Production & Control of Clinical Trials Labels

IT IS THE RESPONSIBILITY OF <u>ALL</u> 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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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	Details of significant changes
1.0	27th July 2015	
2.0	31st July 2017	Two year review
3.0	29th November 2019	Change of author. Change of link to R&D website. Changes to creating labels, authorising new labels, approval of batches and label amendments to reflect current procedure. Removal of reference to Pharm/F40
4.0	12th October 2020	Change of author. Changes to process to create and print labels. Removal of reference to Pharm/F104.

Contents

1   Introduction, Background and Purpose

The labelling requirements of Investigational Medicinal Products used in clinical trials are governed by the Medicines for Human Use (Clinical Trials) Regulations 2004. Depending on the nature of the Investigational Medicinal Product in use in the trial, the requirements of the Medicines for Human Use (Marketing Authorisations) Regulations 1994 and the requirements of Annex 13 of Good Manufacturing Practice will also apply.

This SOP describes:-
* The procedure for producing a dispensing label for an Investigational Medicinal Product (IMP) or Non-Investigational Medicinal Product (NIMP).
* The procedure for recording the creation of a master dispensing label or amendment of a master dispensing label.
* The procedure for authorisation of the final label and to ensure that the master label meets the requirements of Annex 13 of Good Manufacturing Practice (GMP).
* The procedure for printing batches of authorised labels and accountability of the printed labels.

2   Who Should Use This SOP

This procedure should be followed by all members of the Clinical Trials Team within the Pharmacy Departments at York and Scarborough Teaching Hospitals NHS Foundation Trust

3   When this SOP Should be Used

This SOP should be used when creating and approving a master label, printing and approval of label batches and during the dispensing and accuracy checking of a clinical trial prescription.

4   Procedure(s)

All labels created by the Pharmacy Clinical Trials Team for labelling an IMP/ NIMP for use within a clinical trial should comply with the regulations as detailed in the introduction section of this SOP. Although the regulations refer to the use of the IMP and its Marketing Authorisation, the Trust will use a label template which covers all of the requirements of the regulations.

4.1 Labelling requirements for an IMP (regardless of Marketing Authorisation)

IMPs should be labelled according to the requirements for a dispensed medicine (Medicines for Human Use Regulations 1994) and Annex 13 of Good Manufacturing Practice.

All IMPs (where permissible) will be labelled with additional approved labels containing the above information. Care should be taken to ensure that when these labels are placed on original container/packaging the original label is still visible and not obscured (this can be done by flagging the labels with clear flags).

4.2 Creating Labels

Create labels as follows:

1. To create labels for use in a clinical trial, open the Clinical Trials Label Template which can be found within the Admin Labels file on the X:Drive.

2. Use the 'save as' option to save the label template in the relevant trial folder (in the labels folder- draft labels should be saved in a sub folder named drafts). The template should be renamed with the Label ID (This is the R&D reference followed by an identification letter e.g. A) and the version number (version 1.0 for newly created labels). The drug name/dose level can also be added to the file name for ease.

3. Amend the label template to relate to the relevant IMP, study and protocol and version number (this should be situated underneath the hospital details). The information you require on the label will depend on the individual study, hence the template can be added to or altered as required.

4. Select the "Review" tab and then choose the "Restrict Editing" option

5. Highlight the areas which you want to keep open to edit and tick the box in Section 2, then tick the box "Everyone" so this allows us to edit the section without making changes to the rest of the label.

6. Select the "Start Enforcing Protection" and put in the password which is the trial name in capital letters.

7. Save these changes.

8. Repeat the above process to create further labels if necessary. The identification letter should be changed alphabetically for each new label created (e.g. A for the first label created, B for the second label created and so on).

4.3 How to check and authorise a new label

All labels produced by Pharmacy for use in a clinical trial should be checked and authorised by a Pharmacist before use, as follows:-

1. Print the completed label.

2. Print a blank Master Label Form (Pharm/F33) from the R&D website

3. Apply the label to the allotted space on the form.

4. Complete the top part of the form with the relevant information.

5. Complete the prepared by section of the form.

6. The label should be approved by a Clinical Trials Pharmacist.

7. Once the label has been approved the person who approved the label must complete the checked and authorised section of the form and sign over one corner of the label on to the form (care should be taken as not to sign over any printed information).

8. This form is then filed as the Master copy in section 2 of the relevant study's Pharmacy Site File.

9. The approved labels electronic file can be moved out of drafts and into the current labels folder in the relevant trial folder on the X: Drive.

4.4 How to print authorised labels for use.

1. To print labels for use in a study, you will need to access the electronic study file which is kept on the X: Drive.

2. Select the correct referenced label required

3. Check the version selected matches that of the approved master label kept in section 2 of the pharmacy site file.

4. Type in the required patient/visit details onto the label before printing.

5. If creating labels for Bulk Issue or we are not the ones completing the details on the label, leave this blank so that the Dr/ Nurse/other healthcare professional can fill in the information at the time the medication/product is issued required.

6. Select the desired amount of labels needed and print.

7. The labels which get printed need to be documented on Pharm/F105 Record of Label Printed

8. Once documented on the form the dispenser will then sign to say that they printed that amount of labels and the patient it was allocated to.

9. Sign the relevant boxes on the product label.

4.5 How to check authorised labels when checking a prescription

1. Check the labels that have been used match the Master Label Form (section 2 of Pharmacy Site File)

2. Ensure that the correct version of the label has been used (this can be found on the form and in the right hand corner of the label used).

3. Check that the editable information added is correct and matches what is stated on the prescription.

4.7 Label amendments

If at any time during the study the label needs to be amended complete the process as follows:-

1. Amend the label word document and save as the next version number.

2. Complete the form Pharm/F34 (Master Label Amendment Form), ensuring that the new version number is documented.

3. The Clinical Trials Pharmacist will need to approve the new version and sign the Master Label Amendment Form (Pharm/F34), also signing across both new label and form.

4. Supersede the old Master Label, filing the document in the superseded section of the Pharmacy Site File.

5. The new authorised Master Label is then stored in study's label section of the Pharmacy Site File.

6. Electronically the newest authorised label can be moved into the current labels and old versions moved into superseded within the relevant study's folder on the X: Drive.

5   Related SOPs and Documents

Pharm/F33	Master Label Form
Pharm/F34	Master Label Amendment Form
Pharm/F105	Record of Labels Printed
Annex 13, Good Manufacturing Practice	