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/research-sops

Case Report Form (CRF) Completion

SOP No: T4

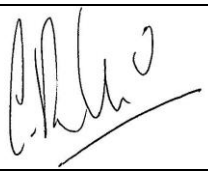
Version No: 4.1

Effective Date: Jan 2019

Supersedes: Version 4.0, Aug 2017

Page: **1** of **7**

Last Review Date: Jan 2019 Next review date: Nov 2022

	APPROVED BY
Name:	Chris Rollinson
Job Title:	Research Governance Manager
Signature:	
Date:	21st Jan 2019

1 Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to inform Investigators and other trial personnel of their responsibilities relating to collecting participant data accurately and in such a way as to allow verification of the data.

A case report form (CRF) is a form on which individual participant data required by the trial protocol are recorded. It may be a printed or electronic document. The CRF data is used to perform statistical analysis for the trial. Design of individual CRFs will vary from trial to trial, but it is essential that the design ensures that:

- adequate collection of data has been performed
- proper paper trails can be kept to demonstrate the validity of the trial (both during and after the trial)

The analysis of the data and the compilation of reports will last for many months after data has been collected. The results of a trial may also be audited or inspected a long time after the trial has been completed, by which time the main protagonists involved in the trial may have moved to other positions, thus it is imperative that CRFs are well designed, completed and correctly archived

CRF data includes pseudonymised details about the participant, study interventions, administration of investigational product (if applicable), study procedures, study outcomes, adverse events and adverse drug reactions.

CRFs are official study documentation and will be scrutinised during monitoring, audit and inspection by the Sponsor or regulatory authorities. The data collated from CRFs are used as the basis for the study report, and in the case of investigational products will make up part of the required regulatory data for approval of a new drug or device.

For commercial projects data are reported to the study sponsor; for own account research, data are reported to the Chief Investigator.

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

Definitions

CI	Chief Investigator
CRF	Case Report form
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HCA	Health Care Assistants

HRA	Health Research Authority
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
UHPNT	University Hospitals Plymouth NHS Trust
PI	Principal Investigators
RD&I	Research Development & Innovation
REC	Research Ethics Committee
RO	Research Office
SOP	Standard Operating Procedure
Source data	All information in original records and certified copies of original records or clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial

2 Who should read this document?

All staff involved in setting up and conducting research 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 Training on use of CRFs

Wherever possible, all personnel who will be involved in completing CRFs should receive training before the trial begins on how to complete the CRFs accurately, and how to deal with corrections.

Authorisation to complete CRFs is a responsibility delegated by the Investigator and must be recorded in the Delegation Log and filed in the Investigator Site File (ISF).

3.2 Collection of participant data

CRFs should be completed according to the specifications of each study, prospectively and where possible as close to the study visit as possible.

A black ballpoint pen should be used for recording study data into paper based CRFs.

If the CRF is printed on carbonless duplicate paper, a suitable separator should be used between pages to prevent overwriting.

If data is unavailable an explanation should be written in the CRF. The terms 'not available', 'not done', or 'unknown' are insufficient and should be further elucidated either by a 'note to file' or a note made in the CRF margin, if permitted.

Data entries must be attributable, legible, contemporaneous, original, accurate, and complete.

All data entries must be verifiable with source data from the participant's hospital records, concomitant medication, laboratory results, ECGs, patient diaries, x-rays etc. Any discrepancies with the source data should be documented.

Entries should not be overwritten; corrections should be made as follows:

I. The incorrect entry should be crossed out with a single line so it can be read easily
II. The original entry must not be obliterated or covered up with correction fluid or any other method.
III. The correct data should be entered
IV. The person responsible for the correction should initial and date the correction.

The participant's identity should remain confidential. The participant should only be identified on the CRF by means of the allocated study number and/or initials. The Subject Identification Log (a confidential record of participants with their full name and study number) must be kept securely by the PI.

The CRF must be signed by the PI or designee to assert that he/she believes the record to be accurate and complete.

CRFs should be kept in a secure location during the course of the study. On completion of the study CRFs should be archived as per study protocol and the local archiving SOP.

3.3 Data to be collected on CRF

This will vary from trial to trial, but should include the following:

- Inclusion/exclusion criteria
- Baseline data and demography data
- Data specifically required by the protocol
- Any dose and/or therapy (including non-trial therapy) taken and/or modified
- Adverse events, concomitant medications and intercurrent illnesses.
- Visits that the participants fail to make, tests that are not conducted, and examinations that are not performed.
- All withdrawals and dropouts of enrolled participants from the trial reported and explained.

Some data will be recorded directly onto the CRF and there will not be any prior written or electronic record of such data. This is considered to be source data.

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 intranet site. Internal Trust Staff are expected to use the RD&I intranet 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

UK Policy Framework for Health and Social Care Research (2017).

ICH Harmonised Tripartite Guideline for Good Clinical Practice. ICH GCP (E6) guideline

Appendix: Checklist for handling CRFs — Appendix 1

I. All investigational staff must receive sufficient information on the trial and on how to complete a CRF. All changes in staff during the study must be documented.

II. All data entered in a CRF must be legible, i.e. use block letters, for multiplecopy CRFs make sure that all copies are legible.

III. All data entered in a CRF should be understandable: i.e. use adequate units of measure for laboratory results, indicate and document when transformation of units has taken place, use only codes which have been predefined.

IV. Errors must be crossed out with a single line leaving the mistake legible. The correction should be initialled and dated by the investigator. Where appropriate, errors should be explained.

V. Correction should be distinctly different from the original, and done consistently throughout the trial (e.g. made in a different coloured ink).

VI. Every effort should be made to collect complete data.

VII. Omissions should be explained.

VIII. The investigator must archive the Investigator Site File (ISF) including copies of the CRFs.

IX. The source data must be readily available and retrievable for monitoring, auditing and inspection.

X. Document everything: Errors and omissions are acceptable but not without explanations

6 Amendment History

Version Number:	4.1
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).

Version Number:	4.0

Date Of Amendment:	Aug 2017
Details Of Amendment:	Updated SOP template and numbering system. Reviewed and updated SOP.

Version Number:	3.2 (minor amendment)
Date Of Amendment:	Jan 2015
Details Of Amendment:	Reviewed and signed off by the current RD&I Director.

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

Version Number:	3.0
Date of Amendment:	Aug 2009
Details of Amendment:	Change in SOP template format.