NHS
Gloucestershire Hospitals
NHS Foundation Trust

Trial Delivery 08 – Medicines Management

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 Research & Development Webpage 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust 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 website:

https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals

SOP reference:	R&D SOP TD 08	
Version:	1.0	
Author:	Chris Ford	
Reviewed by Head of R&D	Chantal Sunter 27 /05 /2021	
Implementation date of current version:	27 / 05 /2021	
Date of Review:	27 / 05 /2023	

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	27/05/2021

This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

Contents

1. Introduction, Background and Purpose

All research involving medicines hosted and sponsored by the Trust must be conducted to the highest quality and standards possible. To do this all staff must be trained in all aspects of medicine management relevant and commensurate with their role and according to Trust policy. This SOP defines the roles of research staff in relation to medicines within a clinical trial.

2. Who should use this SOP?

This SOP applies to all research team members involved in studies containing medicines including medications that are not classified as an IMP Investigational Medicinal Product.

3. When this SOP should be used

This SOP should be regularly referred to during the course of trial delivery to ensure all research staff are aware of their role in regard to medicines within clinical trials and ensuring we comply with Trust policy.

4 Which staff this involves

The Trust policy on ordering, prescribing, and administering, storage and handling of medications (POPAM) defines frontline staff as any health professional (including clerical or ancillary staff) who is the first point of contact with the general public, face to face or over the telephone. In terms of research team this includes research nurses, research coordinators, research support officers, data officers and administrators.

5 Roles and Responsibilities

POPAM states that frontline staff must follow POPAM and associated polices/procedures, participate in training and instruction as policy dictates. All delivery team staff should be trained on medicines management using the Trust e-learning module, updated yearly and be familiar with the POPAM policy.
For new research team members' medicines management competency will be assessed by role play using an adapted version of the POPAM drug round competencies depending on role in medicine management. The research team member's competence in explaining medications will also be assessed during the informed consent competency check.

The roles and responsibilities can be divided as follows, for registered nurse working as a research nurse the following roles can be performed to the nurse's own level of competence and training, remaining at all times accountable for their own actions.

- Explanation of medicines involved in the trial including reason the medication is being used, (therapeutic use), usual dose, side effects, precautions and contraindications and route of administration.
- Administration of a prescribed medication. In some circumstances specific training is required to allow a nurse to administer specialist medicines, e.g. cytotoxic drugs and vaccines. Training and competencies must be up to date if this is applicable to role.
- If an IMP is to be stored outside of Pharmacy then the Lead Clinical Trials Pharmacist will determine whether a risk assessment need be completed in discussion with the PI & Lead Research Nurse. If a risk assessment is completed a SOP will be developed in agreement with the PI and Lead Research Nurse."

- Ensuring patients are discharged/leaving clinic with correct medication and advice
- Performing the second checker role
- Handling drug returns
- Checking patient compliance with medication

For a Research Coordinator

The following roles and responsibilities can be assigned once competency has been assessed using an adapted version of the POPAM drug round competency and using role play. The research coordinator's competence in explaining medications will also be assessed during the informed consent competency check.

- Explanation of medicines involved in the trial including reason the medication is being used, (therapeutic use), usual dose, side effects, precautions and contraindications and route of administration.
- Handling drug returns
- Checking patient compliance with medication

For a Research Support Officer

The following roles and responsibilities can be assigned once the Trust medicines management e-learning module has been completed.

- Collecting named patient medications from pharmacy for a research nurse
- Returning medications to pharmacy

For a Data Officer

The following roles and responsibilities can be assigned once the Trust medicines management e-learning module has been completed.

- Collecting named patient medications from pharmacy for a research nurse
- Returning medications to pharmacy

6. Related SOPs and documents

R&D SOP TD 02 Training
R&D SOP TD 03 Informed Consent for Research

Trust POPAM policy
https://intranet.gloshospitals.nhs.uk/departments/diagnostics-specialties/pharmacy/popam/

GHNHSFT medicine management e-learning
https://intranet.gloshospitals.nhs.uk/hr-training/training-development/search-training/medicine-management-training/