Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Education, Training and Experience**		
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	Name and Position	Signature	Date
Author:	Mrs Louise Dunlop Head of Research Governance		8/12/17
Reviewed by:	Professor James McElnay, Chair Research Governance and Integrity Committee		09-02-2017
Approved by:	Mr Scott Rutherford Director, Research and Enterprise		8.2.2017

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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Final v 1.0
Final v 1.0	10/11/10	Annual Review/ Update following MHRA GCP Inspection	Final v 2.0
Final v 2.0	20/08/2012	Periodic Review	Final v 3.0
Final v 3.0	21/10/2014	Periodic Review	Final v 4.0
Final v 4.0	19/09/2016	Periodic Review	Final v 5.0

1. Purpose

This Standard Operating Procedure (SOP) describes the documentation that is required to be kept in respect of researchers' education, training and experience.

2. Introduction

The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments require Clinical Trials to be conducted according to Good Clinical Practice. GCP provides assurance that the data and reported results are credible and accurate, and that the rights, wellbeing and safety of participants are protected.

GCP states "Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s)" (ICH GCP 2.8). The Research Governance Framework for the DHSSPS, published December 2006 reiterates this requirement.

Therefore, in order to demonstrate compliance with this GCP principle, relevant documentation must be maintained.

3. Scope

The SOP applies to all personnel involved in the conduct of health related research, in particular, those undertaking Clinical Trials of Investigational Medicinal Products (CTIMPs) or Clinical Investigations of Medical Devices. It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff and students.

4. Responsibilities

4.1 Chief Investigator

The Chief Investigator (CI) is ultimately responsible for ensuring that persons involved in the conduct of clinical research are appropriately qualified to do so.

4.2 All staff involved in the research study

It is the responsibility of all staff to maintain their own CV and training record file on an ongoing basis.

5. Procedure

5.1 Documentation

The following documentation constitutes a training file and will be maintained:

- Curriculum Vitae (CV)
  A signed and dated CV that provides concise evidence an individual's education, qualification, prior experience and training. This should be reviewed on an annual basis and updated as necessary. A signed copy of the current CV must be kept in the Trial Master File for CTIMPs and Clinical Investigations of Medical Devices.

- Training Records
  Copies should be kept by individual members of the research team of any certifications of training undertaken. This should include study and/or role specific

training. Where certification is not available/provided a training log should be used to capture training. This should include:

i Title of training programme;
ii Date of attendance;
iii Duration;
iv Location;
v Name of Trainer.

A copy of the current job descriptions must also be retained. This, in conjunction with the University's appraisal process, should be used to review training undertaken and possible future training needs.

- Good Clinical Practice
  All staff are required to complete Good Clinical Practice training when undertaking clinical trial work. A copy of the Good Clinical Practice (GCP) certificate should be retained in the Trial Master File for each relevant investigator involved in the clinical study. The University expects that GCP training should be renewed every 3 years.

- SOP Specific Training
  All staff are required to read, familiarise and understand the SOPs relevant for their role within the study, this must also be documented in the training record.

- Study Specific Training
  All staff will ensure they receive training relevant to their role within the study protocol, and other study related documents. Again, staff need to ensure the training provided is at a level they understand and to question areas of doubt. Study specific training must be maintained, as necessary.

6. References

Medicines for Human Use (Clinical Trials) Regulations 2004 (last accessed October 2016) http://www.opsi.gov.uk/si/si2004/20041031.htm

Research Governance Framework for Health and Social Care, February 2007

DHSSPS http://www.dhsspsni.gov.uk/ (last accessed October 2016)

ICH GCP (1996) (last accessed October 2016)
http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html