Portsmouth Hospitals University NHS Trust

SOP for the Recording of Research Study Information in Patient Records

For Completion by SOP Author	
Reference Number	PHU/RDSOP/024
Version	Version 1.1, 29 September 2023
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For Completion by Research Dept., SOP Controller	
Name of Responsible Committee	Research Delivery Meeting, 25 Sept 2023 V1.1, 29 Sept 2023 [minor changes, see page 9 history log. No need for re-ratification of implementation date update].
Issue Date	29 September 2023
Implementation Date	09 October 2023
Review date	11th September 2026
Electronic location	Insert G Drive Location

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If you are reading this SOP in printed form then you are reading an uncontrolled document. You must therefore verify that the version number and date given below are the most recent, by cross-checking with the Trust research website before proceeding with implementation.

Portsmouth Hospitals University NHS Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This SOP has been assessed accordingly

CONTENTS

1. INTRODUCTION

Good documentation is essential in ensuring that a clinical trial is being conducted in accordance with regulatory requirements and ICH GCP. Historically, the documentation of a person's participation in a clinical trial is held on paper in the participants medical records. However, the NHS is moving towards the use of electronic records, highlighting a need for the Research Department to standardise how documentation is held on electronic patient records.

2. PURPOSE

The purpose of this document is to describe the Standard Operating Procedures for Portsmouth Hospitals University NHS Trust (PHU) position on the recording of research recruitment and ongoing study activities into patient notes and the uploading of research documentation to electronic patient records.

3. SCOPE

The information contained in this document should be used for all studies either hosted or sponsored by PHU.

The Trust recognises that some external sponsors, networks, funders and employers may require the use of their own SOPs for the good governance of research. In such cases it is the responsibility of the PHU user (including those individuals contracted to work on behalf of the Trust), to ensure that the external SOP is compatible with the procedure outlined below. If the external SOP contradicts the Trust's procedure, then approval must be sought in writing from a senior manager within the Research Department.

In the event of an infection outbreak, flu pandemic or major incident, the Trust recognises that it may not be possible to adhere to all aspects of this document. In such circumstances, staff should take advice from their manager and all possible action must be taken to maintain ongoing patient and staff safety.

4. ABBREVIATIONS & DEFINITIONS

Abbreviation	Meaning
PHU	Portsmouth Hospitals University NHS Trust
SOP	Standard Operating Procedure
ICF	Informed Consent Form
PI	Principal Investigator
PIS	Patient/ Participant Information Sheet
GP	General Practitioner
CTIMP	Clinical Trial of an Investigational Medicinal Product
NHS	National Health Service
PAS	Patient Administration System

Term	Definition
PHU Sponsored Studies	Studies which Portsmouth Hospitals University Trust have ultimate responsibility for the initiation, management of and financing for. PHU take primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting.

PHU Hosted Studies	Externally sponsored studies for which Portsmouth Hospitals University NHS Trust are acting as a site but do not have overall responsibility for the management of the trial.
Research Study Team	The people involved in the conduct of a research project. There may be different research teams for the project at different sites.

5. DUTIES AND RESPONSIBILITIES

Summarise the duties and responsibilities of key staff involved in conforming to the SOP

Role	Responsibilities
Investigator	▪ Oversight and knowledge of the procedure
Research Study Team	▪ Ensure the process of document uploads is completed as per the SOP
PHU Research Office	▪ Ensuring this SOP is available to all staff involved in research, and monitoring compliance where appropriate (i.e. as part of routine audit, triggered monitoring etc.)

6. PROCESS

The exact procedure for research study documentation management should be detailed in the individual study protocol. For the purpose of this SOP, the minimum data required (where applicable to the study) includes:

- ICF (consent process should be undertaken as outline in the SOP for "Recruiting and Consenting Patients into Clinical Research")
- PIS
- Consent discussion narrative.
- GP letter
- Study follow-up visit contact
- Follow-up study visit related information
- Re-consent documentation, where applicable.

The member of the study team who receives consent must ensure that the correct version number of all study documents is used and that the signed consent form is legible and completed correctly.

6.1 Informed Consent Form (ICF), Patient Information Sheet (PIS) & Consent Narrative

Once voluntary informed consent has been received from the participant:

1. A copy of the Informed Consent Form (ICF) and Participant Information Sheet (PIS) will be filled in the participants paper medical notes.
2. A scanned copy of the original signed ICF and PIS will be uploaded together as a PDF using the PHU secure scanners and uploaded to the patients electronic notes on Minestrone. (Instructions on how to do this are on page 7 of this SOP).

3. All original copies will be stored as per sponsor agreement.
4. In the event of a protocol amendment that requires re-consent, new ICF and PIS must be uploaded as a PDF and title as ‘re-consent’.

Also, at the point of receiving consent, a member of the research team will record the consent narrative. This will usually be the member of staff receiving consent, but it may sometimes be done on the behalf of another.

The consent discussion narrative can be written directly into the patient’s paper medical notes or their electronic medical notes or, if preferred, in the form of a pre-populated template (see example appendix 1) and uploaded to Minestrone. A pre-formatted version of the consent narrative is also available for use (appendix 1 of this SOP). The minimum data required is as follows:

- Participants name
- Study name
- PI’s name
- Version and date of PIS
- Any questions asked and the answers given
- Given time to consider the study (timings protocol dependant)
- That the participant meets eligibility criteria
- Version number of ICF
- Name of study member receiving consent
- That consent was obtained before any study procedures were performed
- That a copy of the ICF was given to the participant
- ***If the participant is consenting onto a CTIMP, it must be recorded that eligibility was confirmed by an appropriately delegated medic. The name of the medic and the date and time this eligibility was confirmed must be recorded.
- Statement to other healthcare professionals where further information pertaining the patient’s research involvement is stored and the contact details of the central research team should further discussion be required.

A copy of the completed ICF, current version of the PIS and the consent narrative must be available in both the patient’s physical medical notes, and on their digital records via Minestrone.

If you are working in a department which has already gone ‘paperless’, uploads to the specific digital clinical system are acceptable in lieu of paper notes. However, you need to consider carefully, in line with the study protocol and ongoing safety of the patient, whether the participant will have paper notes for unrelated conditions elsewhere in the hospital. If there is a chance that participation in a study may affect their ongoing care or if there is the need for ongoing safety reporting, research stickers and minimum documentation should still be recorded in the paper notes where they exist.

[Please note all study specific, pre-populated, narrative templates must be sent and reviewed by the Research Office before use. This is to ensure the correct information is being recorded for each study and will help to minimise monitoring findings.]

6.2 Other study documentation

All other study related information will be recorded in Minestrone only, unless specifically requested otherwise by the study sponsor. At the outset of a new study, it may be worth discussing this SOP with the monitor of the study to reduce any potential monitoring findings.

It is stated in the template consent narrative documentation that all other study related information will be recorded in patient's electronic notes via Minestrone. Originals will be kept in the study site file, or as per sponsor agreement. This would include documents such as GP letters, follow-up study visits narratives and ongoing consent (which should be completed for every research follow-up visit), safety reports etc. Also included would be copies of investigations that have occurred at another NHS Trust, where the results were requested as part of a research study. If a member of staff in unsure where to file a particular document, they should seek advice from their Senior Research Nurse or from the Research Office.

6.3 Instructions of how to upload electronic documents

All electronic patient notes should be kept for the same period of time as paper notes.

The current computer system used by PHU is called Minestrone. This system has the ability to search for patients using name, NHS number, PAS number or case note number. It stores all clinic letters and discharge summaries as well as linking in with pathology and the inpatient Bedview system. Minestrone is a quick and simple way for clinicians to access information about a patient and is now used across the Trust. It is, therefore, the chosen system to upload research information.

PDF documents can be emailed securely to other team members to upload to Minestrone.

The process to upload onto the Minestrone system is as follows:

- Log in to Minestrone and search for patient using the search bar
- Select correct patient
- Click on to Correspondence Clinical Documents tab and click 'upload document'
- Select document type drop down and scroll down to 'Research/Study'
- Select correct document subtype from drop down
- Add a description – study title and patient's study number.
- Add the date of the document (not the date of upload)
- Add speciality
- Drag PDF version of consent discussion/narrative to the file box or click 'browse, select a file and click open'
- Drag PDF version of the consent form and the PIS into the 'attachments' upload area. This can be done as 2 separate files or together depending on how they have been scanned and saved to PDF.
- Give the attachment/attachments a title
- Click 'save changes'. Upload should then appear in the correspondence list on left hand side of the screen
- Once the document has uploaded, open the document to ensure the correct document has been uploaded. You are responsible for the documents you upload.

If you do not have the ability to add attachments to your document, then please inform your line manager and a request will be sent to add this to your minestrone account.

Writing consent discussion narrative/ other notes directly onto Minestrone:

- Log in to Minestrone and search for patient using the search bar
- Select correct patient
- Click on to "Clinical Documents" tab and click "add note"

- "Author name" and "Author job title" should automatically populate.
- In "speciality" type in the clinical speciality (for example, colorectal). Research is not an available option.
- Select type of note (outpatient, inpatient, telephone, video, email/text message/MDT note). For consent discussion narrative this will be where the consent took place.
- Type in "Description" – include "Research Entry", study title, patient's study id (if applicable).
- Enter consent discussion narrative / other note into the "note" section
- Scroll down and click "submit"

6.4 Safety reporting considerations

Whilst it is accepted that the use of physical medical notes is in decline, all the time where physical and digital notes exist simultaneously, both must be considered as a potential source of safety reporting information.

In alignment with study protocol safety reporting requirements, research delivery teams must ensure that they review all potential sources of safety reporting data. This would include digital sources such as Minestrone, lab test recording systems, theatre list software, digital pharmacy etc. and physical medical notes.

Individual teams should risk assess the likelihood of where safety information may be recorded for participants on a research study on an individual study basis during the set-up of the studies. Teams should consider access to all information to ensure this is put in place proactively (i.e. log ins for systems are active, teams know local arrangements for physical notes etc.). Plans should be put in place to ensure that likely sources of safety reporting information are checked in line with the safety reporting requirements and timelines of the study. Just because, under this SOP, research related visits only need to be recorded digitally, teams may still need to review physical notes for the purposes of safety reporting (please refer to PHU/RDSOP/007 *Recording, Assessing & Reporting Adverse Events in Clinical Research* for more information) . If any further advice is required, teams should liaise with the study Sponsor, their Senior Research Nurse of the PHU Research Office.

7. TRAINING REQUIREMENTS

Members of the Research Team who are responsible for handling study documentation will be trained in this SOP.

"The Research Dept., will endeavour to notify staff of SOP developments that may be relevant to them. SOPs are available on the Research department website. Updates on SOPs will feature in Research newsletters and communications and disseminate at local research meetings. It is the responsibility of all research active staff to ensure that they read the issued updates that may be relevant to them.

When a new SOP is authorised, or when an existing SOP is revised, self directed training must be carried out by all staff to which the SOP is relevant and this training documented in their training record. A template is provided to support this process. A study specific SOP training plan will be developed for investigators on high risk PHT Sponsored studies.

Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification is needed then the trainee should approach their line manager and the SOP Controller who will arrange additional training. All staff should complete their training prior to the published implementation date which will normally be between 2-6 weeks after publication.

All staff are responsible for maintaining their own SOP Training Records and copies must be made available to line managers, the SOP Controller or study monitors on request."

8. REFERENCES AND ASSOCIATED DOCUMENTATION

Associated Documents

- **PHT/RDSOP/005** - SOP for Recruiting & Consenting Patients into Clinical Research

Reference

- Records Management Code of Practice - NHS Transformation Directorate (england.nhs.uk)
- https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/942217/Eight_Caldicott_Principles_08.12.20.pdf

9. VERSION HISTORY LOG

Version	Date Implemented	Details of Significant Changes
1.1	29 Sept 2023	Hyperlink for Records Management Code of Practice updated and typo in appendix 1 corrected

10. APPENDICES

Appendix 1 Example of consent narrative

Please note, the narrative below is also available as a template on PHU History Sheet paper. A template of this as an associated document to this SOP.

DOCUMENTATION OF CONSENT

This patient has been approached to participate in the _____ study.

Trial Number: PHU/____/___. PI:_____

Patient received the Patient Information Sheet (PIS) version _____dated _____ on the ___/___/_____.

Patient had time to read the PIS and consider the study. Study discussed with patient and opportunity given to ask questions. The main questions/points of discussion were:

_____

_____

Consent form sheet version _____dated _____ signed by patient. Copy of consent form given to patient and filed in medical records.

Consent received by _____

Date _____ Time _____

All inclusion/exclusion criteria were met.

Randomisation/Study Number: _____

GP letter sheet version _____dated _____ has been sent (if applicable).

Copies filed in notes: Consent form, PIS, Letter to GP.

Ongoing research related activity will be recorded digitally via Minestrone. This would include (for example) updated information sheets or consent forms, records of study visits, safety reporting documentation , research specific results etc.

If you need further information on the research this participant is involved with, please check Minestrone or contact research.office@porthosp.nhs.uk or extension 6136 if you need to discuss with a member of the team.

Equally, if an important safety event occurs with this patient you think the research team should be aware of, please contact on the email or extension below.

Signed _____ Print _____

Date_____ Ext/Bleep _____

Email address_____

11. CONFIRMATION OF SOP TRAINING RECORD

A copy of this record may be kept in your personal training file to confirm your training in a specific SOP. If required by a study Sponsor a record may also need to be kept in the Trial Master Files (TMF) or Investigator Site Files (ISF)

SOP Details: To be completed by the SOP Controller	
Title of SOP	SOP for the Recording of Research Study Information in Patient Records
Reference Number	PHT/RDSOP/024
Version	1.0
Issue Date	25 September 2023
Implementation Date	09 October 2023

Personnel Details	
Name	
Job Title & Research Role	
Date of Training	
Nature of Training	Self Directed
Records of any meetings to clarify details in SOP	

Signatures
I confirm that I have read and consider myself to be sufficiently trained in the above Standard Operating Procedure with regards to my individual roles and responsibilities Signature of Trainee …… Date ……
I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities

Signature of Trainer …… Date ……..

Additional Notes & Signatures

Signature of Trainer (where appropriate)

I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities

Signature of Trainer …… Date ……..