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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 (CAVUHB) 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 CAVUHB
- 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 CAVUHB
- 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 CAVUHB, or undertaking research duties under contract with the CAVUHB temporary staffing department
- Undertaking clinical research involving CAVUHB patients or staff
- Undertaking clinical research on CAVUHB 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 CAVUHB 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 V3.0 18/07/2023

	• UK Policy Framework For Health And Social Care Research (V3.3 07/11/17) • Cardiff and Vale UHB Informed Consent in Clinical Research SOP (UHB 147)
Approved by	Joint Research Governance Group
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Senior Manager, Joint Research Office 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.*
3.0	18/10/2022	TBA	*Updated 6.2 details for accessing informed consent training* *Updated 6.4 with details of new training resources available via MS Teams*

			Changed title of section 7.0 to Guidance for supervised practice within research teams, updated to include new research staff and research staff completing training, in addition to undergraduate students completing placements with research teams. *Updated Appendix 3 with new internet links for training resources*
4.0	04/11/2025	20/11/2025	*UHB Documents numbers and titles updated. Definitions updated. In-text references and acronyms updated throughout, and reference list updated. 3.0 - grammatical errors amended and "Research" added to describe CV. 4.1 - EU directives updated.5.0 - "Dangerous goods/IATA" added. 6.2 - ESR and NIHR training updated. 6.4 - online training resources updated.*
5.0	15/04/2026	17/04/2026	*Minor changes to reflect updated Clinical trial regulations and Good Clinical Practice.* *Updates to some terminology/department names throughout.* *Updates to training/courses offered via Practice Development Nurses, Healthcare Research Wales, ECOD department and Research Delivery.* *Section 3.0 – detail added regarding staff on known long term absence and removal from delegation logs.* *Section 4.1 – revision to time period for research staff to update their GCP certifications in line with other organisations nationally (3 years).*

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**
CAVUHB	**Cardiff and Vale University Health Board**
ICH GCP	**International Council for Harmonisation Guidelines for Good Clinical Practice**
ISF	**Investigator Site File**
JRO	**Joint Research Office**
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/Investigator**
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 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)” (Section II, 5.1, ICH, 2025). 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 a current Research 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 CAVUHB Research Induction and Training File, including a template Research CV is available for use from the JRO, the Research Delivery SharePoint pages, 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 CI/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 Archiving of Clinical Trial and Research Study Data SOP (UHB 121). Where any staff are expectedly absent from work for a long period of time (i.e 6 months or more) they should be removed from the delegation log to ensure that training records reflect their role and time on the study. These staff members can then be re-entered on to the delegation log on return to work, ensuring that any changes or updates to training are addressed prior to the staff working on the trial.

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 participants (ICH-GCP E6(R3)), 2025). 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 (ICH, 2025) 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); this has been repealed by EU No 536/2014. 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 v3.0, 18/07/2023 outlines who should receive GCP training in CTIMPs.

In CAVUHB 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 CAVUHB must revalidate their knowledge by completing a refresher course every three 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 CAVUHB 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 CAVUHB 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

The JRO 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 (Dangerous Goods/IATA training), 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

The JRO 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 JRO 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 CAVUHB Informed Consent in Clinical Research SOP (UHB147) requires any research personnel who do not receive informed consent as part of their usual duties to have completed an approved informed consent training course before they are permitted to receive informed consent in clinical research studies.

As well as Good Clinical Practice and protocol specific training, it is recommended that staff complete the following:

CAV e learning on ESR:

- 000 NHS Wales - Decision Making and Consent in Wales
- 000 NHS Wales – Mental Capacity Act – Level 1

Valid Informed Consent in Research with Health & Care Research Wales

Any other e learning relevant to their role:

- ESR:
    - 000 Mental Capacity Act: Research Involving People Who Lack Capacity
- NIHR Learn:
    - Informed consent in paediatric research
    - Informed consent in emergency settings
    - Informed consent with adults lacking capacity
    - Remote consent

Competence and suitability to receive informed consent should be assessed by the PI (as outlined in UHB147 Informed Consent in Research SOP), or an appropriately experienced member of staff who has been assessed as

competent to receive informed consent for research. Support for those assessing competence in informed consent will be provided as part of the wider training programme and by the Senior Management Team.

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 (IATA, 2025). 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 JRO.

Online training resources via the Research Delivery SharePoint pages, including training videos for Research Delivery Staff, are also available on the JRO staff intranet page.

7.0 GUIDANCE FOR SUPERVISED PRACTICE WITHIN RESEARCH TEAMS

In some cases, Research Delivery Staff and undergraduate students will be required to complete supervised practice with research delivery teams for the purposes of education, clinical skills training and practice update assessments as part of their role or research placement.

Where staff or 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 staff or students are conducting protocol specific duties as part of their role or extended placement, 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 member of staff or student.

Research awareness training and information will be provided by the allocated team during the new staff induction or at the start of the student's research placement. Staff and students working in clinical areas as part of their role or during their research placement must not carry out any duties outside of their scope of practice. Supervision of staff and students must follow guidelines for standard clinical practice in the UHB.

Training of new Principal Investigators within CVUHB

It is also recommended that any member of staff undertaking an Investigator role for the first time within the UHB, *should* be supervised or supported by another experienced Investigator/Principal Investigator. Further PI training can be accessed through Health and Care Research Wales including 'Principal Investigator: The basics', 'Principal Investigator Workshop: Beyond the basics', or via the Associate PI scheme with the NIHR or some other eligible studies. Other training courses relevant to the PI role can also help to broaden any knowledge, such as 'Essential records' training via Health and Care Research Wales, or via local training sessions which can be accessed by contacting the Senior Nurse for Research Education and Training with the Research Delivery Team (researchdelivery.cav@wales.nhs.uk).

Principal Investigator basics | Health Care Research Wales

Principal Investigator Workshop: Beyond the basics | Health Care Research Wales

Training courses | Health Care Research Wales

8.0 REVIEW

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

9.0 REFERENCES

European Parliament and the Council of the European Union (2014). *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.* [Online] Available at: https://www.legislation.gov.uk/eur/2014/536/contents [Accessed 14th August 2025].

Health and Care Research Wales (HCRW, 2023). *Good Clinical Practice (GCP) Training Requirements (all-Wales) SOP number 2 (Version 3.0)* [pdf]. Available at: https://healthandcareresearchwales.org/sites/default/files/2023-07/Health_and_Care_Research_Wales_SOP_GCP_V3.0_2.pdf [Accessed 15th August 2025].

Health Research Authority (HRA). (2025) *UK Policy Framework for Health and Social Care Research*, Version 3.3. [Online] Available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ [Accessed 21st August 2025].

International Air Transport Association (IATA). (2025) *Dangerous Goods Regulations: 66th Edition*. Montreal: IATA. [online] Available at: https://www.iata.org/en/programs/cargo/dgr/download/ [Accessed 21st August 2025].

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH, 2025). *ICH Harmonised Guideline. Guideline for Good Clinical Practice E6(R3)* [pdf]. Available at https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf [Accessed 14th August 2025].

International Organization for Standardization (ISO). (2020) *ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good clinical practice*. 3rd ed. Geneva: ISO. [online] Available at: https://www.iso.org/standard/71690.html [Accessed 21st August 2025].

Medicines and Healthcare products Regulatory Agency. The Medicines for Human Use (Clinical Trials) Regulations 2004. Statutory Instrument 2004/1031 (2004).UK Government (2025) *The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, UK Statutory Instruments 2025 No. 538*. [Online] Available at: https://www.legislation.gov.uk/uksi/2025/538/contents [Accessed 21st August 2025]

.**WEBSITES:**

Health and Care Research Wales
https://healthandcareresearchwales.org/homepage

NIHR: Online GCP training and updates https://learn.nihr.ac.uk/

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

ICH, 2025

APPENDIX 3: RESEARCH TRAINING RESOURCES

Course Title	Requirement	Information	Link
Good Clinical Practice (GCP)	As specified in this document	Accredited ICH GCP training	GCP | Health Care Research Wales (healthandcareresearchwales.org)
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	Dangerous Goods Training - Insights (mayocliniclabs.com)
Health and Care Research Wales training programme	Optional.	Role specific research training	Training | Health Care Research Wales (healthandcareresearchwales.org)
NIHR Learn eLearning platform	Optional	Role specific research training	https://learn.nihr.ac.uk
UK Clinical Research Facilities Network Competency Frameworks	Optional	Informed Consent Competency Assessment Laboratory Competencies for clinical research staff	Contact: Researchdelivery.CAV@wales.nhs.uk

NIHR Massive Online Open Course (MOOC)	Optional	Understanding clinical research and its role in improving healthcare.	https://www.futurelearn.com/courses/clinical-research