

Standards for prescribing Investigational Medicinal Products and Non-Investigational Medicinal Products for clinical trials

**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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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: <https://www.research.yorkhospitals.nhs.uk/sops-and-guidance/> and/or Q-Pulse

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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	Reviewers	Details of significant changes
1.0	29 th May 2015		
2.0	13 th December 2017		Minor wording changes and point clarification. Removal of reference to an obsolete SOP Addition of reference to a current SOP
3.0	23 rd September 2020		Change of link to R&D website. Change of author. Removal of out dated guidance. Reference to updated SOPs
4.0	21 February 2024	Rachel Spooner	Change of author and addition about EPMA requirements

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1 Introduction, Background and Purpose

Prescribing of clinical trial medication (Investigational Medicinal Products (IMPs) and Non-Investigational Medicinal Products (NIMPs)) is described in the MHRA Good Clinical Practice Guide.

This SOP describes how the guidance is implemented within the Trust, and notes local procedures which aim to ensure that clinical trial medication is prescribed in accordance with trial specific protocols in a safe and effective manner. The SOP also incorporates guidance on non-compliance with prescribing standards and should be used in conjunction with the Trust's latest version of the Medicines Code.

2 Who Should Use This SOP

All clinicians who have a delegated responsibility for prescribing, research nurses, clinical trial assistants, pharmacy staff and all members of the clinical trials team involved with a clinical trial should follow this SOP.

3 When This SOP Should Be Used

This SOP should be followed when clinicians are completing clinical trial prescriptions. It should not be used for prescribing chemotherapy, or prescribing for patients admitted to hospital whilst receiving clinical trial treatment, prescribing chemotherapy should be done in line with the Trusts specific policies for this and in conjunction with Pharm/S92 Prescribing and processing oncology and haematology prescriptions for clinical trials.

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 Who can prescribe clinical trial medication?

- IMPs and NIMPs can only be prescribed by qualified and registered medical practitioners.
- The prescriber must have been delegated prescribing responsibility by the trial Chief or Principal Investigator and have signed the delegation log.

4.2 How clinical trial medication should be prescribed

IMPs and NIMPs must be prescribed on a fully completed prescription form which has been signed (manually or electronically) by a prescriber who has been authorised to prescribe for the clinical trial and has signed the delegation log.

A trial specific prescription should be used whenever possible to ensure that IMPs/NIMPs are prescribed and dispensed according to the trial specific protocol.

The current, authorised version of a prescription must always be used. Older versions will not be dispensed. When a new version of a prescription is issued by the pharmacy department, the previous version must be superseded and all patients receiving trial treatment must be prescribed their medication on the new version.

In order to ensure that IMPs and NIMPs are not dispensed to patients who are not involved in a clinical trial, prescriptions designed for clinical trials or trial specific treatment regimes must not be used for non-trial patients.

Prescribing on EPMA – Where possible a clinical trials specific order set will be produced by the specialist team and checked by the PI for the study, the order set should be prescribed for all inpatient prescribing on the trial. If an order set is not available, then the prescriber should follow the guidance in the protocol and from the Pharmacy Clinical Trials team on how to prescribe the IMP in line with study protocol. There may also need to prescribe the IMP on a paper clinical trials prescription depending on the needs of the trial.

4.3 Completing a clinical trial prescription

Prescriptions must be completed in full by a clinician authorised to prescribe for the clinical trial. As specified in the Trust's Medicines Code, there is a zero tolerance to omission of patient identification and allergies. If a clinical trials prescription has not been fully completed, it will be returned to the prescriber and will not be dispensed until the prescriber has added the missing information.

Printed addressographs may be used.

Incomplete prescriptions must not be pre-signed by a prescriber in advance of the dispensing episode.

If agreed with the trial sponsor, the prescriber may complete a prescription, in full, prior to a patient's visit, provided that the patient's visit is due within six months and that the patient will be assessed at the visit to ensure that they are able to continue the trial medication.

4.4 Prescribing for clinical trials involving medication allocated through an electronic system

If an IMP/NIMP is allocated through a unique pack code using an electronic system (IVRS/IWRS), then it is acceptable for a nurse who is on the delegation log to obtain these codes. The nurse should check that the pack codes match the confirmation fax/email which documents the codes to be prescribed.

Pack codes must be transcribed manually onto the prescription by the prescriber (using the confirmation fax/email), and the prescription signed. Under no circumstances should a prescription which does not contain the allocated pack codes be signed by a prescriber.

Prescriptions must be presented to pharmacy together with the confirmation fax/email, which will be used to check that the correct pack codes have been prescribed.

If an IMP/NIMP is prescribed using a computer generated prescription provided by the Sponsor, the prescription does not need to be accompanied by a confirmation fax/email.

If the computer generated prescription does not comply with the minimum criteria described in the Trust's Medicines Code, the prescriber will be required to transcribe the details onto a prescription designed by the pharmacy clinical trials team.

This process applies to blinded trials in which particular pack (or kit/bottle) codes are allocated using an IVRS/IWRS system. It does not apply to open label trials where particular batch numbers are allocated through an IVRS/IWRS system for stock control purposes only (these may be obtained by pharmacy or the research nurse depending on the study arrangements and are not required to be prescribed).

4.5 Prescribing IMPs/NIMPs for clinical trials being conducted outside of pharmacy

If the prescribing and dispensing/issuing of an IMP/NIMP is being conducted outside the pharmacy then the requirements and arrangements for prescribing and dispensing the IMP/NIMP should be documented in a study-specific SOP. Refer to Pharm/S76 (Storage and dispensing of Investigational Medicinal Products outside of Pharmacy) for further guidance.

4.6 Prescribing errors and non-compliance with prescription completion

If a prescribing error/omission is detected, the prescription will be returned to the prescriber via the research team to be amended. Any changes to the prescription must be completed by a prescriber named on the delegation log for the study. All changes must be error coded according to GCP standards (a single line through the error, signed and dated).

Serious errors will be reported through the Trust DATIX system.

5 Related SOPs and Documents

Pharm/S76 Storage and Dispensing of Investigational Medicinal Products Outside of Pharmacy

Pharm/S92 Prescribing and processing oncology and haematology prescriptions for clinical trials

York and Scarborough Teaching Hospitals NHS Foundation Trust Medicines Code

MHRA Good Clinical Practice Guide 2012