UNIVERSITY OF LEICESTER

UNIVERSITY OF LEICESTER, UNIVERSITY OF LOUGHBOROUGH
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

University of Leicester (UoL) Research Governance Office
SOP S-1020 UoL

Version 3, October 2016

Training for Staff Engaged in Research Sponsored by the University of Leicester

Research Governance Office
Research & Enterprise Division
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Effective Date: April 2017

1 INTRODUCTION

This Standard Operating Procedure (SOP) describes the minimum training requirements for personnel involved in research sponsored by the University of Leicester (UoL). Personnel must be appropriately qualified by training, experience and education, to discharge their responsibilities competently, and be trained in the study protocol. They must demonstrate an understanding of the study and disease area in order to offer a full explanation of the study to subjects, and be deemed competent in the pharmacological aspects of the study where applicable.

To ensure implementation of the International Conference for Harmonisation in Good Clinical Practice Guidelines (ICH GCP) and the relevant legislation, UoL as Sponsor require researchers to undertake ICH GCP training every three (3) years.

Good Clinical Practice training underpins the principles of Good Clinical Practice to be followed for all research studies to ensure:

- the rights and well-being of study participants
- that study results are valid & reproducible

In addition, researchers who are not medically qualified, who intend to consent subjects for research are required to undertake consent training and refresh their training every two years. The exception to this is research which **ONLY** involves focus groups, self-completion questionnaires, surveys or use of anonymous data / tissue studies. Please refer to the SOP S -1021 UoL Informed Consent for Research.

2 SCOPE

This SOP applies to all researchers who are involved in research sponsored by UoL.

3 PROCEDURE

Evidence of GCP Training must be provided for all applications submitted for Sponsor review. It is expected that at the initial Sponsor review stage, evidence of GCP will be required only for the Chief Investigator. It is the responsibility of the Chief Investigator to ensure that **ALL** study personnel have received GCP Training (where appropriate) and provided evidence in form of a certificate of the training before any study related activity is undertaken. Copies of evidence of GCP training must be retained in the dedicated section of the Trial Master File and / or Investigator Site File. Evidence of expired GCP training must also be retained on file to demonstrate that members of the study team were GCP trained throughout the whole period of the study.

It is UoL policy to accept only GCP training evidence issued by the UoL, UHL, NIHR and Trancelerate Biopharma.INC for studies sponsored by UoL. GCP certificates from other external organisations will not be accepted. This is because it is not possible to review the content of external courses and there may be gaps in the training required by UoL.

Multi-Centre Studies

At the current time, resources do not allow for UHL/UoL training to be rolled out across all sites in Multi-centre studies. The NIHR and Trancelerate Biopharma.INC certificate will be accepted, however, where is it not possible to access NIHR or Trancelerate Biopharma.INC training due to eligibility of the research teams, a case by case solution must be discussed during the Sponsor review process.

3.1 GCP Training Sessions

UHL/UoL GCP training sessions are delivered both in a classroom and electronic / on-line format. With effect from April 2016, GCP sessions are available for CTIMP studies and cover all aspects of ICH-GCP, and statutory instruments.

There is a requirement that a classroom session be undertaken for new researchers who have not previously undertaken GCP training. The electronic on-line format is intended as a refresher for those who have existing practical experience in research and in applying the principles of GCP.

A maximum of one (1) on-line refresher GCP session can be undertaken before a further classroom session is required.

3.2 After 1st April 2016, GCP Training is MANDATORY for the following:

- All study personnel conducting any aspect of a research study using Investigational Medicinal Products
- All Chief Investigators and Principal Investigators of interventional non-CTIMP studies.

3.3 After 1st April 2016, training on 'Bite Sized' Topics focusing on specific Principles of GCP will be MANDATORY for all researchers conducting the following:

- All interventional studies
- All study personnel conducting research using devices with or without a CE mark
- Study personnel conducting qualitative interviews
- Sampling and any type of invasive intervention

3.4 After 1st April 2016, training on 'Bite Sized' Topics focusing on specific Principles of GCP will be RECOMMENDED for all researchers conducting the following:

- Study personnel handing out self-completion questionnaires where written consent is not required
- Personnel providing information for a study for a Participant Identification Centre (PIC)
- Studies involving the use of surveys only, the use of anonymous data or tissue

For the next available session visit UHL Research Pages on the Public Website or email RDTraining@uhl-tr.nhs.uk. From March 2017, UoL will offer GCP training for non-CTIMP studies. For details on the next available session visit UoL Research Governance Webpages or email uolsponsor@le.ac.uk.

4 HUMAN TISSUE ACT TRAINING

Researchers who are collecting tissue or samples for the purposes of research are strongly encouraged to undertake training provided by the MRC. This e-learning module provides an overview of human tissue legislation in the UK, best practice and practical tips for compliance. This module was developed by the MRC Regulatory Support Centre in consultation with the Human Tissue Authority, National Research Ethics Service, Scottish Government and others. To access the training you should register and log in using the following hyperlink:

http://byglearning.co.uk/mrcrsc-lms/login/index.php

5 CONSENT TRAINING

ICH-GCP confirms that the Chief Investigator (CI) has overall responsibility for the consent process. However other suitably qualified and trained professionals can receive informed consent for the research study, provided that the Sponsor and CI / PI agree and that this is reflected in an ethics application and has received a favourable opinion.

All personnel who are not medically qualified who wish to receive consent from subjects for research must complete consent training, please see SOP S-1021 UoL Informed Consent for Research. Exceptions to this include researchers undertaking focus groups, self-completion questionnaires where written consent is not required, surveys or use of anonymous data / tissue studies. The certificate is valid for two years from the date of certification. Additionally they must hold a valid GCP certificate and have been approved for the study role by the relevant Research & Development Office.

Those wishing to receive consent must be employed by the NHS Trust or hold an appropriate permission as detailed in the Research Passport Policy. It will be important to confirm that appropriate permissions are in place when confirming appropriateness of staff receiving consent in multi-centre studies.

A maximum of one (1) on-line refresher consent session can be undertaken before a further classroom session is required.

6 TRAINING IN STANDARD OPERATING PROCEDURES / PROTOCOL AND STUDY SPECIFIC TRAINING

For research sponsored by UoL, research staff must demonstrate knowledge of UoL Standard Operating Procedures relevant to their role within the study team. Confirmation that the relevant SOPs have been read by individual study team members must be filed in the Investigator Site File / Trial Master File using the SOP Read Log (See Appendix 3 to SOP S-1011).

Research activities have the potential to generate unique training needs. Staff involved must be trained appropriately to carry out the requirements of the protocol.

The CI/PI should provide or arrange training in the following to enable study teams to follow the protocol and facilitate recruitment:

- Training in the most recent version of the protocol
- Training in the use of devices, particularly if they are novel or being used unconventionally

- Training in the pharmacological aspects of a study, with support from pharmacy especially where an Investigational Medicinal Product is being used

Training must be documented as appropriate on the protocol training log (Appendix 1).

Further information about current training available can be found on the training section of the UHL R&I Public Website, or by email to RDTraining@uhl-tr.nhs.uk.

7 NON-COMPLIANCE

Where it has been identified that study personnel have not been adequately trained, or the training certification has lapsed, the non-compliance SOP S-1016 UoL may be implemented at a minimum of 'other' finding.

8 RESPONSIBILITIES

	Responsibility	Undertaken by	Activity
1.	CI/PI	CI/PI	Ensure all Investigators and staff working on the study are GCP trained and consent assessed as appropriate & that this is reflected on the Delegation of Authority and Signature Log
2.	CI/PI	CI/PI	To keep copies of all training records and certificates in the Investigator Site File / Trial Master File
3.	CI/PI	CI/PI	To update themselves and all members of their research team in all aspects of the trial, including consent, GCP, standard operating procedures and pharmaceutical products (as appropriate) and any protocol amendments
4.	CI/PI	CI/PI / Sponsor	To identify additional training needs of staff involved in research and seek relevant training
5.	Research Team Members	Research Team Members	Ensure that they carry out only those tasks for which they have been delegated and appropriately trained
6.	Sponsor	Research Governance Office	Ensure that the Chief Investigator is fully aware of their responsibilities to ensure appropriate training is provided and kept up to date for all study personnel

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This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

9 DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT

Author / Lead Officer:	Wendy Gamble
Job Title:	Research Governance Manager
Reviewed by:	UoL Research Management and Operations Group (RSMOG)
Approved by:	Professor Nigel Brunskill 
Date Approved	10/04/2017

REVIEW RECORD

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
June 2015	1	Wendy Gamble	Updated to introduce a protocol training log and appropriate GCP certificates.
Oct 2016	2	Diane Delahooke	Updated logos, and amended to reflect UHL bite sized training and UoL GCP training.

DISTRIBUTION RECORD

Date	Name	Department	Received