Gloucestershire Hospitals
NHS Foundation Trust

SOP 09: Medicines Management

SOP reference:	SOP 09	
Version:	2.0	
Author:	Chris Ford	
Approved by Commercial Director:	Claire Richardson 22/09/2023	
Implementation date of current version:	30/10/2023	
Date of Review:	30/10/2025	

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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
2.0	Insertion of link to competencies Training record on EDGE Removal of SOP categories and change of reference codes	30/10/2023

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

Related Documents:

SOPs
SOP 03 - Training
SOP 04 - Informed Consent in Research

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 are 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 midwives 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 all new patient-facing 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 adapted version of the POPAM drug round competencies can be found in the following location Specialist Practitioners competencies (gloshospitals.nhs.uk). Medicines competency needs to be reviewed annually for those patient-facing research staff that are not registered nurses or midwives and a record of this maintained via EDGE. Please refer to SOP TD02 Training Appendix 2 for instructions on how to record this.

Research nurses and midwives will continue to maintain their competency using the Trust e-learning module and familiarity with the POPAM policy. If the nurse/midwife will be undertaking a medicines role they are unfamiliar with, competency will be checked using the adapted version of the POPAM drug round competencies described above and recorded on EDGE.

The roles and responsibilities can be divided as follows, for registered nurses/midwives working as research nurses/midwives the following roles can be performed to the practitioner's own level of competence and training, remaining at all times accountable for their own actions. Research nurses/midwives new to the research team will need their medicines competency assessed as described above.

- 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.
- Checking allergy status with the patient and prescription.
- Administration of a prescribed medication. In some circumstances specific training is required to allow a nurse/midwife 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 needs to 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, and maintained annually. 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/midwife
- 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/midwife
    - Returning medications to pharmacy

6. References

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/