Royal Papworth Hospital
NHS Foundation Trust

Document Title: Research Study Data Sharing

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Summary of Amendments

Version Number	Modification:
V1	New SOP.

Key Related Documents	Trust Policy DN001 Document Control Procedure GD007 Clinical Data Management Study Setup FRM111 Data Sharing

Key Points of this Document

1 Purpose and Contents

a. This document defines the Trust's procedures for the responsibilities in the sharing of data in compliance with the Data Protection Act (2018) and General Data Protection Regulations (2018) for research projects managed by Papworth Trials Unit Collaboration (PTUC) or sponsored by Papworth NHS Foundation Trust.

2 Roles & Responsibilities

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

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

a. Clinical trial data is an important part of all trials and how this data is shared must be properly controlled to ensure compliance and protect participant confidentiality. Data must be shared in compliance with Data Protection Act (2018) and General Data Protection Regulations (2018). **This guidance document does not cover the sharing of anonymised data post publication.**

b. **Why**: Before data is shared, it must be clear why it is being shared. All data sharing must be explicitly permitted by the trial consent form or trial protocol. A data sharing agreement must be considered when the data is going outside of Royal Papworth Hospital / PTUC.

c. **What:** Before sharing data, to comply with the Data Protection Act, only the data that is required should be shared. The following should be considered:

1. Depending on who is receiving the data, sending a limited subset of the data, that will be sufficient for their needs.
2. For blinded studies, care must be taken to know if the recipient is blinded or unblinded, at what stage of the study, and what is appropriate to share. For example, for an interim analysis, there may be an independent statistician who is unblinded, but the study statistician is still blinded. Therefore, for the study

statistician, the randomisation (and other blinded data) should be masked (or similar) in the data files, to maintain blinding. At the end of the trial both statisticians could become unblinded.

3. Removing or reviewing free text fields for sensitive or superfluous data.
4. Personally Identifiable Information (PII) such as date of birth, post codes, rare diseases etc., must be removed or modified (for example changed to year of birth or age) before data sharing unless necessary for analysis, covered by a data sharing agreement (where applicable), and permitted by the consent form. As per GD007 (Clinical Data Management Study Setup), sensitive data such as NHS numbers or NHS ODT donor/recipient numbers should not be collected unless clearly required by the study protocol and explicitly consented to by the participant.
5. Supplying Data Dictionaries, or copies of Case Report Forms, either paper or annotated (pCRFs or aCRFs), alongside the data so the data can be clearly understood.

d. **When**: Data should only be released for one of the following:

1. To create a report for a Data and Safety Monitoring Board (DSMB), Data Monitoring and Ethics Committee (DMEC) or an equivalent body meeting, even at a timepoint not specified by the protocol. Such meetings might be due to an unexpected safety event etc.
2. During the study - data might be shared within the study team for reporting purposes
3. At other time points written into the protocol.
4. Interim Analysis/Lock - sometimes in a trial it is agreed that there will be an early analysis for safety or other reasons. This is usually covered in the protocol or Statistical Analysis Plan (SAP), which should include what data is to be analysed and who will review it.
5. End of Study/Database Lock – this is the time that data is usually shared.
6. A draft dataset might be shared to either prepare the analysis or to look for data errors using statistical methods.
7. At publication - the data might be shared as part of the publication process. This may require additional anonymisation, which is not covered in this documentation.

e. **Who:** Data should only be shared with groups covered by the consent form and other data sharing agreements specific to the trial. If in doubt (or not clearly stated), before sharing, consult with the Clinical Project Manager (CPM) of the trial to get confirmation.

1. Study team –the study team may require access to some of the data for various reporting needs. This can be monthly recruitment, SAE reports, etc., but may also be reports to help on the data cleaning and general study management. Care must be taken to make sure that the study team understand that no analysis of the study endpoints is permitted, as this could affect and bias the study.

2. Statisticians – The needs of the statisticians are a high priority for data management, as their analysis is usually the outcome of the trial. They should be contacted early in the trial to discuss how and when they would like their data. They will often request draft or dummy data, and data dictionaries to prepare their analysis.
    I. PTUC – no data sharing agreements are needed within PTUC.
    II. Non-PTUC – when preparing data for external statisticians, discussions should start as early as possible, as their expectations of data formats, may be different from how standard outputs are generated. Ensure the necessary data sharing agreement is put in place before data is shared externally.
3. Sponsor – trial data should not be released to the sponsor unless it was agreed in the trial contract and usually not until after database lock. Where a trial data set not specified in the trial contract needs to be shared with the Sponsor during the study, first confirm that the sharing is permitted under the trial consent form or protocol. Then, consult the trial CPM and/or Senior Clinical Trial Data Manager to ensure oversight. Only data needed for the purpose of request should be shared. If Sponsor's access to this data poses potential bias in decision-making, it is recommended to also confirm with the Stats team before sharing.
4. External – the data might need to go anywhere else externally. Ensure the necessary data sharing agreement is put in place before data is shared externally.

f. **Where/how:** Data can only be sent via secure methods, the following three are examples that are acceptable. Other methods must be approved by the Trust's Information Governance Manager:

1. NHS emails – emails between nhs.net and nhs.net addresses. There are other addresses that meet the security standard (DCB1596). Further details can be found at the following websites:
   https://digital.nhs.uk/services/nhsmail/guidance-for-sending-secure-email
   https://digital.nhs.uk/services/nhsmail/the-secure-email-standard
2. Secure messaging – using https://sft.royalpapworth.nhs.uk/ messages and files can be transferred to and from Papworth.
3. Secure hard drives – encrypted and password protected hard drive can be used for very large files that are too big for the 2 options above. This should not be used unless other options are not suitable.
4. To ensure traceability, study data extracts that are shared are version controlled by dates and stored in the appropriate folder in the eTMF.

g. **Documenting:** In accordance with GDPR chapter 2 article 5(2), all subject data must be processed lawfully, fairly, and in a transparent manner. Thus, all data sharing activities must be well documented and traceable, to ensure oversight and regulatory compliance. For instance, an email communication filed in the eTMF/TMF that document a data sharing request and delivery should at least contain details like: who made the data

request, what data was requested, reason/purpose for request, who approved the sharing, who shared the data, what data was shared, when and how it was shared. While such email records contribute to traceability, all data sharing activities at PTUC must also be formally documented using form FRM111 (Data Sharing) via eForms and can be approved by the Chief investigator or the Clinical Project Manager.

h. Additional Considerations:

1. **Training and Responsibilities**: Staff involved in preparing, approving, and sharing data must be trained in Good Clinical Practice (GCP), relevant standard operating procedures (SOPs), data protection legislation (e.g., UK GDPR and Data Protection Act 2018), and any system-specific requirements (e.g., encryption, SFTP usage). Responsibility for data sharing decisions should primarily rest with the Clinical Project Manager, Senior Clinical Trial Data Manager, and Trial Statistician (where applicable), in line with the protocol and applicable agreements. Other members of the study team should be consulted as appropriate.
2. **Incident Reporting**: Any data sharing errors (e.g., transmission to the wrong recipient, sending unencrypted files, or unauthorised disclosures) should be escalated to the Quality Assurance team (papworth.randdqa@nhs.net) and R&D management team. This should also be reported on DATIX in line with the Trust's incident reporting procedures to ensure prompt investigation and resolution. The Clinical Project Manager is expected to be kept in the loop on these communications.

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 approved version 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 version 3.3 (07/11/17) and authorised amendments thereafter.

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

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