York Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S88

Creating, reviewing and approving a clinical trial prescription

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and R&D Newsletter for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.northyorksresearch.nhs.uk/sops.html

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	Date:	12th February 2015
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	Signature:	Signed copy held by R&D Unit
	Date:	12th February 2015

This SOP will normally be reviewed every 2 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	12th March 2015	

Contents

1 Introduction, Background and Purpose

This SOP is required to ensure that clinical trial prescriptions created by the pharmacy team are designed to capture all the information required by the specific trial protocol. Trial specific prescriptions facilitate the prompt identification of the clinical trial due to their distinct appearance, and ensure the Investigational Medicinal Products (IMPs) and Non-Investigational Medicinal Products (NIMPs) are prescribed and dispensed according to the trial protocol, and accurate accountability and audit records are maintained.

A range of prescriptions can be used to prescribe IMPs and NIMPs, such as trial specific prescriptions, hospital outpatient prescriptions, hospital inpatient prescriptions, electronic prescriptions generated by the Sponsor, and electronic prescribing systems used to prescribe chemotherapy. The variety of prescription designs used allows the research team and pharmacy to capture the prescribing details as accurately as possible.

The purpose of this SOP is to ensure that clinical trial prescriptions are produced to a standardised quality, and fulfil the prescription requirements described in the Professional Guidance on Pharmacy Services for Clinical Trials produced by the National Pharmacy Clinical Trials Advisory Group (NPCTAG), York Teaching Hospital NHS Foundation Trust Medicines Code, The Medicines, Ethics and Practice guide produced by the Royal Pharmaceutical Society, and the prescribing and dispensing guidance given in the MHRA Good Clinical Practice Guide.

2 Who Should Use This SOP

This SOP should be followed by all members of the Pharmacy clinical trials team involved in designing and approving prescriptions at York and Scarborough Hospitals, which form part of the York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be followed by members of the Pharmacy clinical trials team to create a clinical trial prescription when one has not been provided by the Sponsor, or if a prescription has been provided which needs amending to comply with the Trust Medicines Code.

The prescription template may not be suitable for oncology/haematology clinical trials, as these may need to be prepared by an oncology/haematology specialist pharmacist using the ChemoCare prescribing programme. Prescription design should be considered during study setup at site.

Adherence to this SOP will ensure the prescribing standards for clinical trials are met and that all prescriptions are completed to a high standard enabling safe prescribing and an accurate audit trail to be created.

4 Procedure(s)

4.1 Creating a clinical trial prescription

If appropriate, use the Clinical Trial Prescription Template (Pharm/T15) to create a clinical trial prescription. The template can be adapted for clinical trials involving medication allocated through an IVRS/IWRS (Interactive Voice/Web Response System), or for clinical trials that do not utilise an electronic allocation system.

Amend the template as applicable - delete the sections not relevant for the trial and ensure the trial identifiers at the top of the prescription are completed.

Prescriptions should be reviewed and authorised following the processes described in section 4.3 of this SOP.

4.2 Amending a clinical trial prescription provided by a Sponsor

If the Sponsor has provided a prescription, then this may be used instead of the Clinical Trial Prescription Template (Pharm/T15), and amended as necessary to ensure it captures the required information detailed on the template (ensuring compliance with the clinical trial protocol and section 6 of the York Teaching Hospital NHS Foundation Trust Medicines Code).

If the prescription is missing any information required according to the Medicines Code, then the Sponsor should be contacted to request that the prescription be amended. Upon the addition of the required information, the prescription should be reviewed and authorised following the processes described in section 4.3 of this SOP.

4.3 Prescription review, authorisation and management

Prescriptions produced or amended by the pharmacy clinical trials team should be reviewed and authorised prior to implementation.

A draft version of the clinical trial prescription should be created and given a version number (e.g. version 0.1). This should be sent to the trial Principal Investigator, and either a senior pharmacy technician or pharmacy clinical trials pharmacist/manager for review. Any comments received should be incorporated if applicable.

The final version of the prescription should be version controlled (see example below).

Version number:	Supersedes number:	Written by:
Date active:	Checked and authorised by:	

Once approved by a pharmacist, the prescription should be scanned and saved electronically on the X drive (York) or I drive (Scarborough).

Send a copy of the prescription to the CRA/Sponsor for approval. When the prescription is approved by the CRA/Sponsor, send a copy of the prescription to the research team. File the wet-signed copy of the prescription in the pharmacy trial file.

If processing an amendment that requires a change to the prescription, the previous version of the prescription must be superseded. Ensure a copy of the new prescription is sent to the CRA/Sponsor for approval, and then distributed to the research team following review and authorisation.

4.4 Requests for new ChemoCare regimes, protocols and modifications

Requests relating to trial specific ChemoCare prescriptions must be processed in accordance with SOPSAT6 (Validation of the ChemoCare system and the preparation, modification and approval of chemocare regimes, protocols and drugs).

In addition to the standard patient identifiers and clinical information required, the following information should be captured at the time of preparing the prescription;

- The name of the clinical trial
- EudraCT number
- The treatment arm(s)
- Space to record patient trial ID number
- Space to record IVRS/IWRS pack numbers (if applicable)

5 Related SOPs and Documents

Pharm/T15	Clinical Trial Prescription Template
SOPSAT6	Validation of the ChemoCare system and the preparation, modification and approval of ChemoCare regimes, protocols and drugs

York Teaching Hospital NHS Foundation Trust Medicines Code

MHRA Good Clinical Practice Guide

Professional Guidance on Pharmacy Services for Clinical Trials' produced by the National Pharmacy Clinical Trials Advisory Group (NPCTAG) in October 2013

Medicines, Ethics and Practice. The Professional Guide for Pharmacists (RPSGB).