Royal Papworth Hospital NHS Foundation Trust

Document Title: Data Management Plan

Document Number: PTUC SOP078

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers, Senior Clinical Trial Data Manager
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Section(s):	Modification:
2.0	Minor amendments throughout

Key Points of this Document

- This document sets out the procedures to be followed by all Papworth Staff who are involved in the management of research data, to be managed by Papworth Trials Unit Collaboration, or sponsored by Royal Papworth Hospital NHS Foundation Trust.
- It aims to provide clear guidance on the steps involved in data management to ensure compliance with the Trust's policies.

1 Purpose and Contents

a. This document defines the Trust's procedures for the responsibilities of Data Managers and Chief Investigator(s) (CI) in the development review and approval of the data management plan (DMP) for research projects managed by PTUC or sponsored by Papworth NHS Foundation Trust.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust including: staff that are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties including those within CUHP AHSC and those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

b. It is the responsibility of the department's personnel to ensure that they are familiar with and adhere to all current SOPs, and have signed the relevant log in their training record.

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 Purpose of a DMP

a. The DMP documents the processes and procedures to promote consistent, efficient and effective data management practices for each individual study.

b. The DMP serves as the authoritative resource, documenting data management practices and decisions.

4.2 Requirements of a DMP

a. A DMP should be produced for all trials; this should be created by the Data Management Lead (DML) with input from the Chief Investigator (CI).

b. Identify and define the personnel and roles involved with decision making, data collection, data handling and data quality control.

c. Ensure data management processes are described and defined from study initiation until database lock.

d. The extent of the data management activities described in the DMP is dependent on the trial and the associated risks.

e. The DMP should remain a living form throughout the life cycle of a study, capturing any changes impacting data management made to the protocol or processes being used.

f. The DMP should be kept current and managed by version control or audit history. All responsible parties are aware of and agree to the current content.

g. Any major changes to the DMP should be approved by the CI; any minor changes should be approved by the study project manager. If the project manager deems it necessary they should escalate any amendments for approval by the CI.

4.3 DMP Timeline

a. The DMP is divided into three separate forms: FRM046 DMP Prior to build start, FRM046 DMP Prior to going live, FRM046 DMP Prior to locking. The purpose of dividing the DMP into three forms is so the relevant information required to move on the next stage can be entered and approved, without the need to provide information that is only required for later stages of the study. The relevant section of the DMP should be approved prior to starting on the work it describes.

b. The project manager should sign off the DMP prior to build and the CI should sign off the DMP prior to live and prior to lock.

4.4 DMP Template

a. The DMP form has been developed to ensure consistency and standardisation across all projects. This should be used for all studies, unless the sponsor/funder requires their own format.

b. The DMP is found in the eForms system. The guidance document GD023 eForms system for study documents covers this in more detail.

c. Associated with the form is the guidance document GD016 Data Management Plan, which gives detailed instructions on how to complete the form.

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)*	Current active version approved date
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 (2018)
Key related documents:	Trust Research Policies

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							

Review date:	January 2025

I certify the contents of this SOP has been reviewed and ratified

DocuSigned by:
Dr Patrick Calvert
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11-Feb-2022

Signed by Dr Patrick Calvert, Clinical Director of R&D — Date