York and Scarborough Teaching Hospitals NHS Foundation Trust R&I Department
SOP
Pharm/S101

Transport of clinical trial prescriptions to Scarborough

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

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	Date:	22nd July 2025
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This SOP will normally be reviewed at least 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	Reviewers	Details of significant changes
1.0	8th April 2020		
2.0	15th October 2024	Rachel Spooner	Change of Trust name. Removal of the COVID specific information. Added in things to consider before agreeing a delivery.
3.0	8th September 2025	Rachel Spooner	Change of author. Change of SOP name. Inclusion of process of transporting to Scarborough.

Contents

1 Introduction, Background and Purpose

The Pharmacy Clinical Trials team based at York Hospital store, dispense and account for all IMP used in Clinical Trials across the Trust. As such, all IMP is dispensed/issued from Pharmacy Clinical Trials at the York site, and IMP is then transported cross-site using the internal Pharmacy Trust transport to Scarborough Hospital if required, to be collected by the participant/research team. IMP can also be transported to other outside units or patients' homes if necessary, however this is only in exceptional circumstances.

This Standard Operating Procedure details the process to follow for transporting dispensed IMP from Pharmacy clinical trials at York hospital to the Pharmacy department at Scarborough Hospital, as well as the procedure to follow should IMP need to be transported to other outside units/patient homes.

2 Who Should Use This SOP

This SOP should be used by the Pharmacy Clinical Trials team and any member of the Research and Innovation team who is involved in the transport or receipt of IMP to/from other Trust sites and outside units.
This SOP should also be used whenever a delivery of clinical trial medication is required to a patient under exceptional circumstances.

3 Transporting ambient IMP from York Pharmacy Clinical Trials to Scarborough Hospital Pharmacy department

3.1 Preparing the IMP for Transport

Prior to sending the IMP to Scarborough hospital, ensure both the Scarborough research team and Pharmacy clinical trials team are aware of when the prescription is required for so that it can be dispensed and sent to Scarborough in advance of the patient visit. For patients collecting from Scarborough, prescriptions should be sent on the hospital transport the day prior to collection at the latest.

- Collect a blue transport bag from the storage location in the clinical trials dispensary
- Ensure the dispensed and checked IMP is placed in a paper dispensing bag labelled with the patient details, and place the IMP into the blue transport bag
- Set up a Denward logger via the EasyLog programme using the below steps:
    - Open EasyLog
    - Collect a Denward logger from the storage location in the Pharmacy clinical trials office
    - Plug the Denward logger into the USB of the computer
    - Click 'set up and start USB data logger'

  - Follow the steps to set up the Denward logger, including inputting the correct minimum and maximum temperature in-line with the IMP temperature range on the stock management SOP in the front of the specific PSF
  - Please note: no humidity options need to be set. This step in the EasyLog set-up process can be skipped
  - Set the Denward logger to start via the 'push-to-start' function.
  - Once set up, the display on the Denward logger will flash with 'PS'. Do not press the button on the logger until the logger should begin reading
  - Sign the Denward logger out of the 'logger sign out form' in the Temperature Monitoring folder in the clinical trials office.

- Place the Denward logger next to the dispensed IMP in the blue transport bag
- Use bubble wrap to pack the empty space around the dispensed IMP in the transport bag
- Place one spare red bag tag into the internal pocket of the transport bag for use on the return of the bag from Scarborough, and change the sign on the front of the bag to read the destination of 'Scarborough Pharmacy department'.
- Complete the first section of Pharm/F84 (Transporting IMP between the York and Scarborough sites form), including the details of the trial, the IMP dispensed and the temperature requirements for the IMP.
- Set the bag and form aside in the clinical trials dispensary and do not seal until the bag is ready to be transported to Scarborough.

The Trust transport van leaves York Hospital Pharmacy stores once each day, Monday to Friday, between 11.30 and 12.00, and reaches Scarborough Pharmacy stores at approximately 14.00.

- When the transport is ready to leave, push the button on the Denward logger to start the logger. The logger display will flash with 'LOG' and then will read the current temperature to confirm that it has been started correctly. Place the logger back into the bag next to dispensed IMP.
- Sign and complete the date and time of the first 3 rows of the table under the 'Pharmacy clinical trials' section on Pharm/F84.
- Take a photocopy of the partially completed transport form and the completed clinical trial prescription. Place the **photocopy** of the prescription and the **original** copy of the transport form into the transport bag.
- Seal the transport bag with a red tag and place the bag into the Scarborough transport cage in Pharmacy stores. Note: be aware of the seasonal changes in temperature of the external environment as this may impact the temperature of the transport bag if placed onto the cage too early.
- Confirm with the Scarborough research team via email that the prescription has been sent on the transport.

The copy of the partially completed transport form must be filed in the relevant section of the PSF until the original completed copy is returned from Scarborough.

3.2 Receipt of IMP in Scarborough (carried out by Scarborough Pharmacy Stores staff)

Upon arrival of the transport cage in Scarborough Pharmacy stores, Scarborough Pharmacy stores staff will:

- Open the blue transport bag and check the minimum and maximum temperatures displayed on the Denward logger and check this against the stated temperature requirements for the IMP on the top of form Pharm/F84.
- **If a temperature excursion has been identified** – Scarborough stores staff will contact the Pharmacy clinical trials team immediately to inform them of the excursion and will place the IMP in the designated clinical trials cupboard in the CD room to await further action regarding suitability. Pharmacy clinical trials will investigate into the excursion, requesting authorisation on whether the IMP can still be issued from the sponsor and notifying the Scarborough research team where necessary.
- **If no temperature excursion has been identified** – Scarborough stores staff will unpack the transport bag, placing the IMP and copy of the prescription into the clinical trials cupboard in the CD room in Scarborough Pharmacy awaiting collection by the research team. Scarborough stores staff will also sign the transport form and place alongside the IMP and prescription.
- The blue transport bag is resealed with the Denward logger inside and returned to York Pharmacy stores on the next available transport.

3.3 Collection of IMP from Scarborough Pharmacy (carried out by Scarborough research nurses)

Once notified by Pharmacy Clinical Trials that the IMP has been sent over to Scarborough Pharmacy, the Scarborough Research nurses will then collect the IMP directly from Scarborough Pharmacy at the time of the trial participant's appointment to hand out.

Upon collection, the Scarborough research nurse will sign the final section on Pharm/F84 and will collect both the copy of the prescription and the IMP. The original completed transport form will be retained within the clinical trials cupboard in the Scarborough CD room until it is collected by a member of Pharmacy Clinical Trials, or is returned on the Trust transport.

Note: Only research nurses are authorised to collect IMP from Scarborough Pharmacy. IMP should only be collected at the time of the participant's visit in order to maintain the correct storage conditions of the IMP up until issuing to the participant.

In cases where IMP is unable to be issued to the participant (e.g. due to appointment non-attendance), the research nurse must return the IMP to Scarborough Pharmacy to be retained in the CD room immediately. This is to ensure the secure storage of the IMP under the correct temperature conditions.

3.4 Transport documentation and temperature data

Following return of the transport bag to York pharmacy clinical trials from Scarborough Pharmacy, the Pharmacy clinical trials staff must:

- Download the temperature data from the Denward logger, by following the below steps:
    - Plug the Denward logger into the USB of a computer
    - Open the 'EasyLog' programme
    - Select 'Stop the USB data logger and download data'
    - Save the temperature data file to the study specific folder on the X:Drive. The graph containing the data will then open automatically.
    - Review the graph, ensuring that the temperature of the transport bag remained in range throughout transport to Scarborough
    - Print the graph
    - Unplug the Denward logger from the USB, place back in the designated storage location in the clinical trials office, and sign the Denward logger back into the 'logger sign out form' in Temperature Monitoring folder.
- File the temperature graph alongside the copy of the transport form in the PSF.
- Upon collection/receipt of the original completed transport form from Scarborough at a later date, ensure this is filed in the PSF alongside the temperature graph, and the partially completed copy can be placed in confidential waste.

4 Delivery of prescriptions to patient's homes (exceptional circumstances only)

Following the COVID-19 pandemic, procedures were created to accommodate clinical trials patients to continue to receive their trial medication, without having to attend a hospital site in person. This procedure is in place to ensure there is a process for clinical trial patients to have their treatment delivered to their homes or care facility under exceptional circumstances and following approval from the individual trial sponsor.

This should only be considered and carried out under exceptional circumstances, where all other options have been deemed unsuitable.

The delivery of the clinical trial medication to clinical trials patients needs to be done by members of staff qualified to do so.
Some sponsors may have made allowances for their trial IMP to be delivered to patients homes, there may be approved couriers in place or they may reimburse a delivery fee. This must be clarified with the sponsor prior to agreeing to delivery IMP to a patient. Costs must be logged on the EDGE system.

Prior to agreeing to have to have a patient's IMP delivered to their home or care facility consider:

- Have other options been explored? Could a relative or carer collect or can the can it be collected on another day?
- Could the IMP be delivered to the patient's local GP or outpatient facility utilising established Trust transport routes and transport process followed within Main Pharmacy?
- Storage requirements – is there a need for a temperature logger and/or an insulated cold chain shipper?

- The type of IMP – Is it a high-risk drug or controlled drug?
- Are there any cautionary handling requirements? E.g. cytotoxic
- How long is the journey?
- Can you use a Trust pool car or have the correct insurance?
- Have you got sponsor approval if needed.

1. A patient needing a delivery will need to be identified by the research nurse who is dealing with the patient. When clinical trials medication is required, they should let the clinical trials pharmacy know that this medication will need to be delivered.
2. The prescription and dispensing procedure remains the same and should be conducted as normal.
3. The Pharmacy clinical trials team will also check to see if the sponsor may have made other arrangements for getting medication to patient's homes. Some sponsors are providing a delivery service themselves.
4. When the medication is ready the pharmacy clinical trials will contact the qualified member of staff that is to be delivering the IMP to the patient's home or care facility.
5. Once the relevant member of staff has been selected to deliver the medications the clinical trials pharmacy staff will complete the pharmacy section on the Pharm/F92-Clinical Trials Delivery Form
    - The patient must be contacted before delivery to ensure they will be there to accept the medications. Patient consent must be given by the patient allowing the delivery of their medication by a research nurse or member of pharmacy clinical trials.
    - No information on the form must indicate the patient's care or treatment.
6. The medication will be placed in a pharmacy paper bag.
7. The member of staff collecting and delivering will complete the relevant section of the Pharm/F92-Clinical Trials Delivery Form
8. The member of staff delivering the medication must drive direct to the patient's address.
9. Once at the address, ask the patient or carer to confirm the patient's date of birth stated on the delivery form.
10. Complete the relevant section on the form and return it to pharmacy clinical trial when you are next on site.
11. The completed for must be stored in the pharmacy site file for the study to maintain accountability.

If there are any problems with a planned delivery call the pharmacy clinical trials team on 01904 721684.

5 Related SOPs and Documents

Pharm/F92 Clinical Trials Delivery Form

Pharm/F84 Transporting IMP between the York and Scarborough sites form