



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/research-sops>

Document control / version control general guidelines

SOP No: P8
Version No: 3.1
Effective Date: Jan 2019
Supersedes: Version 3.0, Sep 2017
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Last Review Date: Jan 2019 Next review date: Jun 2022

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Date: 21st Jan 2019

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1 Purpose and Scope

This SOP provides guidance on the version numbering of documents used in the administration of Clinical Trials. Version control ensures that amendments to documents are tracked and verifiable and that the correct version of a document is in use according to the relevant ethical, regulatory or local approval.

This SOP is applicable to all documents produced for all types of clinical trials, including but not limited to SOPs, template documents and training presentations. It may also apply to documents produced by Investigator sites, including but not limited to Clinical Trial Protocols, Patient Information Sheets (PIS) and Informed Consent forms (ICF) and Case Record Forms (CRFs).

Definitions

CI	Chief Investigator
CRF	Case report Forms
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HCA	Health Care Assistant
HRA	Health Research Authority
ICF	Informed Consent forms
MHRA	Medicines and Healthcare products Regulatory Agency
PDF	Portable Document Format
UHPNT	University Hospitals Plymouth NHS Trust
PI	Principal Investigator
PIS	Patient Information Sheets
RD&I	Research, Development & Innovation
REC	Research Ethics Committee
SOP	Standard Operating Procedure

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2 Who should read this document?

All staff involved in setting up and conducting research and in particular staff that create and edit documents e.g. Chief Investigators (CI), Principal Investigators (PI), Research Nurses & Midwives, Health Care Assistants (HCA), RD&I Managers and Clinical Trial Administrative staff

3 Procedure to Follow

3.1. Version Numbers

3.1.1 Use a unique version number to distinguish one version from another. Use this procedure for all documents where more than one version exists, or is likely to exist in the future.

3.1.2 The number system will use consecutive whole numbers, i.e. version 1 for the first, version 2 for the second and so on. A major change (Substantial Amendment) will result in the use of the next consecutive whole number. For a minor change (Minor Amendment) the version number moves on a point i.e. Version 2.0 to version 2.1.

3.1.3 There can be any number of draft copies of each version. If a new document has three draft copies they should be labelled 'version 1, draft 1', 'version 1, draft 2' & 'version 1 draft 3' not 'version 1', 'version 2' and 'version 3'. The first approved version of the document should be version 1.

3.1.4 Put the version number on the document itself. The placement of the version number will depend on the style of the document, but the most common places for version numbers are the document cover, or preferably in the either the header or footer text on each page of the document.

3.2 Naming Conventions

3.2.1 Always add the date, to the header and/or footer, when any changes are made to the document.

3.2.2 The word 'Draft' can be added to the end of the file name to indicate the status of the version.

3.3 Read only Option

3.3.1 To reduce the likelihood of one version being overwritten with another use the read-only tag. Applying the read only tag will prompt users to save the document with a new version number if they make any changes to the original document.

3.3.2 Use this procedure for finalised documents where loss of the original would be a problem e.g. participant clinical study documentation.

3.3.3 To add a read-only tag to your document:

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- On your computer screen, navigate to your document.
- On the mouse right click on the document name and select 'Properties'.
- On the 'General' tab check the 'read-only' box.
- Select 'Apply' and the 'OK'.

3.4 PDF Option

3.4.1 If you are not keeping an editable version, a PDF (Portable Document Format) copy of the document can be created. The creation of these files will involve different methods dependent on which computer systems you may have. If help is required please contact the IT Dept. or the RD&I Office for advice.

3.5 Document Tracking

3.5.1 For regulatory requirements, it is necessary to keep track of document changes to show when and which changes were made. This can be done by a version control/history table or a saved 'tracked changes' file.

3.5.2 A 'track changes' file can be created for every new version by using the 'Track Changes' option found on the Microsoft 'Tools' menu bar. This shows all changes that have been made to the previous version. This document should be saved and filed in the same folder as the document concerned.

3.5.3 Remember to remove track change information from the final version of the document.

3.5.4 An alternative method is to use a table which is updated each time a change is made to the document, with the answers to the following questions:

- What is the new version number?
- What was the change?
- Who made the change?
- When was the change made?

3.5.5 The table can either be included at the start or end of the document, e.g. as in SOPs, or it can be created as a separate document and filed in the same folder as the document concerned.

3.6 Version Control Log

A Version Control Log is often a useful addition to include in Trial Master or Investigator Site Files as it allows you at a glance to see which documents are current and when they were approved. It also provides a useful document history if documents are subsequently amended. A template for a version log can be found at

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<http://staffnet.plymouth.nhs.uk/Departments/ResearchandDevelopment/Documents.aspx>
example of document fields below.

VERSION CONTROL DOCUMENT – keep at front of Trial Site File

THE MOST UP-TO-DATE VERSION OF EACH DOCUMENT MUST BE PLACED UPPERMOST IN THE FILE – Retain all earlier versions for audit purposes and mark: ‘Superseded by Version (No) on (date)’ to avoid accidental use of wrong version.

PROTOCOL

VERSION No.	DATE	DATE APPROVED BY ETHICS	DATE APPROVED BY MHRA	DATE APPROVED BY RD&I	DATE IMPLEMENTED LOCALLY	COMMENTS e.g. date new version sent to co-investigator or to participating sites, acknowledgement of receipt, etc.

PARTICIPANT INFORMATION SHEET

VERSION No.	DATE	DATE APPROVED BY ETHICS	DATE APPROVED BY MHRA	DATE APPROVED BY hra	DATE IMPLEMENTED LOCALLY	COMMENTS e.g. date new version sent to co-investigator or to participating sites, acknowledgement of receipt, etc.

OTHER

VERSION No.	DATE	DATE APPROVED BY ETHICS	DATE APPROVED BY MHRA	DATE APPROVED BY HRA	DATE IMPLEMENTED LOCALLY	COMMENTS e.g. date new version sent to co-investigator or to participating sites, acknowledgement of receipt, etc.

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

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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

International Conference on Harmonisation of Good Clinical Practice 1996
<http://www.ich.org/about/history.html>

Department of Health Research Governance Framework for Health and Social Care 2005
<http://www.nihr.ac.uk/about/nihr-publications.htm>

Medicines for Human Use (Clinical Trials) Regulations 2004
<http://www.legislation.gov.uk/uksi/2004/1031/contents/made>

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6 Amendment History

Version Number: 3.1
Date Of Amendment: Jan 2019
Details Of Amendment: Update logo and Trust name

Version Number: 3.0
Date Of Amendment: Aug 2017
Details Of Amendment: Update SOP template and numbering system. SOP reviewed

Version Number: 2.0
Date Of Amendment: Feb 2014
Details Of Amendment: Updated to make clear the version number convention

Version Number: 1.1 (minor amendment)
Date of Amendment: Mar 2012
Details of Amendment: Cover page - Change of SOP location address.
