following website:

http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/

Once approved by the sponsor, substantial amendments should be submitted via IRAS using a notice of substantial amendment form created in IRAS and in accordance with HRA guidance (see above link).

4.1.3 Non-Substantial Amendments

Amendments considered to be non-substantial by the sponsor should be submitted to the HRA and to the NHS/HSC R&D offices involved in the study in accordance with the latest HRA guidance (http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/). This is done via a notification of non-substantial/minor amendments form, which can be found in the following location together with submission instructions: http://www.hra.nhs.uk/resources/during-and-after-your-study/nhshsc-rd-notification-non-substantialminor-amendment-form/.

4.1.4 HRA Assessment

All amendments are categorized by the HRA into one of the following categories:

Category A: All participating NHS organisations are expected to consider the amendment to determine whether they are able to continue NHS research permission.

Category B: Only those participating NHS organisations affected by the amendment need to be informed of the amendment and are expected to consider the amendment to determine whether they are able to continue NHS research permission.

Category C: Participating NHS organisations are NOT expected to consider the amendment or give continued permission for this amendment.

The HRA Assessment team will categorise the amendment within 5 days and send this information to the CI. Once categorisation has been received, this information along with the rest of the amendment documentation can be shared by the CI with the relevant R&D offices for the participating sites involved in the study so that necessary arrangements can be put in place to continue the site's capability and capacity to deliver the study. The sites then have 35 calendar days to confirm or object to the amendment (for category A and relevant category B amendments). Category C amendments can be implemented once the relevant approvals are in place.

4.1.5 Implementation of the Amendment

Once the relevant approvals are in place and the NHS R&D offices have confirmed continued capability and capacity or not objected to the amendment within the 35 day timeline, the amendment (if category A or relevant category B) can be implemented at site. Category C amendments can be implemented once the relevant approvals are in place.

It is the responsibility of the CI to ensure the amendment information and any updated trial documentation is communicated to the research teams. The Principal Investigator is responsible for implementing the amendment at their local site.

4.1.6 Re-consenting patients

If required, patients should be re-consented in a timely manner and at least by the next study visit. This should be documented in the patient notes.

4.2 Urgent Safety Measures

The Chief Investigator must notify the Sponsor immediately via email of the USM (sponsorship.approvals@bsuh.nhs.uk).

The CI must also notify the REC immediately, at least within 3 days of an USM being implemented in the form of a substantial amendment, notifying them that such measures have been taken and the reasons why.The funder and local NHS R&D offices should also be notified.

If applicable, relevant oversight committees such as the Data Monitoring Committee should review the USM and report any recommendations to the relevant parties.

4.3 Temporary Halt of Trial

The Chief Investigator should notify the sponsor immediately via email of the temporary halt of the study (sponsorship.approvals@bsuh.nhs.uk).

The REC should be notified within 15 days of the decision to temporarily halt a study by submission of a substantial amendment form. The CI is responsible for this. The local NHS R&D offices and funder should also be notified.

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 Referenced SOPs

There are no cross referenced SOPs

7.0 References

http://www.hra.nhs.uk (accessed on 08th November 2016)