Royal Papworth Hospital
NHS Foundation Trust

Document Title: Study Data – Collection and Entry

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Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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Summary of Amendments

Version	Modification:
3.0	Various amendments throughout
4.0	Amendment to section 4.2.1

Key Points of this Document

This document sets out the procedures to be followed by all Royal Papworth Staff who collect and enter data for the purpose of research.

It provides guidance on how data collected in the course of research should be documented and how records should be stored to ensure compliance with the Trust's policies.

1 Purpose and Content

a. This document defines the Trust's research procedures for the recording of study related data in Research Studies and Clinical Trials at Royal Papworth Hospital. This includes the completion of Case Report Forms (CRFs), both electronic and paper, and the recording of source data in medical records. The case report form is a paper or electronic form specifically used in clinical trial research to collect the information as required by the protocol.

b. This document clarifies the requirements for maintaining accurate and thorough records as described in Good Clinical Practice (GCP: 'a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected').

c. This document provides guidance on how research data should be collected and entered so as to comply with the Trust's policies on Information Governance, Health Records Keeping standards (DN224) and Patient confidentiality.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust.

b. Staff collecting and entering study data must comply with the requirements set out in section 4.

c. The Principal Investigator must ensure that if their research staff are recording or handling study data, that they are trained and compliant with GCP procedures. Staff entering data in CRFs must be listed on the study delegation log.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

4 Procedure

4.1 Study Data

a. The responsibility for collecting and recording study data remains with the Principal Investigator. This can be delegated to a responsible member of the site's research team who is deemed to be appropriately qualified by knowledge and/or training. This must be documented on the Study Delegation Log/ Site Responsibility Log.

4.2 Medical Records

4.2.1 For everyone approached for participation

a. Approach for research participation and participation in a research project must be clearly documented in the patients' medical record in the patient's electronic medical record (EMR).

b. For participants who are contacted regarding research and sent a Participant Information Sheet, but then decline to take part, it is not necessary to complete an R&D referral or clinical chart. A clinical note should be made to reflect that the patient was given a Participant Information Sheet (PIS) but were not interested in participation.

c. For participants who do wish to take part, complete an R&D referral and then set-up an R&D clinical chart.

4.2.2 For patients who have given consent

a. The P form tab within the R&D Clinical Chart should be completed.

b. A signed consent form uploaded into the Consent Form tab in the R&D Clinical Chart.

c. A research patient alert should be completed in the Health Issues tab in EMR.

d. A copy of the PIS should be uploaded to EDMS.

e. Where a copy of the REC approved GP letter has been sent to the GP, a copy should also be uploaded to the patients' electronic medical record EDMS.

f. Clinical notes should be recorded as Care Events in the Contact History tab. The details of each stage of the research participation such as visit number, study number, which study procedures have been completed, etc., should be documented in the clinical notes.

4.3 Source Data Documentation

a. The source data identification log (TPL024) should be completed to specify for each part of the protocol where the source data is located. This is usually either in the medicals records, paper Case report Forms (pCRFs) or the electronic Case report Forms (eCRFs).

b. Source Data must be recorded at each study visit and patient encounter.

c. Source data is stored in accordance with Trust Procedures.

4.4 Paper Case report Forms (pCRFs)

a. If pCRFs are used, the following should be followed:

1. The patient is identified by a study code - identifiable information should never be written on the pCRFs.
2. Kept in a secure location during the course of the study and accessed only by authorised members of the study team (as listed on the delegation log), regulatory authorities and monitoring staff.
3. Must be completed in a timely fashion, i.e. during, or as soon as possible after, the study visit has been completed. CRFs are completed according to the specifications of each study.
4. Must be completed in accordance with the standards described in GCP guidelines.

b. Method of documentation:

1. Always use a ballpoint pen; the use of black ink is preferable.
2. Ensure data entry is as complete as possible without omissions. If data is unavailable write, for example, 'not known', 'missing', 'test not done', etc. as defined by CRF Completion Guidelines (if applicable). Avoid using the ambiguous phrase, 'not available'. Where possible an explanation should be provided for the missing data. This should also be initialled and dated by the person completing the document.
3. Ensure all entries are accurate, legible and verifiable with the source data, if pCRF is not source data.

c. Corrections:

1. Cross out the incorrect entry with a single line so that the incorrect entry is still legible.
2. Enter the correct data.

3. Initial and date the correction.
4. Give an explanation of the correction if it is not obvious why the change was made.

d. CRFs should then be archived (Archiving SOP011) when the study has finished in accordance with Trust Procedures and Sponsor requirements.

4.5 Electronic Data entry

a. Data entry can be from pCRFs, from medical records, or directly entered by the study team or patients (using electronic Patient Reported Outcomes).

b. All individuals must be appropriately trained prior to entering data.

c. Most studies will use single data entry, but the data management plan or protocol can specify double data entry.

1. Electronic data entry must be completed in a timely fashion, i.e. during, or as soon as possible after, the study visit has been completed. CRFs are completed according to the specifications of each study.

d. If data entry is from pCRFs/medical records, all data items must be entered exactly as they appear on the data form, including spelling mistakes and grammatical errors.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2023)
Key related documents:	Trust Research Policy

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	No	No	No	No	No	No	No
Positive/Negative	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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