Plymouth Research and Development

University Hospitals Plymouth NHS Trust

Standard Operating Procedure

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Title:	Recording of study data		
Approver		Document No:	T10
Name:	Chris Rollinson	Version No:	3.0
Signature:		Effective Date:	Feb-2022
Date:	02-Feb-2022	Review Date:	Feb-2025

1. Purpose

To describe the procedure for recoding high quality research data.

2. Scope

This Standard Operating Procedure (SOP) relates to all research undertaken at the Trust.

3. Responsibilities

Principal Investigator (PI) is responsible for collecting and recording study data. This can be delegated to a responsible member of the research team.

All research staff must uphold confidentiality and ensure data is collected and stored in accordance with the protocol, participants consent, data protection legislation and Trust procedures.

4. Documents needed for this SOP

- None

5. Related documents

- Remote Monitoring Visit (rMV) Work Instruction
- Access to Electronic Health Records by Sponsor representatives in clinical trials

6. Acronyms

AE: Adverse Event

ALCOA-C: Attributable, Legible, Contemporaneous, Original, Accurate, Complete

CRF: Case Report Form

EHR: Electronic Health Records

HRA: Health Research Authority

ICF: Informed Consent Form

iPM: patient administration system

MHRA: Medicines and Healthcare products Regulatory Agency

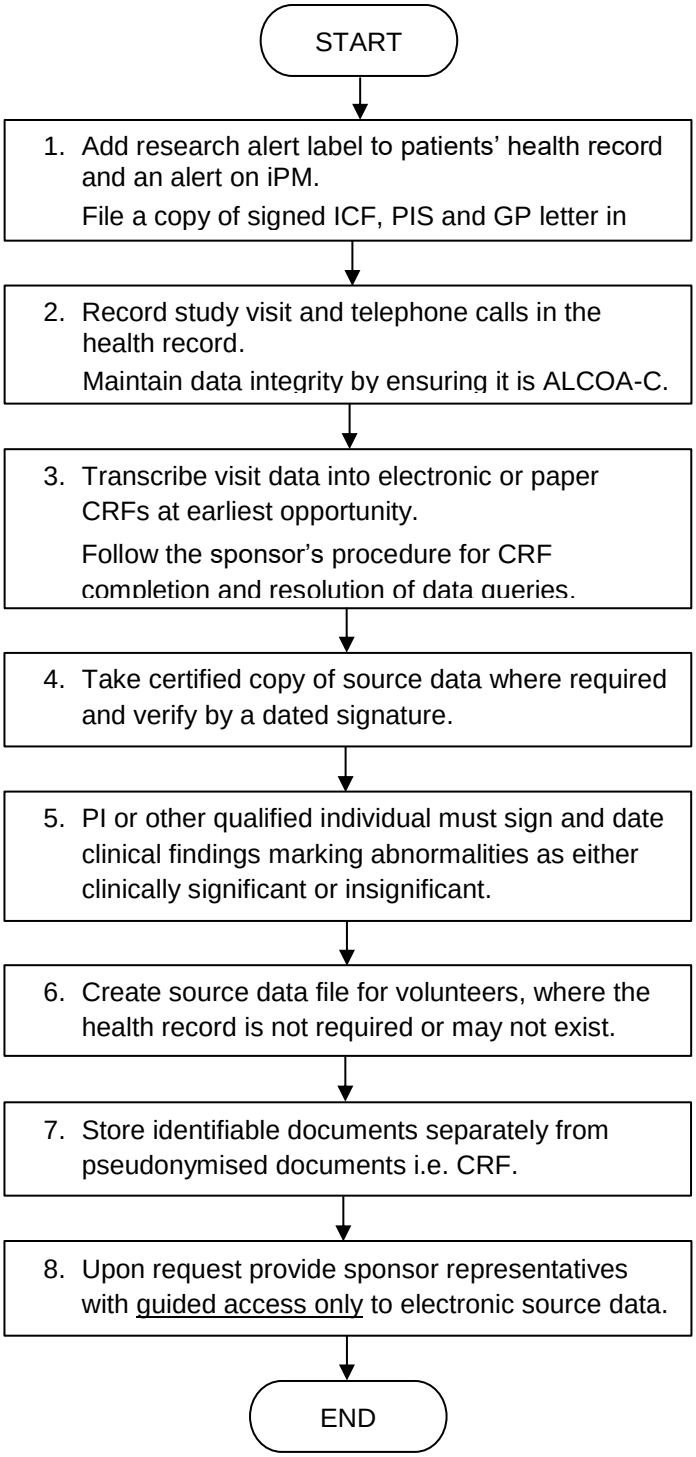
PI: Principal Investigator

PIS: Participant Information Sheet

R&D: Research and Development

SOP: Standard Operating Procedure

7. Process map(s)/ flow chart(s)



8. Procedure

Step	Action	Responsibility
1	Add alert to patients' health record and iPM (Inpatient Management system) indicating participation in research. For paper records affix label inside front cover. Minimum information to be included outlined below. The retention duration will vary depending on the study and located in the protocol. **CLINICAL TRIAL ALERT** Trial Name: Participant Study ID: Date Consented: Investigator: These notes must be retained at the hospital for ____ years following end of trial. DO NOT DESTROY BEFORE: ____ / ____ / ____ File a copy of the signed Informed Consent Form (ICF) in the health record along with a copy of the Patient Information Sheet (PIS). Studies utilising e-consent platforms must have the functionality to download/ print a copy of the signed ICF. Evidence the GP is aware of patient's enrolment onto a study, where applicable, should be filed. If an ethics approved GP letter is supplied as part of the study this must be used.	Clinical research team and administrators.
2	Record each study visit, including telephone calls in the health record including on standard clinical care continuation sheets. Each entry must include date, time, visit number and procedures completed using a ballpoint pen, black ink preferable. Maintain data integrity by ensuring it is ALCOA-C: ✓ **Attributable:** obvious who created a document and when, who made a change, when and why ✓ **Legible:** the record should be easily read ✓ **Contemporaneous:** results recorded as they are observed and signatures attached to a date when it occurred ✓ **Original:** where information is first record (source) ✓ **Accurate:** high level of honesty and accuracy in reporting ✓ **Complete:** maintain adequate, accurate and complete source documents	All research staff.

Step	Action	Responsibility
	Supply explanation where data is missing or incomplete. This also applies to paper Case Report Forms (CRFs) and internal worksheets, where a section is not applicable for example, mark it as such, initial and date. Do not leave it blank. Avoid using shorthand or abbreviations that aren't widely accepted. Strike a single line through errors; add correct value adjacent to it, initial and date and if required provide an explanation. Never obliterate entries that require correction.  Entries may be made retrospectively, do not back date the date of the documentation or alter past-dated entries. Updates may be made through addenda	
3	Transcription of visit data into electronic or paper CRFs must be timely. Enter laboratory values into the CRF without conversion from the source, unless otherwise agreed in writing. Follow the procedure outlined by the study sponsor for CRF completion and resolution of data queries.	Clinical research team and administrators.
4	Take certified copies (print/ photocopy) of source in the following, instances (but not limited to), each copy must be verified by a dated signature: – test results printed on thermal paper i.e. ECGs – scan reports and test results held electronically on information systems – written entries that haven't been made in a dark ink – signed ICFs completed electronically – e-prescribing drug chart for inpatient stay	Clinical research team and administrators.
5	Sign and date clinical findings i.e. blood results. Any abnormalities must be noted and marked as either clinically significant or insignificant. Abnormal results should be recorded as an Adverse Event (AE), depending upon their nature.	PI or suitably qualified individual.
6	Create a source data file for studies involving volunteers, where the health record is not required or may not exist. Exact format of the file should be determined prior to study commencement, and as a minimum contain: – a front sheet that details the participant's details	Clinical research team and administrators.

Step	Action	Responsibility
	– brief details of the trial and importantly emergency contact details – signed informed consent form, participant information sheet and GP letter, if applicable – continuation or worksheets where all research activity is detailed contemporaneously	
7	Store identifiable documents i.e. that hold participants name, address, hospital or NHS number separately from the CRF where participants are identified using a unique study code and initials (pseudonymised data).	All research staff.
8	Upon request provide sponsor representatives i.e. monitors or auditors with guided access only to electronic source data in order to spot check certified copies and verify data entered on the CRF. This may be done remotely and the work instruction for remote monitoring must be followed. More information about how the Trust is addressing the Medicines and Healthcare products Regulatory Agency (MHRA) and Health Research Authority (HRA) joint statement on providing sponsor representatives with access to Electronic Health Records (EHRs) can be found on the Trusts Research and Development (R&D) webpage.	All research staff.

9. Changes from last revision

SOP template change and addition of guided access to electronic source data by sponsor representatives.