Document Title: R&D Staff use of the Shared Care Record (ShCR)

Document Number: R&D SOP129

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	May 2028

Summary of Amendments

Version Number	Modification:
1.0	New SOP

Key Related Documents	Trust Policy DN1 Document Control Procedures

Key Points of this Document

1 Purpose and Contents

a. This SOP sets out the procedure to be followed by research staff in accessing the Shared Care Record (ShCR) for patients participating in Interventional research studies.

b. The ShCR is a secure, safe digital record system introduced to speed up and simplify the sharing of information for direct patient care purposes, across multiple organisations delivering health and social care in the Cambridgeshire and Peterborough area. It does this by joining up information which is currently held by separate health and social care services across Cambridgeshire and Peterborough and serve a population of around 950,000. A person's GP, local hospital, social worker, community, or mental health team all hold different electronic records.

c. The Shared Care Record enables health and social care professionals (clinical and non-clinical) to access up-to-date information about the individuals they are caring for from these systems.

d. Access to the ShCR will support management of patients in Interventional studies.

2 Roles & Responsibilities

a. This SOP applies to all R&D personnel that are conducting interventional research at the Trust.

b. This SOP does not apply to observational studies where ShCR access is not permitted (unless specific written, ethically approved, research consent has been obtained).

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. For research staff on the delegation log for an interventional study the ShCR can be accessed through the link in Lorenzo for patients who have consented to being on a trial, for direct patient care purposes. (How to access shared care record | Intranet).

b. The purposes include, but are not limited to:

1. Reviewing the participants' data to see if any adverse events have occurred
2. Applying a research tag to confirm the participant is on a study
3. Providing timely care and follow-up

c. This SOP does not relate to observational studies where ShCR access is not permitted (unless specific written, ethically approved, research consent has been obtained).

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 (2023)

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							

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