NHS

Clinical Trials Wardlist Check Instructions
Procedure to check the Core Patient Database (CPD) for inpatients taking part in a clinical trial

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

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This SOP will normally be reviewed every 2 years unless changes to the legislation require otherwise

UNCONTROLLED DOCUMENT WHEN PRINTED

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	Details of significant changes
1.0	20th August 2015	

Contents

1   Introduction, Background and Purpose

The Pharmacy clinical trials team need to check wardlist on a daily basis to see if any newly admitted patients to hospital are taking Investigational Medicinal Products (IMPs) and/or Non-Investigational Medicinal Products (NIMPs). A patient admitted to hospital who is on a clinical trial will have a flag alert on the Core Patient Database (CPD) indicating which trial they are participating in. This check needs to be done so we can confirm the patient has brought their trial medication into Hospital with them. If this is not the case a re-supply may need to be given.

This SOP details the procedure for identification of such patients and the actions to be taken by the Pharmacy clinical trials team. It describes the procedure to be followed by the ward Pharmacist when a trial patient has been admitted to their ward. This SOP details what course of action should be taken in the event of a patient being admitted to hospital who is taking part in a clinical trial not hosted by York Hospital or Scarborough Hospital which form part of the York Teaching Hospital NHS Foundation trust.

2   Who Should Use This SOP

This SOP should be used by all members of the Pharmacy clinical trials team at York Hospital or Scarborough Hospital, which form part of the York Teaching Hospital NHS Foundation Trust who need to check wardlist for newly admitted clinical trial patients.

3   When this SOP should be used

This SOP should be used every weekday (except on Bank Holidays) to check for newly admitted patients on IMPs and/or NIMPs at York and Scarborough Hospital, which form part of the York Teaching Hospital NHS Foundation Trust.

4   Procedure(s)

4.1   Access wardlist on CPD and view current in-patients on a clinical trial

1. Log onto the Core Patient Database (CPD).
2. Go to Forms, Inpatients and then List patients on ward (Wardlist).
3. Type YD (for York) and SH (for Scarborough) in the Hospital box.
4. Click Filters.
5. Click on the clipboard next to Select Alerts.
6. Click Drug Trial and click OK.
7. Click Save and Close.

4.1.1   Check for newly admitted patients

1. Tick Admin (this then displays how long a patient has been in Hospital).
2. Tick LoS (Length of stay) button (this will put the number of days a patient has been in hospital in ascending/descending numerical order as you click).
3. Check for newly admitted patients that have been admitted into hospital since the last check was done.

4.1.2 **Identify which trial the patient is taking part in**

1. Click on the exclamation mark (!) next to the patients name to determine which trial they are participating in and if it involves IMPs and/or NIMPs. Document accordingly on a Pharmacy Clinical Trials Wardlist Check Form (Pharm/F102). This form must be completed even if we have no patients on IMP's and /or NIMP's by annotating NA (not applicable) in the relevant fields. Click close then repeat this exercise for each patient.
2. Close CPD.
3. At the end of each month, file the completed form in the designated file. Forms should be retained for 12 months. Forms older than 12 months should be destroyed by placing into confidential waste.

4.2 **Procedure to follow if a patient is on a clinical trial**

4.2.1 Once a patient on a clinical trial has been identified, check the relevant clinical trials file to determine whether the patient is currently receiving treatment with IMP's or NIMP's. Record patient and medication details on form Pharm/F102.

4.2.2 If a band 2/3 completes the above procedure (4.2.1) they must inform a clinical trials Senior Pharmacy Technician or clinical trials Pharmacist of the patient(s) name and which trial they are taking part in and the ward they have been admitted to.

4.2.3 The Senior Pharmacy Technician should inform the ward Pharmacist of any trial patient(s) on their ward, the medication involved, including the dose, duration and date of last dispensing episode.

4.2.4 The Senior Pharmacy Technician should inform the relevant research team of any trial patients that have been admitted to hospital and which ward they have been admitted to.

4.2.5 The Senior Pharmacy Technician should ask the ward Pharmacist to confirm that the patient has their trial medication with them and that there is an appropriate quantity to cover their stay in hospital. (Scarborough Hospital Senior Pharmacy Technician may undertake this procedure as needed). If a sufficient supply of medication isn't available then the ward Pharmacist will be given the research teams contact number by the Senior Pharmacy Technician and they should proceed to contact the relevant research team to inform them. The research team will advise the ward Pharmacist if any further course of action needs to be taken.

4.2.6 The Pharmacy clinical trials team do not need to take any further action if the patient is not currently receiving trial specific medication other than record this on Pharm/F102.

4.3 **Procedure for ward Pharmacists to follow when checking a patient drug chart**

4.3.1 The pharmacist must ensure all trial medication has been prescribed appropriately on the drug chart if clinically appropriate.

4.3.2 A clinical trial inpatient label (which will be provided by the pharmacy clinical trials team on request) or hand written annotation should be placed / entered on the drug chart in an appropriate space by the ward Pharmacist. The clinical trials in-patient label or hand written annotation should be completed with the name of the clinical trial the patient is participating in and the location of the trial specific medication (e.g. patient's own locker). If there is space

available in the 'additional instructions' section of the drug chart, next to each trial specific drug, write 'Use trial specific medication'.

4.3.3 The Pharmacist should inform the Nurse involved in the patients care or Ward Sister that they have a patient on a pharmacy clinical trial and where the trial medication is being stored.

4.4 **Procedure to follow when a patient is admitted into hospital whilst taking part in a clinical trial not hosted by York Hospital or Scarborough Hospital which form part of the York Teaching Hospital NHS Foundation Trust.**

4.4.1 If a patient is admitted into hospital and is currently taking part in a clinical trial not hosted through York Hospital or Scarborough Hospital, which form part of the York Teaching Hospital NHS Foundation Trust, this would not show up on our Core Patient Database. The ward Pharmacist would inform the Pharmacy clinical trials team of any such patient. The clinical trials Senior Pharmacy Technician should advise the ward Pharmacist to contact the trial Sponsor and inform them of a newly admitted patient. The relevant name and telephone number to contact will be on the trial label which has been applied to the IMP. The ward Pharmacist should take advisement from the Sponsor to see if any further action is required.

5   Related SOPs and Documents

Pharm/F102 Pharmacy Clinical Trials Wardlist Check Form