STANDARD OPERATING PROCEDURE

S60 – Electronic Transfer of Prescriptions to Trials Pharmacy

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Controlled document

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It is the responsibility of all users of this SOP to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

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Full History			
Version	**Date**	**Author**	**Reason**
1.0	28 July 2014	Gayle Githens-Mazer, Clinical Research Nurse Manager	
2.0	DD MM 2019	Samantha Keenan, Senior Research Practitioner	*Minor changes to contact details and transfer to new template.*

Associated Trust Policies/ Procedural documents:	
Key Words:	*SOP* *Trials Pharmacy* *Prescription*
In consultation with: Quality Assurance Group (June 2019) Directorate Governance Group	

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1 INTRODUCTION

The Royal Devon & Exeter NHS Foundation Trust (RDEFT), Research & Development (R&D) Department develops, collects and manages research Standard Operating Procedures (SOPs) on behalf of the Trust. The purpose of the SOPs is to define and formalise some of the tasks that researchers and other staff have to perform in relation to research.

SOPs are defined in the ICH Good Clinical Practice (GCP) guideline as *"detailed written instructions to achieve uniformity of performance of a specific function (Section 1.55); they are step-by-step "best current method"* guidelines aimed at reducing the variability of a process. SOPs should be clear, concise, of common style, format and content, available where and when needed and be subject of a system of document control.

2. PURPOSE

The purpose of this SOP is to outline the safe electronic transfer of clinical trial prescriptions to the Clinical Trials Pharmacy (CTP) to initiate dispensing prior to presenting the original prescription to the pharmacy team.

3. SCOPE

The SOP should be referred to whenever electronic transfer of a prescription is required.

Electronic transfers of prescriptions cannot be used for control drugs.

4. DEFINITIONS

CI	Chief Investigator
CIMD	Clinical Investigation of a Medical Device
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
LRM	Local Research Meeting
MHRA	Medicines and Healthcare products Regulatory Agency
R&D	Research & Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate
TMF	Trial Master File
CTP	Clinical Trial Pharmacy

5. DUTIES AND RESPONSIBILITIES OF STAFF

Research Teams shall follow this protocol when electronically transferring prescriptions.

The person collecting the trial medication has the responsibility to provide the original prescription to the pharmacy team when collecting study drugs.

Only trust encrypted devices must be used for electronic transfer of prescriptions; personal smart phones or devices are not be used.

It is the responsibility of the **research team** to assure that no alterations to the prescriptions are made post electronic transfer to Clinical Trials Pharmacy (CTP), as this will invalidate the sent prescription.

The **pharmacist or pharmacy technician** has the responsibility to validate the electronically transferred prescription against the original before releasing the completed prescription.

6. PROCEDURES

Ensure the prescription is valid. Ensure this is signed by a prescriber on the delegation log.

Transfer prescription securely e.g. email photo of prescription. Using email rde-tr.pharmacyTrials@nhs.net

Call trials pharmacy to inform them of how you have electronically transferred a prescription and confirm receipt.

Take original prescription to pharmacy when ready for collection. If prescription differs from electronically transferred prescription or has been altered in any way from original it will not be accepted by pharmacy.

Delete any copies of photos/scans from electronic devices (e.g. Sent box of your e-mail) after collection of the study medication.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the RDE Research website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

7.3 *If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.*

8. MONITORING COMPLIANCE AND EFFECTIVESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	The prescription is valid and signed by a prescriber on the delegation log.	Checking prescriptions against named personnel, and their training, on a study delegation log.
2.	Pharmacy accepts original prescriptions only, and checks them against the electronically transferred copy.	Evidenced by auditing the original prescriptions held by Trials Pharmacy.

8.2 Outcomes from audit will be presented to the R&D Quality Assurance Group which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to the R&D Divisional Governance Group.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the RDE research website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

Guideline for Good Clinical Practice-
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

RDE Research - https://rderesearch.co.uk/