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

Delegation of Duties

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Page: **1** of **8**

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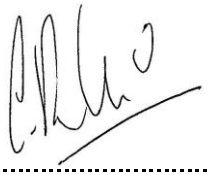
Signature: 

Date: 21st Jan 2019

1 Purpose and Scope

This SOP will outline the procedure for the delegation of study duties.

The Chief Investigator (CI) has overall responsibility for the proper conduct of the study and the Principal Investigator (PI) is responsible for the proper conduct of the study at the local site; however trial duties may be delegated to appropriately qualified staff.

A study duty is a task essential to the conduct of the study that is documented in the study protocol. A Delegation of Study Duties Log records all delegated duties.

It is a requirement of The Medicines for Human Use (Clinical Trials) Regulations 2004 and the UK Policy Framework for Health and Social Care Research that personnel employed to work on research studies are qualified to do so by education, training and experience.

Researchers must also be adequately supervised and supported in order to discharge their duties. It is the responsibility of the Investigator to meet these requirements.

Therefore, to ensure research is conducted in accordance with regulatory requirements, study related duties must be undertaken by appropriately qualified and supported personnel. This includes personnel directly involved in the conduct of the study including:

- Chief Investigator (CI)
- Principal Investigator (PI)
- Co-investigator
- Research Nurses
- Study Co-ordinators (e.g. Data managers/Research Assistants)

In addition there may be staff associated with, but not directly involved in the research including:

- Clinicians
- Specialist Nurses
- Pharmacists
- Laboratory staff
- Radiologists
- Support staff

For a study to be conducted appropriately, it is essential that all involved personnel are aware of the anticipated extent of their involvement, their responsibilities relating to ICH GCP and the UK Policy Framework for Health and Social Care Research and the limits to their authority.

The Investigator and other research staff where appropriate, must review the protocol and discuss and agree on the study requirements. The delegation of tasks will be

dependent on the qualifications and experience of team members. Tasks commonly associated with clinical research team roles are listed in Appendix 1. It is the local Principal Investigators responsibility to ensure the Delegation log is completed and kept up to date, even though they may delegate the task to another team member.

In scope: research hosted by, and/or sponsored by UHPNT.

Definitions

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HCA	Health Care Assistants
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
UHPNT	University Hospitals Plymouth NHS Trust
PI	Principal Investigator
RD&I	Research, Development & Innovation
REC	Research Ethics Committee
RO	Research Office
SDL	Study Delegation Log
SOP	Standard Operating Procedure

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, Health Care Assistants (HCA), RD&I Managers and Clinical Trial Administrative staff.

3 Procedure to Follow

3.1 Individual study related tasks must be defined, established and allocated prior to the initiation of a study.

3.2 The Investigator will delegate tasks to appropriately qualified personnel; this will be recorded on the Study Delegation Log (SDL). The SDL must be completed for every member of staff who works on the study. A template of a Study delegation log can be found on the UHPNT RD&I webpage site under RD&I templates.

3.3 The SDL will:

State names of staff delegated to specific tasks.

Be signed and dated by the CI/PI.

Be made available to the Sponsor if applicable.

Be updated when new members join the team and as otherwise required.

Be filed in the Investigator Site File.

Be retained following archiving, including a copy of each version, for audit purposes.

3.4 All personnel accepting a delegated duty sign and initial against each duty identified on the SDL.

3.5 The CI/PI must sign and date to validate all entries to the SDL.

3.6 The CI/PI will update and amend the SDL if delegated duties or personnel change during the course of a study.

3.7 External sponsors should be made aware of the planned division of tasks and of the names and roles of any other individuals involved in the study.

3.8 It is important for the Investigator to note that although tasks maybe delegated, responsibility cannot. Therefore it is important that the investigator makes sure all tasks are delegated to appropriately trained personnel.

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 ***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

Research Governance Framework for Health and Social Care: second edition
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf

ICH Good Clinical Practice (GCP) E6(R1)
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

Integrated Addendum to Good Clinical Practice (GCP) E6(R2)
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

The Medicines for Human Use (Clinical Trials) Regulations 2004 – Statutory Instrument 2004 No. 1031
http://www.legislation.gov.uk/uksi/2004/1031/contents/made

Appendix: Clinical research team roles — Appendix 1

Co-Investigators	Medical care of subjects Screening of patients for eligibility Informed consent Signing of consent forms Randomisation Administration of IMPs (where applicable) Collection of study specific biological samples Completion and where applicable return of CRFs Responds to data queries Prescriptions Documentation of adverse events in source data Timely SAE reporting Ethics commit and RD&I applications, amendments and other communication Be available for audit and inspections Add study specific duties
Other study physicians	Medical care of subjects Screening of patients for eligibility Informed consent Signing of consent forms Randomisation Administration of IMPs (where applicable) Collection of study specific biological samples Completion and where applicable return of CRFs Responds to data queries Prescriptions Documentation of adverse events in source data Timely SAE reporting Ethics committee and RD&I applications, amendments and other communication Be available for audit and inspections Add study specific duties

Research Nurse	Nursing care of subjects and their families and/or carers Screen patients Informed consent Randomisation Completion and where applicable return of CRFs Responds to data queries Documentation of adverse events in source data Study Site File set-up and management Be available for audit and inspections Ethics committee and RD&I applications, amendments and other communication Preparation of SAE reports for medical input and causality assessment Collection of study specific biological samples Add study specific duties
Data Manager	Data entry Completion and where applicable return of CRFs Manage data queries Support monitoring visits, audits and inspections Add study specific duties
Research Pharmacist	Acknowledge receipt of study supplies Drug accountability and monitoring of compliance Dispense IMPs Complete dispensing logs Maintain pharmacy site file Monitor storage of IMPs Add study specific duties

6 Amendment History

Version Number:	5.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Update logo and Trust name.

Version Number:	5.0
Date Of Amendment:	Aug 2017
Details Of Amendment:	Update SOP template and numbering system. SOP reviewed.

Version Number:	4.0
Date Of Amendment:	Jan 2015
Details Of Amendment:	Reviewed

Version Number:	3.1 (minor amendment)
Date Of Amendment:	Mar 2012
Details Of Amendment:	Cover page - Change of SOP location address.

Version Number:	03
Date of Amendment:	Aug 2009
Details of Amendment:	Change of SOP template, reference to The Medicines for Human Use (Clinical Trials) Regulations 2004 added and update of Study delegation log