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/or Q-Pulse 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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 and/or Q-Pulse

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	Signature:	Signed copy held by R&D Unit
	Date:	23rd November 2017

This SOP will normally be reviewed every 3 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	
2.0	21st December 2017	Rewritten to provide clear instructions. Addition of instructions when dealing with sponsor produced prescriptions. Change of Author.

Contents

1 Introduction, Background and Purpose

The use of specific prescriptions for clinical trials enables prompt identification of those trials, facilitates accountability and ensures that Investigational Medicinal Products (IMPs) and Non-Investigational Medicinal Products (NIMPs) are prescribed and dispensed according to the appropriate protocol. Prescription design should be carefully considered during study setup at site.

A variety of prescriptions may be used to prescribe IMPs and NIMPs e.g. trial specific prescriptions, hospital inpatient and outpatient prescriptions or electronic prescriptions generated by the Sponsor or via ChemoCare. Prescription requirements are 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.

This SOP aims to ensure the standardisation and quality of any clinical trial prescriptions produced within York Teaching Hospital NHS Foundation Trust.

2 Who Should Use This SOP

This SOP should be followed by all members of the pharmacy clinical trials team in York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

Follow this SOP when creating a clinical trial prescription, or when amending a sponsor provided prescription to ensure compliance with the Trust Medicines Code. Note that the associated prescription template (Pharm/T15) may not be suitable for oncology or haematology clinical trials, which may need to be prepared by a specialist pharmacist using ChemoCare.

4 Procedure(s)

4.1 Creating a clinical trial prescription

Use the Clinical Trial Prescription Template (Pharm/T15) to create a clinical trial prescription if this is appropriate for the trial.

Ensure that the clinical trial identifiers at the top of the prescription are completed.

Adapt the template for clinical trials involving medication allocated through an IVRS/IWRS (Interactive Voice/Web Response System), or for clinical trials that do not utilise this system as appropriate for the designated trial.

Amend the template to further suit the needs of the clinical trial ensuring that sections which are not relevant to the trial are deleted.

Once the prescription is complete save it on the X:/ drive in the appropriate section of the trial electronic folder. The prescription should then be reviewed and authorised as described in section 4.3.

If the study requires the use of a ChemoCare prescription, place a file note stating this into the appropriate section of the pharmacy site file. Approved wet-signed copies of ChemoCare prescriptions are kept with the oncology team and can be provided upon request.

4.2 Amending a clinical trial prescription provided by a Sponsor

Sponsor prescriptions may be used in place of clinical trial prescriptions generated using template (Pharm/T15) providing they contain all the information required by the Trust Medicines Code.

If information is missing from the prescription, contact the sponsor to either request that they amend the prescription to include the missing information or to request permission to amend the prescription on site.

4.3 Prescription review, authorisation and management

If amendments to a sponsor prescription are made by the clinical trials team, then the prescription must be reviewed and authorised by the sponsor before it is taken into use.

Create a draft version of the prescription, save it in the appropriate folder on the X;/ drive and send it to a senior pharmacy technician and the pharmacy clinical trials manager for review and comment. Comments received should be incorporated if appropriate.

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

The approved prescription should be version controlled. File the wet signed copy in the pharmacy site file.

Send a photocopy of the wet signed prescription to the research team. Note that electronic copies of prescriptions should never be distributed to research teams.

If changes need to be made to a prescription during the trial, amend the prescription and ensure that the amended version is reviewed and authorised as above including obtaining CRA/Sponsor approval where necessary.

Supersede the previous version held in the pharmacy file and replace it with the wet signed version of the new prescription.

Send a photocopy of the wet signed prescription to the research team and request the return of any copies of the previous version. Note that electronic copies of prescriptions should never be distributed to research teams.

If the prescription is from a sponsor produced prescription pad, obtain permission to supersede the whole pad and/or its destruction. A single copy should be superseded and retained for reference within the pharmacy site file

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 also 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).