Health and Care Research Wales
Good Clinical Practice (GCP) Training Requirements (all-Wales)

SOP number: 2

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

Standard Operating Procedure: **SOP number : 2**

TITLE: Good Clinical Practice (GCP) Training Requirements (all-Wales)

Version No:	**Version 3.0**					
Compliance	**Mandatory**	**x**	**Advisory**		**Template**	
Implementation Date:	**1st July 2018**					
Supersedes:	**N/A**					

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JOB TITLE: Research Delivery Manager/Senior Training Manager DATE: 6/4/18

APPROVAL: **DATE: 9/6/18**
(Chair of NHS R&D Delivery Board)

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Version Record		
Version Number	**Effective Date**	**Reason for Change**
0.1	**31/07/17**	**New SOP**
0.2-0.7	**23/08/17– 09/02/18**	**Incorporating comments and new information**
1.0 Final	**06/04/18**	**Incorporating comments following consultation period**
2.0	**07/06/18**	**Amended Final Version following ratification at NHS R&D Delivery Board**
3.0	**18/07/23**	**Updated web links, typographical edits, updated post-Brexit medical device legislation**

Contents

1. Purpose

1.1. To outline an all-Wales approach to adopt the UK guidelines advocating appropriate and proportionate requirements for Good Clinical Practice (GCP) training to ensure the research workforce is appropriately qualified, trained and experienced to conduct studies competently, in accordance with their study role and in compliance with UK research governance and applicable legislation.

2. Background

2.1. Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

2.2. GCP training is a requirement for clinical trials of medicinal products (CTIMPs), but there is no legal requirement for other types of research.

2.3. All staff involved in CTIMPs must be appropriately trained to comply with UK regulatory requirements. The Medicines for Human Use (Clinical Trials) Regulations (2004) and subsequent amendments implement the EU Clinical Trials Directive 2001/20/EC and the EU GCP Directive 2005/28/EC which are based on the principles of ICH GCP (1996). Principles based on Articles 2 – 5 of the EU GCP Directive implemented into UK law states 'Each individual involved in conducting a research study shall be qualified by education, training and experience to perform his/her tasks'.

2.4. In October 2017 the UK Policy Framework for Health and Social Care Research was introduced replacing the research governance frameworks in each of the four nations. It states:

"The UK policy framework for health and social care research sets out principles of good practice in the management and conduct of health and social care research that take account of legal requirements and other standards."

2.5. Principle 2, under the principles that apply to all health and social care research, states:

"All the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks."

2.6. Although UK legislation includes the requirements to comply with the conditions and principles of GCP, the International Conference on Harmonisation's Topic E6 (R1 and amended R2) – "Guideline for Good Clinical Practice" is not explicitly mentioned in the UK legislation, but, as part of European guidance (EudraLex Volume 10), should be taken into consideration as an established standard for GCP.

2.7. Both the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA) advocate a proportionate approach to the application of GCP and the appropriate training of staff involved in clinical trials and as such, released a joint HRA/MHRA statement in 2017 on the Application of Good Clinical Practice Training for Researchers to clarify requirements for GCP training.

This has been endorsed by all four UK nations. This statement has now been updated and lists HRA, MHRA, Devolved Administrations for Northern Ireland, Scotland and Wales (10 Feb 2020). https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/joint-statement-application-good-clinical-practice-training-researchers-hra-mhra-devolved-administrations-northern-ireland-scotland-and-wales/

2.8. The joint statement states training forms one component of the systems for ensuring high quality research. Training should be appropriate and proportionate to the study type, relevant to specific research roles and activities undertaken by staff involved in health and social care research and may range from a detailed knowledge of GCP principles and associated UK Regulations to an awareness of particular GCP principles.

2.9. Previously some NHS organisations have interpreted the ICH GCP principle 2.8 *'Each individual involved in conducting a research study shall be qualified by education, training and experience to perform his/her tasks'* as a requirement for ALL individuals involved in research to complete GCP training, regardless of the type of study or their specific duties within the study, which may not be the most appropriate or effective approach.

2.10. Researchers have sometimes been required, inappropriately and often disproportionately, to undertake GCP training when they do not conduct research in the field of clinical trials of investigational medicinal products (CTIMPs) or where their involvement in the trial is minimal and entirely within their expertise. The UK Policy Framework for Health and Social Care (2017), identifies that that decisions about research team members' suitability *"should not be based on inappropriate HR processes such as disproportionate training expectations (e.g. GCP for individuals, roles or projects that do not need it)"*

2.11. If an activity is part of a person's normal clinical role and all other protocol activities are undertaken by a member of the research team, then no GCP training may be required; however this should be reviewed as part of the risk assessment for a trial.

3. Scope

3.1. All research delivery personnel supporting research studies within the NHS across Wales.

3.2. At the time of implementation this SOP was compliant with all applicable UK legislation and guidelines. Should new legislation or guidelines come into force this SOP will be updated to take account of the changes at the earliest opportunity.

4. Responsible Personnel

4.1. All research delivery staff, for example, chief investigators (CIs), principal investigators (PIs), trials administrators, research officers, clinical studies officers, research nurses, team leads, co-investigators.

5. Responsibilities

5.1. The responsibility for ensuring staff are appropriately qualified to carry out their research role is shared by a number of individuals and organisations such as employing organisation of research staff, the chief investigator and members of the research team.

5.2. It is the responsibility of the CI/PI to ensure that all staff allocated duties on the Delegation of Duties Log are suitably trained in activities, including GCP as appropriate, linked to those duties.

5.3. All staff engaged in research are responsible for ensuring that they are competent to perform any tasks delegated to them and for undertaking appropriate training if necessary before agreeing to accept the delegation.

6. Definitions and Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of an investigational medicinal product
ICH	International Conference of Harmonisation
EU	European Union
GCP	Good Clinical Practice
HCP	Health care professional
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
R&D	Research and Development
SOP	Standard Operating Procedure

6.1. Interventional research: Research involving a change in treatment, care or other services made for the purpose of the research; it does not refer to research involving other methodological 'interventions', e.g. issuing a postal survey

6.2. Clinical Trial of an Investigational Medicinal Product (CTIMP): A study that looks at the safety or efficacy of a medicine/foodstuff/placebo in humans, as defined by the Medicines for Human Use (Clinical Trials) Regulations 2004

6.3. Non-CTIMP: Trials that do not involve an Investigational Medicinal Product (IMP) as defined by the MHRA, and therefore do not fall within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004.

6.4. Device studies: to demonstrate the safety and performance of a non-CE marked medical device, or a CE-marked device that has been modified or is to be used for a new purpose, defined by the Medical Devices Regulations. At the time of writing, the UK medical device market has a new route to market, the UKCA marking, and both marks are currently accepted. CE marking will continue to be recognised in Great Britain until 30 June 2023.

6.5. Devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, prior to the end of the transition period, gave effect in UK law to the directives listed below:

Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
Directive 93/42/EEC on medical devices (EU MDD)
Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)
This means that the Great Britain route to market and UKCA marking requirements are based on the requirements derived from the above EU legislation. (See MHRA website for further info)

7. Procedure

7.1. Section 7A and Appendix 1 should be followed by staff delivering or supporting the delivery of CTIMPs.

7.2. Section 7B should be followed for staff delivering or supporting the delivery of all other types of study

7A CTIMPs ONLY

CTIMPs and GCP

7.3. If a study is to be included as part of a marketing authorisation application then it is an expectation that the International Conference on Harmonisation GCP Guideline (ICH GCP) standard should be complied with.

7.4. Sponsors of CTIMPs which are not part of a marketing authorisation application can choose to comply with ICH GCP[1] as a standard in its entirety or they can take a more proportionate approach depending on the nature of the trial (further information can be found in the MHRA guidance on risk adapted approaches in the management of CTIMPs).

7.5. For all CTIMPs it is the high level “conditions and principles” of GCP set out in the UK Clinical Trial Regulations (SI 2004/1031, as amended) that must be complied with

CTIMPs and extent of GCP training

7.6. Each person involved in a CTIMP should receive GCP training commensurate with their roles and responsibilities identified on the study delegation log (please see Appendix 1 to help identify extent of training required).

[1] If organisations/sponsors claim compliance with ICH GCP as a quality standard, or cite compliance with ICH GCP within protocols, then it is expected that ICH GCP is the standard followed.

Frequency of GCP training

7.7. Each applicable member of staff should undertake GCP training before commencing work on a CTIMP.

7.8. The frequency of GCP training is not defined in the regulations although it is recommended that training is given at appropriate intervals to ensure staff maintain awareness of the current UK regulations and other applicable European guidelines.

7.9. How often this training is repeated is a business decision for the organisation concerned.

7.10. Individual training may be updated when legislation has changed, new policies or practice have been implemented, different research activities are to be undertaken, or a significant period of time has elapsed since research activities have been conducted.

7.11. This SOP and Appendix 1 (together with other training requirement SOPs/guidelines) should be referred to as a minimum:

- When staff are assigned delegated responsibilities within a research study for the first time.
- When staff are delegated additional or new responsibilities in an ongoing or new study.
- When an amendment to an ongoing research project has training implications for staff.
- When there are significant regulatory updates.

7B Procedure (All other types of research excluding CTIMPs)

7.12. There is no legal requirement for other types of research (ie studies which are not CTIMPs) to be conducted in accordance with the conditions and principles of GCP. However, it is still important that such research is always conducted in a manner that provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable. Members of the research team in such studies are expected to be qualified by education, training or experience and, whilst not a legal requirement, are encouraged to undertake GCP/good research practice training.

Other types of research and extent of GCP training

7.13. In the case of pragmatic trials, involving only minimal risk related to the research, it may be appropriate for some members of the research team simply to have an awareness of GCP requirements. For example, a practice nurse taking a blood sample in a pragmatic trial for the purposes of research, might be considered to be undertaking an activity which they would do as part of their normal clinical duties, for which the HCP is suitably qualified to undertake by virtue of education, training and experience without undertaking detailed GCP training.

8. References

- NIHR CRN Coordinating Centre Delegation and Decision Aid
- Medicines for Human Use (Clinical Trial) Regulations (2004); Amended Regulations (2006); Amendment No.2 (2006)
- ICH Harmonised Tripartite Guideline – Guideline for Good Clinical Practice E6 (R1) 10th June 1996
- Integrated Addendum to ICH E6: GCP E6 (R2)
- MHRA – Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products, Oct 2011.
- EudraLex Volume 10
- Joint Statement on the Application of Good Clinical Practice to Training for Researchers (HRA, MHRA, Devolved Administrations for Northern Ireland, Scotland and Wales (10 Feb 2020)
- UK policy framework for health and social care research (v3.3 7/11/17)
- York Foundation Trust R&D Unit SOP (S25) – Providing and Documenting Training for Researcher

Suggested Web pages

- Health and Care Research Wales https://healthandcareresearchwales.org/training/training-courses
- Health Research Authority: http://www.hra.nhs.uk/
- Human Tissue Act: https://www.hta.gov.uk/
- Data Protection Act: https://www.gov.uk/data-protection/the-data-protection-act
- Medical device regulations https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk

Appendix 1: GCP Training Requirements for CTIMPs

Study role	Leading study team	Delivery staff role examples		Roles identifying potential participants	Staff just needing an awareness
Staff roles	• Chief Investigator • Principal Investigator	Staff roles: delegated duties on delegation log, E.g. • Pharmacy staff • Technician • Research nurse • Research officer • Research administrator • Data entry • Medic • GP • Practice Nurse • Clinical research practitioner	Staff roles: limited roles on delegation log, e.g. • Dispensing study drug • Administering study drug • Phlebotomist • Pathology labs • Radiology	• Screening notes, databases, lists • Participant Identification Centres • Secretaries	• Receptionists • Out-patient department staff • Administrative staff • Secretaries • Staff on pragmatic trials conducting normal clinical duties* *See section 7.13
Training required	**Full GCP training**	**Full GCP training** Study specific training	• NIHR Learn fundamentals e-learning (Research practice in clinical settings; Fundamentals of clinical research delivery for laboratory staff; Fundamentals of clinical research delivery for IMP management) • Study specific instructions		• In-house awareness training • Research awareness factsheet (link)
Record	**Always check with your study sponsor and local requirements on the level of training needed for study roles** See appendix for further training courses to consider.				
	Recorded in training logs, research CVs and SOP reading logs in the investigator site file, and personal files				
	Knowledge of SOPs plus policies and procedures apply to all				

Reference: NIHR CRN Coordinating Centre Delegation and Decision Aid

Appendix

List of other training courses to consider (and where to access them)

Fundamentals of research delivery https://learn.nihr.ac.uk/
Valid informed consent http://www.healthandcareresearchwales.org/
Consent with vulnerable groups https://learn.nihr.ac.uk/
Managing essential documents http://www.healthandcareresearchwales.org/
Principal Investigator Workshop http://www.healthandcareresearchwales.org/
IRAS applications https://www.myresearchproject.org.uk/ELearning/IRAS_E_learning.htm
Attributing costs http://www.healthandcareresearchwales.org/, https://rdforum.nhs.uk/
Health Research Authority training https://www.hra.nhs.uk/planning-and-improving-research/learning/e-learning/ ,
Medical Research Council training https://byglearning.com/mrcrsc-lms/