brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

This is a controlled document
Any printed versions of this document will be classed as uncontrolled

Writing a Research Protocol

SOP Reference:	**SOP/RD/012**
Version Number	**Final 4.0**
Date:	**08th Nov 2016**
Effective Date:	30th Jan 2017
Review by:	30th Jan 2020

Author: Gemma Earl **Designation:** Deputy Head of R&D: Trial Management & Quality Assurance, Brighton and Sussex University Hospital NHS Trust	**Signature**	**Date** 05 Jan 17
Authorised By: Scott Harfield **Designation:** Head of Research & Development, Brighton and Sussex University Hospital NHS Trust		5/1/17

Version	Date	Reason for Change	Author
1.0		Review required. Incorporating guidance from the SPIRIT checklist. Restructure of the SOP	Gemma Earl
2.0		Inclusion of the SPIRIT guideline based HRA template and guidance and link to their website	Hannah Butler
3.0		Minor updates including HRA changes and removal of CTIMP guidance	Gemma Earl

1. PURPOSE

This Standard Operating Procedure (SOP) describes the Brighton and Sussex University Hospital NHS Trust (BSUH) process for writing a clinical research protocol to GCP (Good Clinical Practice) standards. In addition to this SOP, the Research and Development department can offer guidance and advice on writing a protocol. This SOP is not relevant for the development of CTIMP (Clinical Trial of Investigational Medicinal Products) protocols, please seek advice from the Brighton and Sussex Clinical Trial Unit if you are considering designing a CTIMP.

2. INTRODUCTION

The Declaration of Helsinki states that the design and performance of every research study must be clearly described and justified in a research protocol. Production of the protocol may involve a number of parties, for example medically qualified doctors, medical statisticians, pharmacists, pharmacovigilance experts, data managers, laboratory staff, trial managers and any other ancillary input, dependent on the nature of the research.

In collaboration with a wide range of partners including the international SPIRIT guideline team (Chan et al., 2013), the HRA have published templates and guidance for developing protocols.It is strongly recommended that researchers intending to obtain sponsorship from BSUH use the appropriate template and follow this guidance when writing a protocol.

3.0 Responsibilities

Chief Investigator

The CI who has overall responsibility for the research (and may also be the Principal Investigator), is responsible for ensuring that the protocol is scientifically sound as well as being clear and detailed.

The CI is responsible for overseeing the production of the protocol and any amendments.

If BSUH is the sponsor, it is the responsibility of the CI to submit the protocol and other documentation to the applicable authorities including where relevant the HRA (Health Research Authority), research ethics committee (REC) and local R&D departments at each site participating in the research study. These applications can be created through IRAS (Integrated Research Application System). These duties may be delegated to an appropriate member of the research team.

Sponsor

The Sponsor is responsible for authorising the final protocol and any amendments. For BSUH sponsorship please refer to SOPRD008 Sponsorship Approval.

4.0 Procedure

It is acknowledged that not all sections will be relevant to every type of research study. For advice and guidance, a member of the R&D team should be contacted.

The HRA guidance and template can be accessed here:

Guidance and template for research protocol:

http://www.hra.nhs.uk/about-the-hra/consultations-calls/closed-consultations/qualitative-protocol-guidance-and-template/

4.1 Other BSUH Guidance

Amendments to the protocol once the research study has begun may be required. Every effort should be made to ensure the final protocol is as clear and detailed as possible to reduce the need for amendments once the study has been approved.

Any amendments to the approved protocol should be reviewed by the Sponsor. The Sponsor will determine whether the amendment is substantial or minor and if substantial, which authorities are required to approve it. For BSUH sponsored studies, please refer to SOPRD008 Sponsorship Approvals.

Final protocols should be signed off by the CI and the Sponsor. For multi-centred studies, the principal investigator at each site should sign a protocol acceptance form or similar to confirm receipt and agreement to work to that version of the protocol.

Research funders may have specific requirements for the content and presentation of the protocol. The funder may need to be informed of any changes and agreement obtained prior to implementing amendments (depending on contractual obligations).

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

SOPRD008 Sponsorship Approval

7.0 References

Chan A-W, et al. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200-207.

World Medical Association, Declaration of Helsinki Ethical Principles of Medical Research Involving Human Subjects, Oct 2013, Section 22