RD&I	NHS University Hospitals Plymouth NHS Trust **STANDARD OPERATING PROCEDURE**

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Trust's website: https://www.plymouthhospitals.nhs.uk/researchers

Research Training

SOP No: S1

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Page: **1** of **6**

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APPROVED BY

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Date: 18th Jan 2019

1 Purpose and Scope

The UK Policy Framework for Health and Social Care Research (2017) and the Medicines for Human Use (Clinical Trials) Regulations 2004 stipulate that each member of the research team be 'qualified by education, training and experience to discharge his/her role in the study'. It is also the responsibility of the Investigator to ensure that research staff have 'adequate supervision, support and training'.

In order to provide evidence of compliance with this requirement to regulatory authorities, records of research team experience, education and training are required. The maintenance of an up to date Research *Curriculum Vitae* (CV) provides a means of demonstrating the adequate training and experience of research staff involved in the conduct of clinical trials.

This SOP outlines the procedure for evidencing research training and applies to Chief Investigators (CI), Principal Investigators (PI), research teams including clinical trial administrative staff and to RD&I office staff.

Definitions

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CV	*Curriculum Vitae*
GCP	Good Clinical Practice
HRA	Health Research Authority
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
RD&I	Research Development & Innovation
REC	Research Ethics Committee
RO	Research Office
SOP	Standard Operating Procedure
UHPNT	University Hospitals Plymouth NHS Trust

2 Who should read this document?

All staff involved in setting up and conducting research e.g. Chief Investigators (CI), Principal Investigators, Research Nurses & Midwives, RD&I Managers and Clinical Trial Administrative staff.

3 Procedure to Follow

3.1 Trust Mandatory Training.

Staff new to the Trust must undertake mandatory training prior to commencement of their post. The Trust's Workforce Development team keeps a database holding information on staffs mandatory training and will send reminders to staff detailing when their mandatory training is due to be renewed (typically one month in advance). It is an individual's responsibility to ensure that they are up-to-date with Trust mandatory training.

3.2 Research Governance training

All UHPNT staff working on research studies must attend Research Governance training (includes clinical trial regulation & ICH GCP) prior to commencing work on a study and this training must be subsequently updated every two years.

3.3 Study Training

The Sponsor is responsible for ensuring staff participating in research studies are appropriately qualified and trained. If the Trust is the Sponsor, this duty has been delegated to the CI/PI. The CI/PI is responsible for appropriate training of research staff and for ensuring all staff participating in clinical trials shall attend Research Governance training as soon as possible.

CI/PI must also ensure that research staff without Research Governance training will not be involved in research activities. The PI has overall responsibility for ensuring that staff are familiar with the study protocol and have undertaken all study specific training before they assign research tasks and sign staff onto the delegation log.

Delegated staff must ensure they are familiar with the study protocol, processes, procedures and their responsibilities before they undertake any study related activity.

6.4 Training Records

The RD&I department keeps a register of Research Governance training attendance and research staff CVs.

All UHPNT staff that work on research studies must prepare a research CV outlining experience pertinent to the study on which they are employed.

- The CV should contain details of clinical experience and relevant research training.
- This should be filed in the Investigator Site File (ISF).
- Further, any individual undertaking research within the Trust must also submit a current research CV (signed and dated paper copy or signed and scanned e-copy) with the RD&I Office. The CV must be updated, as a minimum, every two years after completing Research Governance training.
- For a research CV template contact the RD&I department.

Relevant study team training should be recorded either on a study training log or within the individuals research CV and filed in the ISF in order to provide evidence of completion of training.

Responsibility for maintaining a research CV and ensuring that the RD&I Office has the most up to date copy lies with the individual researcher. The studies CI/PI is responsible for ensuring that an up to date CV is placed in the ISF for all researchers involved on their study.

Creation, updating and archiving of CVs
The following process will be used for the creation, updating and archiving of CV records:

- Before starting any research study, the individual will create a research CV and forward a copy to the RD&I Office and to the studies CI/PI.
- The RD&I Office will review researcher's CV's on a rolling basis to ensure completeness and requested updated CVs if not already submitted.
- When an individual leaves their post a copy of their research CV must remain in any study site files they were actively involved in. The date of leaving should be added to the study delegation log. The researcher's CV must be archived with the study documentation for the correct archiving period.

6.5 Training Needs Analysis

It must be recognised that each team member will have different training needs according to their qualifications and experiences. An assessment of individual need should be performed on appointment by the appropriate line manger to establish a baseline framework of skills and competencies. This will serve to identify specialist knowledge that can be shared, and gaps in knowledge to be filled. Following the initial assessment, training needs will be formally reviewed at the time of the Trust appraisal. Individual training needs may be addressed by a combination of internal/external training courses and national symposia/conferences. Managers should also consider a variety of other activities including e-learning programmes, video/sound tapes, secondments/visits to other areas and departments.

4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the ***RD&I Manager or their Deputy***.

Non-significant amendments to this document may be made, under delegated authority from ***a senior RD&I manager***, by the nominated author. These must be ratified by the ***a senior RD&I manager***.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I internet site. Internal Trust Staff are expected to use the RD&I internet site to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

- Inclusion in the Trust weekly e-bulletin Vital Signs
- Direct email to Trust Researchers and or teams

4.2. Training in this SOP

4.2.1. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

5 Reference material

- TRW.HUM.POL.1053.2 Appraisal and Personal Development Policy
- SOP P9 Trial Master File & Investigator Site File

6 Amendment History

Version Number:	5.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name. Reduce signature requirement to single senior RD&I Manager. Updated references to the UK Policy Framework for Health and Social Care Research (2017). Removal of appendix 1 research CV template.

Version Number:	5.0
Date Of Amendment:	Jun 2017
Details Of Amendment:	Change research CV review to match current practice and make clear who the SOP applies to and their responsibilities. SOP template and SOP numbering updated.

Version Number:	4.1 (minor amendment)
Date Of Amendment:	Mar 2012
Details Of Amendment:	Cover page - Change of SOP location address.

Version Number:	4.0
Date Of Amendment:	Nov 2011
Details Of Amendment:	SOP re-written to ensure research training is documented within a Research CV and a signed and dated copy is maintain by the R&D Dept.

Version Number:	3.0
Date of Amendment:	Aug 2009
Details of Amendment:	New SOP template and re-write SOP to include details of research training record.