STANDARD OPERATING PROCEDURE 24
Essential Training and Training Records

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Revision Chronology:	Effective date:	Reason for change:
Version 3.0	07 Nov 2023	Updates to reflect new training log system, removal of the use of Q-Pulse for oversight of mandatory training and addition of expectation around training, access to systems and the potential for escalation.
Version 2.0	12 October 2022	Biennial review: Updated to new version of SOP template. Updated links. Included provision of induction plan and link to Welcome Hub in 4.2. Updated essential training table and included link to WCTU staff essential training page in 4.3.1. Updates to section 4.3.2. Minor amendments to text.
Version 1.5	5 June 2020	Biennial review: Updated to new version of SOP template. Updated to reflect the UoW essential training requirement. Link added to essential training portal. Removed references to PDFs. Updated to include UoW required reading, SOPs, and provisions for temporary and honorary staff.
Version 1.4	21 February 2018	Biennial review: Updated to new version of SOP template. Updated to reflect SOP sign off via Q-pulse. Minor amendments to text. Link added to UoW policy on retention of records. Included information regarding Epigeum research integrity online training.
Version 1.3	9th September 2015	Biennial review: Updated to include reference to the University's Research Code of Practice
Version 1.2	15th August 2013	To include provisions for archiving PDFs.
August 2011		Biennial review – no changes.
Version 1.1	22nd May 2009	Biennial review. Minor changes to text regarding review process.
Version 1.0	23rd April 2007	

STANDARD OPERATING PROCEDURE 24
Essential Training and Training Records

1.   Purpose and scope

This Standard Operating Procedure (SOP) describes the essential training required for staff working on University of Warwick (UoW) Sponsored research projects and the procedure for documenting training on tasks relating to research activities to comply with Good Clinical Practice (GCP) Guidelines. This is applicable to all members of staff working on research studies sponsored by the UoW and/or studies managed by WCTU.

2.   Definitions

Training Record	A record of a person's experience and competencies that evidences their ability to perform their responsibilities. The record can also show their personal development.
Personal Development Log (PDL)	For WCTU staff, the PDL is a list of training events, SOPs and completion dates. The PDL also contains renewal information. This information feeds into WCTU Training Compliance data.
Personal Development Record (PDR)	For WCTU staff, the PDR is a repository of documents which support the PDL. This might include CVs, Job Descriptions, or evidence of competency for training that has been completed.

3.   Background

International Conference on Harmonisation (ICH) GCP guidelines state that "Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s)." (Section 2.8).

To comply with these guidelines, all research staff must maintain a complete record of their on-going training and personal development to demonstrate that they are competent to perform study related duties appropriate to their role. It is important that staff are appropriately trained prior to being given access to systems to protect the integrity and security of records related to clinical research studies.

4.   Procedure

4.1   Responsibilities

All staff	• Maintain an accurate and complete record of all their personal development and training. • Read and acknowledge all SOPs required for their role in a timely fashion (ideally within 3 months of its issue)
Line Managers	• Periodically check training records of line reports for completeness • Assess for ongoing training needs. • Ensure line reports read and acknowledge SOPs in a timely fashion. • Discuss barriers to training and SOP compliance and escalate to senior management if necessary

WCTU Specific Responsibilities:	
WCTU Governance Committee	• Monitor ongoing compliance within WCTU and to escalate ongoing non-compliance via line managers or the appropriate associate directors according to the agreed escalation process. • Consider innovative methods to ensure uptake and increased awareness of responsibilities
WCTU QA Team	• Maintain oversight of essential WCTU and UoW training completion and SOP sign-off to provide assurance to the WCTU Governance Committee (GC) • Provide summary reports to the WCTU GC on training and SOP compliance within WCTU along with recommendations for improvement

For studies being managed outside of WCTU, research staff should be able to demonstrate experience and/or up to date training that is relevant to their role.

4.2   When?

Upon starting a new position all new staff members should be provided with an induction plan containing the required induction training and reading for their role. This should be completed in conjunction with the requirements detailed in the UoW's Welcome Hub pages. Their line manager should review the induction plan to confirm completion of all required tasks. Training should be complete before staff are given access to systems containing clinical research records.

For WCTU staff, all training should be recorded in an individual's PDL. Access to individual PDLs will be provided to all new members of staff working on clinical trials via a Microsoft Team. A new starter email will be sent to each individual, which includes links to essential training and important documents for completion.

Staff should update their individual training records on a regular basis and review periodically for completeness. Staff should also ensure their training records are always available for audit or inspection by internal or external parties.

Research staff working elsewhere in the University should maintain a record of relevant training in accordance with local departmental policies and in a format agreed with their line manager.

4.3   How?

For WCTU staff, it is recommended that the following should be included in a person's training record:

Induction Documentation	• Induction Plan • Evidence of competency from induction related tasks (if applicable)
Job Descriptions	• These should be present in ascending order and labelled with start and replacement dates (where applicable)
Full Curriculum Vitae (CV)	• This should be relevant for the role being performed, signed, and dated
Training Records (PDL/PDR)	• Essential training (see section 4.3.1) • Protocol and key document Sign-off

	• Study specific training (e.g. Protocol training, training on data management processes, working instructions, and other non-agenda driven training) inc. competency sign-off/confirmation where it is appropriate • IT training • Divisional seminars • Events, courses, conferences not organised by the UoW. • Copy of request/authorisation to attend. • Details of Course/Agenda • Certificate of attendance (where available)
Copy of Publications, Abstracts, Conference Presentations	• Copies of publications • Copies of abstracts • Copies of conference presentations

For other research staff, documentation proportionate to an individual's role and research activities should be maintained.

4.3.1   Essential Training

The UoW has identified essential training which all UoW staff are required to complete as appropriate for their role. A list of the essential training for academic and professional services staff and access to the training modules can be found on the [Welcome Hub Induction Training page](#).

For WCTU staff, the requirements for essential training are in the table below along with how often they require renewal and which members of staff are required to complete them.

Area of training	Renewal requirement and who is required to complete	Training available via:
Good Clinical Practice	Every 2 years. *All WCTU staff.*	CTU internal delivery or online National Institute for Health and care Research (NIHR) module
Information Security Smart	During Induction period. *All UoW staff.*	University internal online training course
Data Protection (UK GDPR) and Information Security Refresher	Annually after completion of induction training. *All UoW staff.*	University internal online training course
Inclusion Training (or any update to this UoW training package)	Every 3 years. *All UoW staff.*	University internal online training courses
Health & Safety Induction	Every 3 years. *All UoW staff.*	University internal online training course
Fire Safety Training	Every 3 years. *All UoW staff.*	University internal online training course
Unconscious Bias: Foundation	Every 3 years. *All UoW staff.*	University internal online training course
(Epigeum) Research Integrity	No renewal date. *The Research Integrity training is a requirement for any staff member involved in research.*	Epigeum Impact online training course

Additional essential training items may be required for completion depending on the staff members' role and updates to training requirements made by the UoW.

WCTU staff can check their essential training status by visiting the Competency Check tab on their individual PDL. Orange or White fields may indicate the need for training to be completed.

4.3.2   University of Warwick required reading
All UoW staff should read the Leadership and Management of Health and Safety document which details role specific requirements. Staff only need to read sections of the document applicable to their role. UoW staff involved in research must read the Research Code of Practice. Evidence of this should be in their training record.

There are additional institutional policies e.g., IT Compliance, Financial Regulations and Procedures, Human Resources Policies, which staff are required to read as part of their contract of employment. These can be identified by visiting the UoW's Welcome Hub pages.

4.3.3   Standard Operating Procedures
All staff involved in research studies sponsored by the UoW and/or managed by WCTU are required to have read the relevant SOPs for their role. Confirmation of reading and understanding each SOP should be acknowledged within the PDL for WCTU staff. New starters are requested to have read and acknowledged all relevant SOPs within 10 working days of their start date. Where staff are not currently involved in undertaking the procedure outlined in a particular SOP, acknowledgement can be on the basis that staff have understood the scope of its contents or key changes from reading the available SOP Summaries. It is expected that staff will revisit and read the SOPs in detail prior to undertaking a related task.

New or updated SOPs will be re-distributed to WCTU staff via notifications in the WCTU Personal Development Team and via email. Staff should acknowledge the new/revised SOP within 3 months of distribution. Compliance with this will be monitored by the WCTU Governance Committee on an ongoing basis and escalation on non-compliance will be via line managers or the associate directors.

UoW researchers working on Warwick sponsored projects that are not managed by WCTU are also required to follow the relevant SOPs that are applicable to their role from the SOPs for University of Warwick Sponsored Studies published on the WCTU webpages and also follow any local departmental guidance regarding relevant SOPs.

4.3.4   Non-compliance with training expectations
The WCTU Governance Committee will agree an escalation policy for staff that demonstrate persistent non-compliance with training expectations. Persistent non-compliance could result in temporary loss of access to systems.

4.3.5   Temporary and Honorary staff working with WCTU
All temporary and honorary staff working with WCTU will be required to evidence their competency to perform their role. This includes completion of essential training and acknowledgment of SOPs specific to their tasks and responsibilities.

Most temporary and honorary staff working within WCTU will be sent a new starter email by the QA team with relevant documents attached for completion. Evidence of completion should be returned

to the QA team, who will provide oversight of temporary and honorary staff compliance outside of the Personal Development System.

Honorary staff and temporary staff working on Warwick sponsored research projects outside of WCTU, should receive guidance from their line manager/supervisor regarding the training required for a particular role and completion of the training should be documented according to local departmental guidance.

4.3.6 Retention of training records from WCTU staff leaving the University

Training records for staff working on WCTU managed studies may be required for inspection purposes at any time, including after staff have left employment at the UoW. Therefore, when a WCTU staff member leaves, the QA Team will request their training record for retention. Individual records will be archived in a dedicated area within the WCTU's document storage area or in an electronic archive for a period of at least five years from the end date of the last study they worked on, or longer as stipulated by the UoW's Research Data Management policy.

List of Abbreviations

eQMS	electronic Quality Management System
GC	Governance Committee
ICH GCP	International Conference on Harmonisation Good Clinical Practice
NIHR	National Institute for Health and care Research
PDL	Personal Development Log
PDR	Personal Development Record
QA	Quality Assurance
R&IS	Research and Impact Services
SOP	Standard Operating Procedure
UoW	University of Warwick
UK GDPR	UK General Data Protection Regulation
WCTU	Warwick Clinical Trials Unit