STU-SOP-TM-014 – Standard Operating Procedure on Managing a change of CI

Version No:	4	**Effective Date:**	10-Apr-2026
Description of changes:	SOP reviewed in light of clinical trial regulations 2025 and GCP updates. Specific references to QPulse as the QMS have been removed. We now only refer to a QMS system.		

List of Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
REC	Research Ethics Committee
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure for changing the Chief Investigator (CI) of a research project.

2. Background

In the UK Clinical Trial Regulations, the term CI is used to describe a healthcare professional with primary responsibility for the conduct of a Clinical Trial of an Investigational Medicinal Product (CTIMP). This definition is similar to the term 'Coordinating Investigator' found in Good Clinical Practice (GCP) to denote an investigator with responsibility for the direction of investigators at individual research locations.

The term 'Principal Investigator' (PI), commonly used to describe a lead investigator of any research project in the UK is not specifically defined. The term is often used to denote the lead investigator at an individual research location.

The CI is responsible for the conduct and leadership of the entire research project, whether or not they are an investigator at any particular research location. The CI should have the necessary experience, training and in-depth understanding of the research project and of their responsibilities in respect of the trial.

It is essential that there is clear, documented evidence of a change of CI at any stage of a research project. This may occur due to retirement, resignation, change in employing institution or inability to continue in the role for example due to illness.

3. Roles and Responsibilities

The **Sponsor** is accountable for the conduct of all research and for ensuring that each member of the research team understands, and is capable of undertaking their role(s). They are responsible for approving an incoming CI and seeking ratification from relevant third parties e.g. funding body, Research Ethic Committees (RECs).

The **Trial Steering Committee / Trial Management Group (TSC/TMG)** may have delegated responsibility from Sponsor for recommending a replacement CI or overseeing responsibilities for instances where the CI is incapacitated until a new CI is appointed.

The **Chief Investigator (CI)** responsible for notifying the research Sponsor as soon as they have formal confirmation of a change to their employer, retirement or otherwise demitting their role as CI of a research project. This role may be delegated or completed by another member of the research team if the current CI is unable to action this personally.

The **Trial Manager (TM)** is responsible for notifying sites when a change in CI has been implemented and for ensuring that relevant documentation is disseminated and stored.

The **STU Executive Team** can be asked to support the decision making concerning the appointment of a new CI.

External use of SOP: This SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 Notification and Sponsor Approval of a change in CI

The CI, or delegate, must formally confirm the CI is demitting their role in a research project to all relevant organisations including:

- Research Sponsor
- Clinical Trials Unit
- Project committees e.g. Trial Steering Committee (TSC), Trial Management Group (TMG)
- Funding Body
- Ethics committee
- R&D departments
- Regulatory bodies e.g. the Medicines and Healthcare Products Regulatory Agency (MHRA)

These notifications are additional to the usual procedures involving Human Resources.

The CI may also nominate a named representative to have responsibility for research project data or samples maintained in an archive. If the CI is unable to nominate an individual one will be agreed by the TSC/TMG and Sponsor.

The Sponsor, funder and TSC/TMG should agree the suitability of the proposed CI prior to applying for approvals.

4.2 Applying for approvals of a new CI

Following Sponsor and funder approval of a new CI, a substantial amendment must be submitted to the REC, R&D departments and regulatory bodies as relevant.

The new CI cannot assume any CI duties for the trial until all required approvals are in place. An exception to this would be instances where the CI was incapacitated or otherwise unavailable, in which case the sponsor (or delegate) will nominate a person(s) to complete the handover.

All relevant communication and documentation will be held in the Trial Master File (TMF) and Investigator Site Files (ISF) as relevant.

4.3 Handover to a new CI

The outgoing CI, or delegate, must ensure the incoming CI receives a comprehensive handover of all information and documentation relating to the research project. This will include, but not be limited to:

- TMF
- ISF (if relevant)
- Electronic database
- Access to relevant email communication
- Access to source documentation
- Funder resources or documentation e.g. online portal

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2025 - https://www.legislation.gov.uk/uksi/2025/538/contents

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
N/A	N/A	N/A