York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S50

Preparation, Review and Approval of Pharmacy Trial Instructions

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference:	Pharm/S50
Version Number:	5.0
Author:	Rachel Spooner
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Approved by:	Name/Position:	Poppy Cottrell-Howe – Pharmacy Clinical Trials Manager
	Date:	17th January 2024
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	17t January 2024

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

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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	1st March 2012		
2.0	16th April 2012		Correction of spelling mistake. Removal of North and East Yorkshire R&D Alliance references.
3.0	8th February 2016		To include new templates and new process for writing trial specific instructions
4.0	9th July 2020		Change of author. Change of link to R&D website. Update of templates used to include additional process SOP template. Included reference to HRA pharmacy review. Included staff member will be named on pending studies board. Removal of aseptic process SOP reference. Updated process of how to review and check the final documents. Removed two yearly reviews.
5.0	14th February 2024	Rachel Spooner	Change of Trust name. Change of author. Change of name from 'accuracy and clinical checking' to 'final checking'. Inclusion of trial instructions version control forms

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Contents

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1 Introduction, Background and Purpose

All Pharmacy site files should contain comprehensive trial instructions and checklists specific to that trial.

This SOP describes how pharmacy trial instructions should be prepared, reviewed, approved and implemented for pharmacy related studies.

The pharmacy trial instructions and checklists should cover trial activities specific to that trial such as:

- Trial Details and Summary (including unblinding)
- Dispensing
- Final check checklist
- Trial Stock Management
- Transporting of IMP (if applicable)
- Conducting a pharmacy monitoring visit (if applicable)
- Any specific or special requirements of the study

The purpose of the trial instructions is to ensure that:

- Investigational Medicinal Products/Non-Investigational Medical Products (IMPs/nIMPs) are appropriate for use, procured, handled, stored and used safely and correctly.
- IMPs are managed and dispensed in accordance with the protocol.
- Trial procedures comply with relevant guidelines and regulations; The Medicines for Human Use regulations (as amended), Good Clinical Practice (GCP) and Annex 13 of Good Manufacturing Practice.

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2 Who Should Use This SOP

This SOP should be used by all members of the clinical trials team involved in initial study set up or checking and authorising of a new pharmacy clinical trial study file. This applies to all staff working within the Pharmacy clinical trials team at York and Scarborough Teaching Hospitals NHS Foundation Trust.

3 When this SOP Should be Used

Use this SOP when writing, reviewing and approving trial instructions for pharmacy related studies.

4 Procedure(s)

Pharmacy trial instructions should be based upon the study protocol or other documentation provided by the Sponsor for the purposes of running the trial e.g., Pharmacy manual, sponsor provided SOPs or approved documents such as the HRA pharmacy review. These can be referred to and referenced.

4.1 How to Create New Trial Instructions

The following process will apply when Pharmacy Trial Instructions need to be prepared:

1. It is the responsibility of all staff within the pharmacy clinical trials team to ensure all pharmacy trial instructions are up-to-date, implemented, tracked and reviewed appropriately.

2. The Pharmacy Clinical Trial Manager will identify an appropriate lead for the trial.

3. The lead will collate the information and documentation required to prepare the SOP (e.g. protocol, sponsor instructions, HRA pharmacy review) and is responsible for contacting the Sponsor or Sponsor's representative (Clinical Research Associate or Trial Manager), to obtain any missing information.

4. The lead will work their way through the different stages of the "Pharmacy Clinical Trial Set up Form" (Pharm/F14) the lead will write a draft of the trial instructions using the templates listed below.

5. Guidance within the templates should be deleted and replaced with appropriate text.

Pharmacy trial instructions will therefore be made up of the following documents (created using the following templates):

- Pharm/T40 - Trial Details and Summary (including unblinding)
- Pharm/T42 - Dispensing
- Pharm/T43 - Final check checklist
- Pharm/T16 - Additional Pharmacy Process SOP Template (this template is to be used for any additional task/process specific to the study which is not already included in the other sections of the pharmacy instructions)

Each of the above will be an individual document with a unique reference number, this number is the next sequential number obtained from the Trial Instructions tracker spreadsheet (this is located on the X drive in the clinical trials folder).

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4.1.1 Trial Details and Summary

Using template Pharm/T40, create a short summary of the purpose or objectives of the study, the possible treatment arms or randomisations involved and the medication involved in the study.

Indicate whether the trial is open label or blinded and in the case of blinded studies include a full description of the code break procedure specific to the study.

4.1.2 Dispensing

Using Pharm/T42, create a clear and accurate dispensing procedure for all IMPs/nIMPs involved in the trial to ensure any appropriately trained member of Pharmacy clinical trials staff can follow the procedure and dispense the trial medication with confidence. Include any details of accountability logs that are needed to be completed, any IWRS process required at the time of dispensing and the labelling process.
Include any other information you feel appropriate in this section but keep the description brief and easy to follow.

Ensure that the complete dispensing process is documented in the dispensing checklist grid.

4.1.3 Final Check Checklist

Using Pharm/T43, create a checklist for final checking, using the template as guidance. This checklist is intended for use by an ACT accredited, appropriately trained, clinical trials pharmacy technician or registered pharmacist.

4.1.4 Trial Stock Management

Using Pharm/T39, complete instructions for each task. These instructions should be brief, clear and concise and should reflect each step involved.

4.1.5 Additional Pharmacy Process SOP

This template is to be used for any additional task/process specific to the study which is not already included in the other sections of the pharmacy instructions. This may include:

- How to use study specific equipment
- If pharmacy are performing the blinding process
- How to send IMP on transport to other sites approved by the sponsor
- How to perform study specific pharmacy monitoring visits
- If research staff are performing any pharmacy processes

Once the instructions/templates have been written, the following applies:

1. The draft trial instructions must be reviewed/checked by either the pharmacy clinical trials manager or a senior pharmacy technician for clinical trials (if one of the members of staff listed above wrote the instructions they must give to the other member of staff to check). The lead will collate reviewers responses and incorporate them (if appropriate) into a revised draft of the trial instructions. You can use tracked changes or save a version with the required changes but the original document must be retained to compare the changes. The checked/reviewed draft version should be saved on the x: drive as a new document. The original draft should not be deleted.

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2. The lead author should discuss changes with the checker/reviewer and use the appropriate sources to reach a final version of the trial instructions.

3. The lead (or delegated individual) will prepare the trial instructions for publishing and implementation. This will include getting the documents authorised by the lead pharmacist for pharmacy clinical trials.

4. A paper copy of the final trial instructions will be printed on yellow paper, then signed and dated by the author, checker and authoriser by completing the version control at the bottom of the document. The documents will then be laminated and filed in section 1 of the pharmacy site file, as well as scanning a signed copy on to the X: drive in the studies electronic folder as the most current version.

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4.2 How to formally review Pharmacy Trial Instructions

Reviews of pharmacy trial instructions will take place following a study amendment or change in practice for the trial.

All members of the pharmacy clinical trials team are responsible for identifying differences/changes to pharmacy trial instructions. A new version of the instructions should be created. Follow the steps in section 4.1.5.

Only the relevant section of the trial instruction needs updating. E.g. if an amendment is submitted regarding changes to code break/unblinding there is only a need to update the Trial Details and Summary document. Ensure the version control at the bottom of the document is updated and old versions are superseded on the x: drive and in the pharmacy site file see point 4.3 on how this is done. Once a new version of the trial instructions is implemented in the Pharmacy site file, Pharm/F35 (Pharmacy Trial Instructions Version Control Form) should be completed documenting the version number, date implemented, author and who approved the document, and a summary of significant changes. There should be one version control form per trial instruction document in the relevant section of the Pharmacy site file.

4.3 How to Manage Pharmacy Trial Instructions

All pharmacy trial instructions must be retained in the Pharmacy Clinical Trial File and archived as *Essential Documents*. Where paper/laminated copies of older versions of a trial instruction exist, a line should be placed through all pages of the superseded version and “superseded” written across the top and signed and dated. Superseded versions should be kept in Pharmacy site file in the superseded section to enable identification of the version in use when any particular step was taken in the research. The electronic version should also be placed into the superseded section for the study on the x: drive.

4.4 Training

When a new Trial instruction is authorised, or when an existing trial instruction is revised, as a minimum self-directed training must be carried out by all staff to

which the trial instruction is relevant, and this training documented on the study personnel training log. There should be adequate time for appropriate training for all relevant staff before the trial instruction is formally implemented. Staff should take time to read and fully understand the trial instruction and relevant documents, ensuring that they are able to implement it when required.

4.5 Archiving

Paper/laminated copies of all signed, approved and published study-specific trial instructions will be stored in Pharmacy Clinical Trial Files while the study is ongoing. At the end of the study, all trial instructions will be archived.

5 Related SOPs

Pharm/T39	Trial Stock Management
Pharm/T40	Trial Summary and Unblinding Trial Instructions Template
Pharm/T42	Dispensing Trial Instructions Template
Pharm/T43	Final Checking Checklist Template
Pharm/T16	Additional Pharmacy Process SOP Template
Pharm/F35	Pharmacy Trial Instructions Version Control Form

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