Document Title: Direct to Patient Delivery of IMP

Document Number: R&D SOP084

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers, Clinical Trials Pharmacist
Document author/owner:	Senior R&D Manager, Clinical Trials Pharmacist
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	June 2027

THIS IS A CONTROLLED DOCUMENT

Whilst this document may be printed, the electronic version maintained on the Trust's Intranet is the controlled copy. Any printed copies of this document are not controlled. ©Royal Papworth Hospital NHS Foundation Trust. Not to be reproduced without written permission.

Summary of Amendments

Version Number	Modification:
2.0	**Minor changes**
1.0	**New SOP**

Key Points of this Document

- To establish the scenarios in which IMP (Investigational Medicinal Product) may be distributed direct to patients i.e. without a patient visit to the hospital.
- To establish the roles and responsibilities in organising and approving this process.

1 Purpose and Contents

a. To establish the scenarios in which it would be appropriate to deliver IMP direct to patients.

b. To establish who is responsible for arranging, organising and paying for this service.

c. To develop a procedure for the safe handling of IMP in line with GCP whilst it is being delivered including accountability.

d. To ensure relevant contracts are in place.

e. This SOP also applies where Royal Papworth Hospital is the sponsor.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust. Staff involved in the preparation, review and dissemination of SOPs must comply with the requirements set out in section 4.

b. The clinical trial manager of any study that may require the delivery of IMP direct to a patient should discuss this with pharmacy and the sponsor prior to set up, signing of contract and SIV if the situation is foreseen.

c. The sponsor has overall responsibility for the risk assessment of the study drug; choosing of a delivery service; setting up of contracts and payments for delivery.

d. Pharmacy in collaboration with the research team will work with the sponsor to establish a workable detailed procedure for IMP delivery.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

b. Royal Papworth Hospital will not cover the costs of a courier or postal service of any IMP requiring delivery as part of a commercial research programme.

c. IMP should only be delivered direct to patient if:

1. There is direct instruction in the approved protocol to do so (in a foreseen scenario) or an approved communication from the sponsor to do so.

2. The sponsor has identified a delivery service and provided clear instruction on how to deliver the IMP.
3. There is provision in the contract for courier/posting costs to be reimbursed or a communication from the sponsor that describes a process for reimbursement.
4. And the patient has consented to have their details passed onto a courier (if applicable).

d. In exceptional or unforeseen circumstances when it is in the best interests of the patients and research, to continue to supply study drug without them attending for the standard visit, then the sponsor should follow the latest advice from the HRA (Health Research Authority) where relevant advice exists, for example in the case of a national pandemic.

e. If there are no current exemptions applicable to the request to deliver drugs direct to patients, then the appropriate approvals should be sought in line with standard HRA guidance in this scenario.

f. The patient must also consent to the proposed method of delivery – this must be documented and made available to those who will be responsible for arranging the delivery.

1. Depending on the requirements of the IMP (sponsors own risk assessment) then the sponsor should identify a suitable contractor to fulfil the posting requirements such as temperature monitoring, provision of temperature validated shipping containers, proof of delivery, same day delivery etc.
2. If the sponsor would like the Trust to provide their own delivery contractor, then they will need to approve this in writing and specify the shipping requirements.
3. Similarly for the use of Royal Mail, the sponsor should approve this decision and specify the type of posting required.
4. All costs associated with posting must be covered i.e. packaging, time for preparing the package, actual posting costs and time required for following up, such as phone calls or checking the proof of delivery.

g. If any IMP is to be posted outside of the UK, the sponsor should check with the MHRA and local authorities to confirm requirements for posting IMPs to other countries

4 Procedure

a. **For Royal Papworth sponsored studies**: The pharmacist or technician for clinical trials in conjunction with the Clinical Project Manager, should discuss the option of delivery to the patient at study set up, or whenever it becomes necessary and develop a procedure for the delivery of IMP to patients.

b. A risk assessment (FRM075) should be completed covering the following:

1. IMP status – is it hazardous or controlled in any way, what is the risk of spillage, and particular handling requirements.
2. IMP Packaging – could this be easily damaged eg: Glass, does special packaging need to be procured or can courier supply.
3. IMP storage requirements: how stable is the drug, has it been modified in any way, what is the likely time the drug will spend in transit, requirement for temperature monitoring, validated shippers etc.
4. Accountability requirements – how will the shipment be confirmed once received, it is important that IMP is received by the patient only and not delivered to an alternative address without prior agreement.
5. IMP returns – will returns be sent back to site via the same method, what about failed deliveries?
6. Does the delivery company/method have adequate insurance cover.
7. Might emergency delivery be required – how will this be managed?
8. Discussion with patient regarding IMP storage and documentation of this.

c. **For commercial sponsors** the same risk assessment will be carried out and be approved by relevant site staff including the PI or delegate and Clinical Trials Pharmacist.

d. Depending on the outcome of the risk assessment the following options are available to consider:

	Trackable	Proof of delivery	Temperature controlled vehicle	In transit temperature monitor	Liaison with recipient	Nursing staff at home managing visits
Courier service: Advanced	X	X	X	X	X	X
Courier service: Intermediate	X	X	x	X		
Courier Service: Basic	X	X				
*Postal service i.e Royal Mail Signed for ™	X	X				

*NB: Royal Mail signed for delivery would be the minimal recommended level of traceability. The Royal Mail website should be regularly checked for up-to-date information on permitted items. https://www.postoffice.co.uk/mail/what-can-i-send

e. The trust has a contract with a courier provider who can provide validated shipping boxes. If a temperature-controlled delivery van or temperature monitoring is required, then alternative providers will need to be sought and contracts put in place. Any service chosen should comply with the general principles of Good Distribution Practice and have adequate insurance cover.

f. Where Royal Papworth is the sponsor Pharmacy will write a detailed procedure covering all the requirements for IMP delivery; for trials not sponsored by Royal Papworth, Pharmacy will write a procedure if one has not been provided - this should be approved by the sponsor.

g. Where the decision to deliver IMP direct to patient defers from the approved protocol then sponsor approval should be sought for protocol deviation and if the scenario is likely to happen again then an amendment to the protocol should be submitted to the appropriate authorities.

h. It is the responsibility of the site research team in conjunction with pharmacy to develop a process that works for the study, patient, and site staff. The research team must document in the research notes, patient specific requirements and consent and communicate these to pharmacy as appropriate.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2023)
Key related documents:	Trust Research Policy Trust Policy DN1 Document Control Procedures

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	June 2027