Plymouth Research and Development

University Hospitals Plymouth NHS Trust

Standard Operating Procedure

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Title:	Research training		
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1. Purpose

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.

2. Scope

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 R&D office staff.

3. Responsibilities

Any staff involved in setting up and conducting research e.g. Chief Investigators (CI), Principal Investigators, Research Nurses & Midwives, R&D Managers and Clinical Trial Administrative staff have responsibility to make sure they are appropriately trained for each study undertaken.

4. Documents needed for this SOP

- R&D research CV template.

The R&D research CV template is a short CV, which does not include identifiers such as date of birth or home address, so complies with the spirit of data protection in keeping personal identifying data to a minimum.

5. Related documents

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

6. Acronyms

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

R&D: Research and Development

REC: Research Ethics Committee

RO: Research Office

SOP: Standard Operating Procedure

UHP: University Hospitals Plymouth NHS Trust

7. Procedure

Step	Action	Responsibility
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.	All staff.
2	**Research governance (GCP) training** All UHP 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.	All research associated staff
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 have completed	Sponsor, CI & PI

Step	Action	Responsibility
	Research Governance (GCP) training prior to working on a study. CI/PI must also ensure that research staff without Research Governance (GCP) 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.	
4	**Training records** The R&D department keeps a register of Research Governance (GCP) training attendance and research staff CVs. All UHP 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 (e-signature aceptable) with the R&D Office. The CV must be updated, as a minimum, every two years after completing Research Governance (GCP) training. • For a research CV template contact the R&D 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 R&D 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.	CI/PI's, all research associated staff and research governance team

Step	Action	Responsibility
	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 R&D Office and to the studies CI/PI. • The R&D 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.	
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.	Line managers

9. Changes from last revision

Updated Dept. name (RD&I to R&D). Statement on the use of the R&D research CV template and Data Protection considerations.