brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

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SOP Good Clinical Practice (GCP) Training

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Version	Date	Reason for Change	Author
1.0	13th Aug 2009	Simplified	Gemma Earl
2.0	21st Nov 2014	Online NIHR GCP course rather than Epigeum	Gemma Earl
3.0	05th Jan 2017	Addition of SOP Training Matrix	Gemma Earl

1.0 Purpose

To outline the requirements for GCP (Good Clinical Practice) training for BSUH staff and those working on BSUH sponsored research studies.

2.0 Introduction

Regulation 28 of Statutory Instrument 2004/1031 states that no person shall conduct a trial otherwise than in accordance with the conditions and principles of GCP. Therefore, each person that is involved in conducting a research study must be trained in GCP in relation to their roles and responsibilities in the study.

Although the frequency of GCP training is not specified in the regulations, BSUH requires all staff involved in research to undertake GCP training at least every 2 years.

Ad hoc training may be required in the event that there are significant regulatory updates between the scheduled training intervals.

3.0 Responsibilities

BSUH staff and researchers involved in BSUH sponsored research are responsible for ensuring their GCP training is up to date, in line with this SOP.

4.0 Procedure

4.1 Booking onto a GCP Course

For BSUH Staff, there are different two options for GCP training courses.

1) NIHR Facilitator-Lead GCP training. This is a face to face course and sessions are either introductory (full day) or refresher (half day). These are currently run locally, every month and are recommended over web-based training.

2) On-line NIHR GCP training at http://www.crn.nihr.ac.uk/learning-development/good-clinical-practice/

Please contact R&D to enquire about booking on to a GCP training course.

4.2 Evidencing GCP Training

For BSUH staff, a copy of the GCP certificate must be forwarded to the R&D administrator. It is recommended that a copy is also retained for the individual's personal training record.

For researchers involved in BSUH sponsored research, documented evidence of training must be kept in the Investigator Site File (ISF) for all staff on the delegation log for a research study.
This should include:

- A curriculum vitae (CV) to demonstrate current and previous education and experience relevant to their role in the study. The CV must be signed and dated within the last year.
- Confirmation of Good Clinical Practice (GCP) training including reference to the UK Statutory Instruments and EU Directives.
- Study-specific training relevant to the researcher's roles and responsibilities in the study.

The majority of research staff will be expected to undertake full GCP training. Authorisation from the Research & Development team must be sought if tailored

GCP training is to be given to individuals. Training should be relevant to the roles and responsibilities undertaken by an individual. For example, a ward nurse whose only responsibilities within a trial are to obtain blood samples from a trial patient (which they would do as part of their normal clinical duties anyway) may not be expected to undertake full GCP training. Training in relevant areas of GCP such as adverse event reporting, documentation of activities in the source and escalation of any issues alone could be appropriate.

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

Medicines for Human Use (Clinical Trials) Regulations 2004, Regulation 28 of SI 2004/1031

Good Clinical Practice Guide, MHRA, Chapter 14, page 449-45