Standard Operating Procedure on Training Requirements for staff participating in CTIMPs Sponsored by UCL

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SOP ID Number:	**Effective Date:**	**Reason for Change:**	**Author:**
JRO/SPON/S12/01	01/04/2010	First document	John Wyatt
JRO/SPON/S12/02	01/08/2012	Clarify and simplify the process, change the scope to remove trials not sponsored by UCL.	Helen Cadiou
JRO/SPON/S12/03	02/08/15	Reference to new legislation	Helen Cadiou
JRO/SPON/S12/04		Updated following the new Joint Statement on the Application of Good Clinical Practice to Training for Researchers	Farhat Gilani

ACRONYMS:	
CTIMP	Clinical Trial of an Investigational Medicinal Product
JRO	Joint Research Office http://www.ucl.ac.uk/jro
GCP	Good Clinical Practice
HRA	Health Research Authority
SOP	Standard Operating Procedure
CI	Chief Investigator
PI	Principal Investigator
TMF	Trial Master File
ISF	Investigator Site File
MHRA	Medicines and Healthcare Products Regulatory Agency
QA	Quality Assurance

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1. PURPOSE

This Standard Operating Procedure (SOP) has been written to describe the UCL GCP training procedure.

Please ensure that you are reading the last version of this SOP, http://www.ucl.ac.uk/jro

2. JOINT UCLH/UCL RESEARCH OFFICE (JRO) POLICY

All SOPs produced from the JRO must be used in conjunction with local NHS Trust and UCL policies and procedures.

The JRO acts as the representative of the Sponsor UCL and will be the official name used on all SOPs.

3. BACKGROUND

All SOPs are written in accordance with applicable GCP requirements as outlined in Directives 2001/20/EC and 2005/20/EC (in the UK, these Directives were transposed into UK law by SI 2004/1031, SI 2006/1928) and subsequent amendments and when applicable Regulation 536/2014 and subsequent relevant SIs. Where applicable it incorporates elements of ICH GCP tripartite guidelines (E6).

The JRO organises face to face training courses on the principles of Good Clinical Practice (GCP). For all CTIMPs it is the high level "conditions and principles" of GCP set out in the UK Clinical Trials Regulations that must be complied with and interpreted in proportion to the risks posed to the participants and to the integrity of the results.

The course objectives are as follows:

- Understand the key principles of GCP enshrined in the Medicines for Human Use (Clinical Trials) Regulations 2004 and as amended, the fundamentals of the EU Clinical Trials Directive and when applicable Regulation 536/2014 and subsequent relevant SIs. Formulate strategies for incorporating the principles of GCP in to systems at the trial site in order to comply with the UK regulations
- Be aware of the ethical approval process and the definition and responsibilities of the Sponsor and Investigator
- Understand the regulatory requirements for informed consent
- Understand the regulatory requirements for assessing, recording and reporting :
  - Adverse Events (AEs)
  - Adverse Reactions (ARs)
  - Serious Adverse Events (SAEs)
  - Serious Adverse Reactions (SARs)
  - Suspected Unexpected Serious Adverse Reactions (SUSARs)
  - Urgent Safety Measures and serious breaches

- Outline the Essential Documents required for a CTIMP to be held in the Trial Master File (TMF) (CI only) or Investigator Site File (ISF)
- Understand the principles of an MHRA systems inspection and recognise the requirements of the sponsor's monitoring and audit systems
- Be aware of the best sources of further information and practical guidance for UK Regulations
- Outline recent changes in UK legislation
- Emphasize the need to archive for the length of time outlined in the protocol by the sponsor.

In addition to the initial GCP training courses, refresher courses are provided for staffs that has previously completed the GCP training, to ensure that staff working on CTIMPs are aware of latest regulations.

Further training is available via the NIHR CRN GCP courses which are available free of charge to the NHS, UK universities, and other publicly funded organisations conducting and supporting clinical research.

4. SCOPE OF THIS SOP

To describe the Good Clinical Practice (GCP), as per UK clinical trials regulations, training procedure for all staff undertaking CTIMPs Sponsored by UCL which fall under the UK Medicines for Human Use (Clinical Trials) Regulations 2004 and when applicable Regulation 536/2014 and subsequent relevant SIs.

5. RESPONSIBLE PERSONNEL

All investigators and delegated individuals conducting any CTIMP as defined in the UK Medicines for Human Use (Clinical Trials) Regulations 2004 and when applicable Regulation 536/2014 and subsequent relevant SIs, to attend a GCP training course and obtain a certificate of attendance.

All individuals completing CTIMP related functions, to maintain a personal training record or equivalent.

CI running multicentre trials to ensure participating PIs and trial teams are appropriately trained and records maintained in the ISF or as appropriate.

JRO staff, when applicable, will receive initial and regularly updated training in GCP and the UK Regulations.

All individuals conducting any CTIMP related procedures or involved in the care of patients participating in a CTIMP are to receive GCP training **proportional** to the level of trial activity they complete.

6. PROCEDURE

6.1 Training

The named CI or PI may delegate duties within a CTIMP delegated individuals must be listed on the JRO Delegation Log (or equivalent) which must include their roles, start date on the trial and each entry must be signed off by the named CI or PI to confirm delegation of duties.

If a member of clinical staff can be identified from the TMF or ISF, for example through a signature on an Essential Document, then that member of staff should be listed on the trial delegation log.

Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
All members of staff on the trial delegation log should have attended a GCP course (organised by the JRO or equivalent course) in the last two years and have a certificate of attendance available for review.

Where a member of staff is performing limited duties within a CTIMP, such as IMP dispensing only, then GCP training received may be proportional to the level of activity in agreement with the JRO.

Where a member of staff is performing routine duties involved in the care of CTIMP patients an overview or short course in GCP may be appropriate.
For example, Laboratory/diagnostic staff undertaking routine testing where the results will be used within a CTIMP, should have an overview of GCP. Full training is not mandatory but laboratory/diagnostic staff should be trained for the tasks they undertake within each CTIMP. The head of each laboratory participating in a CTIMP should attend a GCP course and assess which aspects of GCP are relevant to the lab staff.

GCP training must be delivered by a qualified individual or appropriate organisation.

Details and booking instructions for forthcoming courses are provided on the JRO website at http://www.ucl.ac.uk/jro/training-education/training-courses or the NIHR website https://learn.nihr.ac.uk/course/index.php?categoryid=5

6.2 Revalidating knowledge

All Investigators and delegated staff on a trial should have a GCP training certificate prior to trial initiation. This should have been obtained in the last 2 years. At sites, where the requirements are different, PIs and their teams should follow their local procedures.
Following a substantial amendment to the regulations, the JRO will disseminate the changes to the regulations to the CI and/or will recommend that GCP training is revalidated sooner than the frequency listed above.

6.3 Records of attendance

The JRO maintains a central database of all investigators who have attended GCP training provided by the JRO.
Individual team members are responsible for maintaining records of their CTIMPs training and these details must be included in the trial member CVs which form part of the ISF (in addition to a copy of their GCP certificate).

6.4 Audit/ assessment of clinical trials training

Investigator training records will be assessed by the JRO prior to trial commencement and evidence of GCP training attendance will be required and investigators will be informed of the training requirements set out in this SOP. GCP certificates should be stored in a safe place and a copy held in the TMF or ISF. This applies to all certificates as they are updated. Out of date certificates should be kept and not destroyed.
Site training records will be reviewed in accordance with the Monitoring Plan for the trial.
The GCP course content will be reviewed from time to time and following amendment of the regulations or other applicable guidance

Relevant information about Serious Breaches is communicated to the education team in order to inform the content of GCP training courses.

6.5 Additional recommendations

Trial investigators and teams will be strongly encouraged to attend the one-day "principles of research governance course" provided by JRO.

See http://www.ucl.ac.uk/jro/training-education/training-courses

7. REFERENCES

http://www.ucl.ac.uk/jro/resources-templates

Joint Statement on the Application of Good Clinical Practice to Training for Researchers; HRA, MHRA, Devolved Administrations for Northern Ireland, Scotland and Wales

ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996)

The UK Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031

The UK Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, SI 2006/1928

The UK Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006, SI 2006/2984

The UK Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008, SI 2008/941

The Medicines for Human Use (Miscellaneous Amendments) SI 2009/1164

Regulation 536/2014

8. APPENDICES

9. TEMPLATES/LOGS ASSOCIATED TO THIS SOP

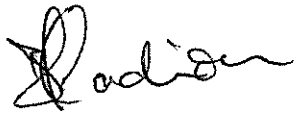
JRO Delegation of Responsibilities Log

10. SOP DISSEMINATION AND TRAINING

SOPs will be distributed to the concerned staff, by the named author on the front page of the SOP. Staff concerned by the SOP will sign the SOP training log (12. SOP TRAINING LOG) which is part of each SOP. The training will constitute the member of staff reading the SOP and being provided with the opportunity to ask specific questions to the author of the SOP.

Where applicable, the SOPs and relevant templates and logs will be available on the JRO website shortly after having been released.

11. SIGNATURE PAGE

Author and Job Title:	Farhat Gilani
Signature:	
Date:	6/8/2018
Authorised by: **Name and Job Title**	Helen Cadiou Head of QA
Signature:	
Date:	06/08/18

12. SOP TRAINING LOG

	Name of Staff (Capital letters)	Job Title: Department:	Training Date	I confirm that I understand & agree to work to this SOP SIGNATURE	Name of Trainer (if training required)	Signature	Date
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