STANDARD OPERATING PROCEDURE FOR PRESCRIBING INVESTIGATIONAL MEDICINAL PRODUCTS TO PATIENTS IN HOSPITAL

SOP NUMBER:	**Fife R&D SOP51**
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1. PURPOSE

This document describes the procedure to be followed to ensure that Investigational Medicinal Product (IMP) is prescribed and administered appropriately to hospital inpatients.

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via StaffLink, the R&D section of the NHS Fife website (www.nhsfife.org/research) and EDGE (https://www.edge.nhs.uk). For guidance, contact the R&D Department via fife.randd@nhs.scot

2. APPLICABILITY

This document applies to all staff involved in the prescribing, dispensing and administration of IMPs within NHS Fife.

3. PRINCIPLES

3.1 Only staff listed on the delegation log can prescribe IMPs.

3.2 Admitting Clinicians adding details of continuing IMP to the Kardex do not need to be listed on the delegation log.

4. PROCEDURE

4.1 Patient Recruited While an Inpatient

When a hospital inpatient requires a supply of a clinical trial drug to be administered on the ward it must be prescribed on the medicine chart and the entry should include, along with dosing and administration instructions, the study name, and the patient trial identification number.

4.2 Patient Admitted Following Recruitment as an Outpatient or During a Previous Admission

When a participant is admitted as an inpatient in NHS Fife having been prescribed study medication as an outpatient or during a previous admission, on becoming aware of the admission, the R&D Research Team must alert the PI or other clinician delegated the task of prescribing IMP. The research team will then facilitate the discussion regarding the continuation of study therapy to the participant between the PI/delegated clinician and the doctor in charge of the patient's hospital care.

4.2.1 The decision to continue or discontinue study therapy must be documented by completing the appropriate sections of the Inpatient Study Drug Review Confirmation Form (Doc Ref 51-01) and the medical admission notes. This documentation should include the details of the individual(s) involved in the decision making - PI, delegated research clinician, doctor in charge of the patient's care.

4.2.2 A red 'Trial Participant' sticker must be attached to the drug Kardex to alert clinical staff of the trial medication.

4.2.3 The original completed Study Drug Review Confirmation Form (Doc Ref 51-01) must be filed in the participant's medical records for their current admission and a copy filed in the Investigator site file and uploaded to the participant's medical record via SCI-Store.

4.2.4 If the PI or delegated research clinician is not on site to sign the completed Study Drug Review Confirmation Form (Doc Ref 51-01), the research team must annotate the form to confirm the outcome of the discussion with the PI, and this unsigned form can initially be added to the patient's admission notes, and the signed and dated copy also added once it is available.

4.2.5 If the patient is admitted outwith the working hours of the research team, the clinical alert associated with the patient's electronic medical records will direct the admitting clinical team to call the on-call member of the pharmacy team for further advice. On return to work the research team will be notified of the admission and follow up the prescribing of the IMP as per this SOP.

4.3 The clinical staff should be advised to contact the research team if a re-supply of IMP is required whilst the patient is in hospital. The research team will then arrange a re-supply of medication as per study protocol.

4.4 On discharge, any unused IMP must be sent home with the patient as part of their personal property rather than retained by the ward.

4.5 Guidance for adding Clinical trials medication to the electronic discharge document can be found on the Blink IDL workflow Medication - Clinical Trial Drugs

5. ASSOCIATED DOCUMENTS

Doc Ref 51-01 - Study Drug Review Confirmation Form

Safe and Secure Use of Medicines Policy and Procedures
https://app.joinblink.com/#/hub/6b46e035-0ae6-47cb-86e0-350ae687cb26

IDL Workflow - Medication - Clinical Trial Drugs
https://app.joinblink.com/#/hub/019808f0-7eae-7789-a251-c9fdad592acb

6. ABBREVIATIONS

IMP	Investigational Medicinal Product
ISF	Investigator Site File
PI	Principal Investigator
R&D	Research & Development
SOP	Standard Operating Procedure

7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Karen Gray Acting Associate Director, RIK	24 November 2025	New

8. APPROVAL

APPROVED BY	Date
Karen Gray, Acting Associate Director, RIK, NHS Fife Signature: 	24 November 2025