

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Author:	Cheryl Donne
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Approved by:	Name/Position:	Poppy Cottrell-Howe, Pharmacy Clinical Trials Manager
	Signature:	
	Date:	7 <sup>th</sup> June 2022
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	
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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.

<b>Version</b>	<b>Date Implemented</b>	<b>Details of significant changes</b>
1.0	1 <sup>st</sup> September 2016	
2.0	8 <sup>th</sup> March 2019	Change of author. Change of link to R&D website
3.0	26 <sup>th</sup> July 2022	Update of staff able to perform relabelling tasks.

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## **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/ pharmacy clinical trials manager. 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 Senior Pharmacy Assistant for clinical trials and checked by a clinical trials trained technician that has appropriate clinical trials training and experience perform a final check or a pharmacist.

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 and Scarborough 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 and Scarborough Teaching Hospitals 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.
- 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/clinical trials technician.
- Attach a label from the labels provided to the back of Pharm/F117 if possible (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 / clinical trials senior technician / clinical trials manager 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.
- Fulfil any of the sponsor’s requirements of the completed paperwork.
- Inform or record this activity for costing purposes by recording this activity on the finance tracker or verbally to the person due to next raising an invoice to the sponsor.
- 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

UNCONTROLLED DOCUMENT WHEN PRINTED