York Foundation Trust R&D Unit
SOP
Pharm/S51

Expiry Date Extensions and Re-labelling of IMPs

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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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	Signature:	Signed copy held by R&D Unit
	Date:	25th July 2016

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	1st September 2016	

Contents

1 Introduction, Background and Purpose

On occasion the Sponsor of a clinical trial will receive new information which will allow them to extend the expiry date of an Investigational Medicinal Product (IMP), which is already in circulation. In this case the Sponsor will contact the participating site in writing, giving a procedure and relevant documentation for the process of re-labelling the trial Investigational Medicinal Product with the new expiry date – this must include a list of batch numbers (and for individually numbered packs- the pack numbers) to be re-labelled.

The re-labelling documentation must be approved by a clinical trial pharmacist before re-labelling proceeds. The extension and re-labelling process may be carried out by a monitor sent by the Sponsor, working under the supervision of a senior clinical trials technician/pharmacist. If the procedure requires an expiry date extension to be carried out on site by Trust staff this will be performed by a clinical trials technician and checked by a pharmacist with appropriate clinical trials training and experience.

Re-labelling of different batches/products must be segregated so that only one product and batch is re-labelled at any one time. An area check will be performed at the beginning of the re-labelling process and a product and label reconciliation check at the end of the process to ensure that all packs are assembled and re-labelled correctly before proceeding further.

The re-labelling process will be recorded on form Pharm/F117 in addition to any documentation provided by the Sponsor.

2 Who Should Use This SOP

This procedure should be followed by all members of the clinical trials team within the pharmacy department at York and Scarborough Hospitals, which form part of the York Teaching Hospitals NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be followed during the process of extending and re-labelling of expiry dates of Investigational Medicinal Products hosted or sponsored by York Teaching Hospital NHS Foundation Trust.

4 Procedure(s)

4.1 Re-labelling

- Prepare an area to carry out the re-labelling. Ensure that this area is free from any items and labels. Have this area checked by a monitor, pharmacist or technician before proceeding.
- Assemble the original IMP packs to be over labelled according to the documentation provided by the Sponsor.
- Assemble the labels provided by the Sponsor.
- Complete the required information of Pharm/F117 and the worksheet provided by the sponsor.
- Have the IMP and labels checked by a monitor/pharmacist.
- Attach the first and last label from each sheet of labels provided to the back of Pharm/F117 (and on the worksheet provided by the Sponsor, if requested to do so).
- Carry out the re-labelling.
- The labels should be placed next to the original expiry date (unless otherwise instructed by the Sponsor). Take care that any peelable patient information labels are not impeded by the re-labelling. Do not cover the original batch number or pack numbers (where applicable).
- Sign and date the “Batch re-labelled by” section of Pharm/F117 and worksheet provided by the Sponsor.
- Complete the “label reconciliation” part of Pharm/F117 and worksheet provided by the Sponsor.
- If there are any discrepancies with the IMP or label accountability or between the Sponsor documentation and the worksheet these must be recorded and accounted for on Pharm/F117.
- The trial monitor or pharmacist must perform the release check.
- Once the batch has been released the re-labelled IMP may be returned to the correct storage area ready for use.
- Pharm/F117 and the Sponsors re-labelling documentation will be stored in the Pharmacy trial file.

4.2 Checking Process

Area checks may be performed by a clinical trials technician, Pharmacist or study monitor.

Perform the following checks:

- Stock assembled is for the correct clinical trial.
- Correct IMP and dose assembled.
- Batch numbers of IMP packs assembled is correct against the Sponsor’s re-labelling documentation.
- Only one batch of IMP has been assembled.
- Count number of IMP assembled and check that this is correct against Sponsor’s re-labelling documentation.

- The area is clear of any items which are not to be used for the batch being re-labelled.

Once all of these checks are completed complete the “Area Checked” box Pharm/F117.

4.3 Label Check

Label checks may be performed by a senior clinical trials technician or pharmacist or study monitor.

Perform the following checks:

- Check all information on the main body of the labels is exactly the same as that on the sample labels attached to Pharm/F117 (or sponsor provided worksheet).
- Check that the batch number and expiry date on the label is correct.
- Check that the pack numbers on the labels match those on the assembled packs (where applicable).
- Check the labels are aligned correctly.
- Count the number of labels used and record on Pharm/F117.
- Check that the information on the labels matches that on the Sponsor’s documentation.

Once all checks are completed sign and date the “Label Check” box on form Pharm/F117.

4.4 Release Checks

Release checks must be performed by a clinical trials pharmacist or the trial monitor.

Perform the following checks:-

- Check that form Pharm/F117 and the Sponsor’s provided worksheet are completed in full.
- Check the IMP to ensure that the correct drug, strength and batch have been used.
- Count the number of IMP packs that have been re-labelled.
- Check that the correct label has been applied to each IMP pack.
- Check that the positioning of each label has been applied to the right area.
- Perform the label reconciliation check and destroy any unused labels.
- Where the IMP is individually numbered, check that the packs have been re-labelled matches the inventory list provided by the sponsor.
- Also check that the pack number on the new label matches that on the original pack (where applicable).

Once all of the checks have been completed, sign and date the “Batch Release by” section of Pharm/F117.

The IMP can then be returned to the appropriate storage area.

5 Related SOPs and Documents

Pharm/F117 Expiry Date Re-labelling Worksheet