**York Foundation Trust R&D Unit**
**Standard Operating Procedure**
**Pharm/S103**

# Creating, reviewing and approving clinical trial accountability logs

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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



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| Author: | Sacha Honour |
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| Approved by: | Name/Position: | Jax Westmoreland, Principal Pharmacist Clinical Trials & Research |
| | Signature: | Signed copy held by R&D Unit |
| | Date: | 12th June 2017 |
| | Name/Position: | Sarah Sheath, SOP Controller |
| | Signature: | Signed copy held by R&D Unit |
| | Date: | 12th June 2017 |

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 | 29th May 2015 | |
| 2.0 | 10th July 2017 | Two year review. Minor changes |
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## Contents

# 1 Introduction, Background and Purpose

Accurate accountability is essential for clinical trials to enable a full audit trail to be created to document the receipt, dispensing, and return/destruction of Investigational Medicinal Products (IMPs). Recording details such as the batch number and expiry date of the products issued to participants is essential for ensuring IMP recall procedures can be followed.

Master accountability logs enable an accurate inventory of IMPs at site to be recorded; whilst participant specific accountability logs capture the details of all dispensing episodes and accountability activities relating to a specific participant. Accountability logs will be closely examined during monitoring, auditing and inspection visits.

This SOP describes the procedures to be followed when creating, reviewing and approving drug accountability logs for use in a clinical trial. The design of an accountability log and its subsequent completion should allow data to be recorded in a precise, clear and unambiguous way thus ensuring standardisation and consistency.



# 2 Who Should Use This SOP

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

# 3 When this SOP Should be Used

This SOP should be used when creating, amending, reviewing and approving accountability logs to be used for a clinical trial.

# 4 Procedure(s)

## 4.1 Creating a master or participant specific drug accountability log

If a Sponsor has not provided a master or participant specific drug accountability log (and one is required), then create an accountability log using the relevant template. The following templates are available;

- Pharm/T36 (Template master accountability log (double blind trial))
- Pharm/T37 (Template master accountability log (open label trial))
- Pharm/T38 (Template participant specific accountability log)

Amend the templates accordingly to ensure they enable all information required to be captured for the specific trial. Follow section 4.3 for guidance on reviewing, approving and managing the documents.

## 4.2 Amending an accountability log provided by a Sponsor

If a Sponsor has provided an accountability log, this may be used if it captures all of the information required to enable full accountability is recorded. The following templates can be referred to for comparison;

- Pharm/T36 (Template master accountability log (double blind trial))
- Pharm/T37 (Template master accountability log (open label trial))
- Pharm/T38 (Template participant specific accountability log)

If the log needs to be amended to ensure all the necessary details are captured, then the CRA/Sponsor representative should be contacted to request that the accountability log be amended. If the Sponsor amends the logs, they are responsible for the version control.The Sponsor may inform us that we can make the amendment to the logs, following this amendment follow the process described in section 4.3.

## 4.3 Accountability log review, approval and management

Accountability logs produced or amended by the pharmacy clinical trials team should be reviewed, and authorised prior to implementation.

A draft version of the accountability log should be created and given a version number (e.g. version 0.1). This should be sent to a senior pharmacy technician and the pharmacy clinical trials pharmacist/manager for review. Any comments received should be incorporated if applicable.

The final version of the accountability log should be version controlled (see example below);

| | | |
|---|---|---|
| Version Number: | Supercedes Number: | Written by: |
| Date active: | Checked and authorised by: | |

Once authorised by the clinical trials pharmacist, the accountability log should be scanned and saved electronically on the X drive. Send a copy of the authorised accountability log to the CRA/Sponsor representative for approval, once we have received approval print the email and file in the Pharmacy File in the relevant section. File the wet-signed copy of the accountability log in the pharmacy trial file.

When processing an amendment that requires a change to the accountability log, follow the process described above to create a new version. The previous version of the log must be superseded and file in the superseded section of the Pharmacy File.

# 5 Related SOPs and Documents

Pharm/T36 Template master accountability log (double blind trial)

Pharm/T37 Template master accountability log (open label trial)

Pharm/T38 Template participant specific accountability log

Pharm/S79 Receipt and review of Protocol amendments in Pharmacy