Reference Number: UHB 317 **Version Number:** 2	**Date of Next Review: 06 Apr 2022** **Previous Trust/LHB Reference Number: N/A**

TRAINING REQUIREMENTS FOR RESEARCH STAFF, INCLUDING GOOD CLINICAL PRACTICE (GCP)

Introduction and Aim

All individuals undertaking clinical research must have knowledge and training to ensure the rights and safety of participants in research are protected and that the results of clinical trials are credible and accurate.

This SOP supports the Cardiff and Vale UHB Research Governance Policy (UHB 099) and aims to ensure all staff involved in clinical research are appropriately trained.

Objectives

- To set out the minimum training requirements for staff involved in clinical research at Cardiff and Vale University Health Board (C&V UHB)
- To provide an SOP which can be referred to during preparation of, and throughout the conduct of a clinical research study sponsored or hosted by C&V UHB.
- To identify appropriate timescales for renewal of GCP training.

Scope

This policy applies to all personnel undertaking clinical research in the UHB, including those individuals:

- holding substantive or honorary contracts/titles with the UHB, holding letters of access within C&V UHB, or undertaking research duties under contract with the C&V UHB temporary staffing department
- Undertaking clinical research involving C&V UHB patients or staff
- Undertaking clinical research on C&V UHB premises

Equality Impact Assessment	An Equality Impact Assessment has not been completed. This is because a procedure has been written to support the implementation the C&V UHB Research Governance Policy (UHB 099). The Equality Impact Assessment completed for the policy found there to be a no impact.
Health Impact Assessment	A Health Impact Assessment (HIA) has not been completed. This is because a procedure has been written to support the implementation the C&V UHB Research Governance Policy (UHB 099)
Documents to read alongside this Procedure	• Cardiff and Vale UHB Research Governance Policy UHB 099 • Health and Care Research Wales Good Clinical Practice (GCP) Training Requirements (all-Wales) SOP 2 V2.0 01/07/2018 • UK Policy Framework For Health And Social Care Research (V3.3 07/11/17)

	• Cardiff and Vale UHB Research, Consent and Mental Capacity SOP (UHB 147)
Approved by	Research Governance Group

Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Senior Manager, Research and Development Senior Nurse, Research Education & Training

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1.0	13/07/2016	07/07/2016	This SOP is a new document and replaces the existing 'Good Clinical Practice Policy for Personnel undertaking Clinical Research' (UHB 015). The requirement for appropriate training is set out in the Research Governance Policy (UHB 099) and this SOP is expanded to cover research training requirements, including but not limited to GCP training.
2.0	06/09/2019	11/10/2019	This procedure has been reviewed in light of the implementation of the All Wales Good Clinical Practice (GCP) Training Requirements SOP on 01/07/2018. V2.0 contains information about the contents and maintaining of research training files, other research training requirements in addition to GCP, and guidance for research staff supporting undergraduate students on placement, to reflect current practice.

CONTENTS

1.0 DEFINITIONS

CI	**Chief Investigator.** ***For the purpose of this SOP, CI refers to those CIs who are undertaking research activities within Cardiff and Vale UHB***
CTIMP	**Clinical Trial of an Investigational Medicinal Product**
CV	**Curriculum Vitae**
C&V UHB	**Cardiff and Vale University Health Board**
ICH GCP	**International Conference on Harmonisation Guidelines for Good Clinical Practice**
ISF	**Investigator Site File**
MHRA	**Medicines and Healthcare Products Regulatory Agency**
MRC	**Medical Research Council**
NIHR	**National Institute for Health Research**
Non CTIMP	**All clinical research other than that which requires MHRA approval (CTIMPs or Clinical Device investigations)**
PI	**Principal Investigator**
R&D	**Research and Development**
SDL	**Study Delegation Log**
SOP	**Standard Operating Procedure**
Sponsor	**The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research**

2.0 ROLES & RESPONSIBILITIES

It is the responsibility of the Chief Investigator (CI) or Principal Investigator (PI), as appropriate, to be familiar with this SOP and ensure the standards of training required for themselves and other members of the research team are suitable for carrying out their allocated responsibilities as recorded in the Study Delegation Log (SDL) throughout the life of the study.
It also is the responsibility of each research team member to ensure they have completed appropriate training before they commence work on any study as well as throughout the life of the study. They must also ensure they both fully understand and are competent in the requirements of their role.

3.0 RESEARCH STAFF TRAINING RECORD

It is the responsibility of individual members of research teams to maintain their own training record on an ongoing basis to show they are “qualified by education, training and experience to perform his or her respective task(s)” (ICH GCP 2.8). All staff working on clinical research studies should ensure that they are familiar with these requirements.

It is a requirement to include a copy of the current CV, updated to include the current post, in the training record. A suggested list of items for inclusion in the training record is provided in Appendix 1. A copy of the Cardiff & Vale UHB Research Induction and Training File, including a template research CV is available for use from the R&D office, or can be provided by a line manager.

Appropriate training records of the research team members, as required by the Sponsor, or a file note describing the whereabouts of the training records should be held in the Investigator Site File (ISF). This training record must be available for inspection by the Sponsor, regulatory authorities and other relevant bodies, in addition to internal audit if required.

Where any member of the research team ceases to work on a study the PI should ensure a copy of their training record is kept with the study documentation and the date of leaving added to both the CV and the SDL. The training record should be archived as outlined in SR-RG-001 Archiving of Clinical Trial and Research Study Data SOP.

4.0 GOOD CLINICAL PRACTICE TRAINING REQUIREMENTS

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. GCP training is a requirement for clinical trials of medicinal products (CTIMPs), but there is no legal requirement for other types of research. 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. A summary table of GCP training requirements in research is provided in Appendix 2.

It is the responsibility of the CI/PI to ensure that all staff allocated duties on the Study Delegation Log (SDL) are suitably trained in activities linked to those duties. Where GCP training is not deemed necessary by the CI/PI, staff are required to undertake topic related GCP training specific to their role. It is the responsibility of the CI/PI to ensure that each member of the research

team has access to and has completed the appropriate training and their training and qualifications are documented and retained in the ISF and in the individual's training record.

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.

4.1 GCP TRAINING REQUIREMENTS: CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CTIMPS)

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'.

The Health and Care Research Wales Good Clinical Practice (GCP) Training Requirements (all-Wales) SOP 2 V2.0 01/07/2018 outlines who should receive GCP training in CTIMPs.

In Cardiff and Vale UHB full GCP training must be completed by Researchers, Principal and Chief Investigators and all staff named on the SDL. GCP training should be completed prior to starting work on a CTIMP trial. Staff whose sole contribution to a CTIMP study is limited to routine care are not required to complete full GCP training, however proportionate training applicable to their role should be completed as determined by the CI, PI and/or the Trial Sponsor.

As a minimum, researchers of CTIMP studies in Cardiff and Vale UHB must revalidate their knowledge by completing a refresher course every two years, unless more frequent training is required by the CI/PI, the Trial Sponsor or in the event of new or amended UK regulations and other applicable Guidelines.

4.2 GCP TRAINING REQUIREMENTS: CLINICAL TRIALS THAT DO NOT INVOLVE AN INVESTIGATIONAL MEDICINAL PRODUCT (NON CTIMP)

It should be noted that there is no legal requirement for other types of research (i.e. studies which are not clinical trials of investigational medicinal products) to be conducted in accordance with the conditions and principles of GCP. 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 that is proportionate to their role in the study.

In Cardiff and Vale UHB full GCP training is encouraged for Chief and Principal Investigators of non CTIMP studies, and all staff who are delegated duties as part of the SDL. It is recommended that training is repeated at appropriate intervals to ensure staff maintain awareness of the current UK regulations and other applicable guidelines.

4.3 GCP TRAINING REQUIREMENTS: CLINICAL INVESTIGATIONS OF MEDICAL DEVICES

For Clinical Investigations of Medical Devices, the standard EN ISO 14155, which outlines good clinical practice, may be followed.

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 that is proportionate to their role in the study.

In Cardiff and Vale UHB full GCP training is encouraged for Chief and Principal Investigators of Clinical Investigations of Medical Devices, and all staff who are delegated duties as part of the SDL. It is recommended that training is repeated at appropriate intervals to ensure staff maintain awareness of the current UK regulations and other applicable guidelines.

4.4 OTHER INSTANCES WHEN GCP TRAINING MAY BE REQUIRED

Cardiff and Vale UHB R&D Office reserves the right to require that at any time before or during a research study, any identified research team member(s) should source and complete GCP training where necessary. This will be decided on an individual basis as part of the established study risk assessment process, and will be communicated accordingly by the Research Governance Team.

4.5 EVIDENCING GCP TRAINING

Those who have completed GCP training should keep a record of the certificate and subsequent updates in their research training file and the study ISF.

5.0 ADDITIONAL GOOD RESEARCH PRACTICE TRAINING

It may be necessary and/or useful for staff to undertake other training courses, for example informed consent, sample handling and shipping, effective communication, or research methods.

Clinical training, for example venepuncture, sample handling, working with dry ice, device operation or other may also be required in order for a research team member to fulfil their role.

Staff undertaking Clinical Investigations of a Medical Device may require specific device training.

The CI/PI is encouraged to arrange project-specific training where such training needs are identified. These should be recorded in the staff member's training record and retained in the ISF.

5.1 OTHER INSTANCES WHEN GOOD RESEARCH PRACTICE TRAINING MAY BE REQUIRED

Cardiff and Vale UHB R&D Office reserves the right to require that at any time before or during a research study, any identified research team member(s) should source and complete any formal or informal training deemed necessary.

6.0 ACCESSING TRAINING

6.1 GCP TRAINING

Health and Care Research Wales are the GCP Training providers for Wales and provide a free, high-quality, needs-driven, accredited training programme accessible to health and social care researchers in Wales. The NIHR also provide free, accredited online GCP courses. Details of how to access both Health and Care Research Wales and NIHR GCP courses can be found on Health and Care Research Wales website training pages and Appendix 3 of this document.

Other accredited GCP courses include those provided by private Organisations such as Infonetica and Institute of Clinical Research. Courses may be available from different providers. Information regarding these attended or online GCP courses can be accessed by searching the individual Organisations' websites via your internet search engine. Please contact the C&V R&D Office or your substantive employer who may be able to advise regarding the suitability of other courses. Trial specific GCP training alone, such as that provided by Commercial Companies for specific trials will not be accepted as valid GCP training.

6.2 CONSENT TRAINING

The Cardiff and Vale UHB Standard Operating Procedure Research, Consent and Mental Capacity (UHB 147) requires any research personnel who do not take informed consent as part of their usual duties to have undertaken an approved consent course before they are permitted to take consent in clinical

research studies. Training may be accessed via UHB online consent training (details found in SOP UHB 147). It is recommended that the online training package is revalidated every three years. An informed consent competency assessment document is available from the R&D Office.

Health and Care Research Wales support centre also provide training on Valid Informed Consent in Research, and additional training for staff working on research with children, and adults who lack capacity to consent.

6.3 IATA (INTERNATIONAL AIR TRANSPORT ASSOCIATION) DANGEROUS GOODS TRAINING FOR SHIPPING BIOLOGICAL SAMPLES

By law, those who transport dangerous goods out, those who receive dangerous goods and any person who causes dangerous goods to be transported by a public carrier must follow specific regulations and have proof of dangerous goods training. See Appendix 3 for details of how to access the e-learning package. This training must be updated every 2 years.

6.4 CARDIFF & VALE RESEARCH TRAINING PROGRAMME

Additional research training will be delivered throughout the year for Cardiff and Vale staff. The training programme is developed and prioritised depending on identified training needs and trends in governance issues reported to the R&D Office.

7.0 GUIDANCE FOR UNDERGRADUATE STUDENTS COMPLETING PLACEMENTS WITH RESEARCH TEAMS

Research awareness training and information will be provided by the allocated team at the start of the student's research placement.

During their placement, where students are conducting standard/routine clinical practices under the direct supervision of a GCP and protocol trained member of the research team, they are not required to receive full GCP or protocol training, or be on the study delegation log.

Where students are completing an extended placement (i.e. more than one week) and/or conducting protocol specific duties they will be required to receive training proportionate to their role, and to work under the direct supervision of a GCP and protocol trained member of the research team.

All source documentation must be completed or countersigned by the trained and delegated member of staff who is providing direct supervision to the student.

Students working in clinical areas during their research placement must not carry out any duties outside of their scope of practice.

8.0 REVIEW

The Procedure should be reviewed every 3 years or more regularly if deemed necessary.

9.0 REFERENCES

International Conference on Harmonisation: Harmonised Tripartite Guideline for Good Clinical Practice E6 (CPMP/ICH/135/95), European Commission (1996)

Medicines and Healthcare products Regulatory Agency. The Medicines for Human Use (Clinical Trials) Regulations 2004. Statutory Instrument 2004/1031 (2004).

Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (Statutory Instrument 2006/1928). The Medicines and Healthcare products Regulatory Agency (2006).

Medicines for Human Use (Clinical Trials) Amendment (No. 2) Regulations 2006 (Statutory Instrument 2006/2984). The Medicines and Healthcare products Regulatory Agency (2006)

UK policy framework for health and social care research Version 3.3 07/11/2017

Health and Care Research Wales SOP 2 Good Clinical Practice (GCP) Training requirements (All Wales) Version 2.0 01/07/2018

Websites

Health and Care Research Wales
http://www.healthandcareresearch.gov.wales/

NIHR: Online GCP training and updates
https://learn.nihr.ac.uk/course/index.php?categoryid=38

MHRA
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Medical Research Council (MRC)

https://mrc.ukri.org/

APPENDIX 1

SUGGESTED CONTENT OF STAFF TRAINING RECORD

An individual's training record should contain the following information as a minimum:

- Current job description and any previous job descriptions which are relevant to the current post. Ensure the dates of these positions are noted in the Curriculum Vitae (CV).
- Current, signed CV which demonstrates education, training, qualifications and experience to date. The UHB recommends that the CV is signed every 2 years to show it is still current, if there has been no update.
- Training record logs, both current and previous training record logs. These should list all training that the individual has undertaken which shows that they are able to undertake the responsibilities delegated to them in a study.
- Certificates of course attendance and agenda/content of courses and meetings. These may be photocopies or originals.
- Details of any relevant training conducted prior to appointment, which may not be listed in the current CV.

APPENDIX 2
GCP TRAINING REQUIREMENTS.

Type of Clinical Research	Research Team Member	GCP Training required
CTIMPs	CI/PI	Formal GCP training required
	Staff delegated duties on the SDL	Formal GCP training required
	All other staff	Role specific GCP training as determined by CI/PI
Non - CTIMP	CI/PI	Formal GCP training encouraged but not mandatory
	Staff delegated duties on the SDL	Formal GCP training encouraged but not mandatory Role specific GCP training as determined by CI/PI
	All other staff	Role specific GCP training as determined by CI/PI
Clinical Investigations of Medical Devices	CI/PI	Formal GCP training encouraged but not mandatory
	Staff delegated duties on the SDL	Formal GCP training encouraged but not mandatory Role specific GCP training as determined by CI/PI
	All other staff	Role specific GCP training as determined by CI/PI

APPENDIX 3: RESEARCH TRAINING RESOURCES

Course Title	Requirement	Information	Link to training
Good Clinical Practice (GCP)	As specified in this document	Accredited ICH GCP training	https://www.healthandcareresearch.gov.wales/training-courses/what-courses-we-offer/
Dangerous Goods Training	Mandatory for all staff shipping biological samples	International Air Transport Association (IATA) training for safe handling, packaging and shipping of dangerous goods	http://www.mayomedicallaboratories.com/education/online/dangerousgoods/index.html
Health and Care Research Wales training programme	Optional.	Role specific research training	https://www.healthandcareresearch.gov.wales/training-courses/what-courses-we-offer/
NIHR Massive Online Open Course (MOOC)	Optional	Understanding clinical research and its role in improving healthcare.	https://www.futurelearn.com/courses/clinical-research