STANDARD OPERATING PROCEDURE

Dispensing Clinical Trial Materials

1 Scope

This procedure documents the requirements for the activities associated with the dispensing of clinical trial materials (CTM) in the Royal Children's Hospital (RCH) pharmacy department. The procedure also encompasses the safe dispensing and labelling of medicines to ensure the site meets Good Clinical Practice (GCP) principles, Pharmacy Board of Australia Guidelines for Dispensing of Medicines and protocol or pharmacy manual specific requirements when dispensing CTM.

2 Responsibilities

2.1 Pharmacist/Pharmacy Technician

(i) Ensure that staff involved in processes associated with the dispensing of CTM have completed Good Clinical Practice training meeting Minimum Criteria v.2.0 for ICH E6 (R2) GCP Investigator Site Personnel Training identified by TransCelerate BioPharma, Inc., as necessary to enable mutual recognition of GCP training among trial sponsors.

(ii) Ensure that all equipment and consumables required are assembled prior to dispensing CTM.

(iii) Complete all necessary records associated with dispensing of CTM according to Institutional, Study Protocol and Regulatory requirements.

3 Procedure

3.1 A prescription and where appropriate a prescription guide will be received by the clinical trial pharmacist from an investigator for a designated CTM.

3.2 The prescription and prescription guide are assessed to ensure all required information is included and the information is appropriate for the study, including participant enrolment in the study.

3.3 The following information will be present on either the prescription or the combination of the prescription and prescription guide:

- Patient identifiers such as name, address, study specific participant number(s), date of birth and medical record number (MRN).
- Patient's weight (if required).
- CTM name, strength, form, directions for use and quantity.
- Protocol specific details such as protocol name, number and RCH HREC number, visit name
- Investigational prescriber's name, date and signature.

3.4 All applicable CTM prescription documentation will be reviewed for protocol compliance.

3.5 Where required the clinical trials pharmacist will perform or confirm randomisation is correct according to a previously provided randomisation schedule.

3.6 The CTM is collected by a clinical trials team member from the CTM storage facility.

3.7 If required by the protocol the clinical trials pharmacist completes relevant CTM log forms for dispensing of CTM for example: Paper based overall and/or individual Accountability log forms or online Interactive Web Response Systems (IWRS) or Interactive Response Technology (IRT).

3.8 The clinical trial medication is appropriately labelled preferably using an electronic dispensing system, including any ancillary labels. Sponsor required information will not be obscured. The following information is present on the label:

- Name of clinical trial, protocol number and if space permits the RCH Human Research Ethics Committee (HREC) number.
- Clinical trial medication name, strength, form and quantity.
- Patient identifiers such as name, study specific participant number(s) and MRN.
- Directions for use of clinical trial medication, including frequency and dose.
- Instructions for the return of used or unused clinical trial medications.
- Date of dispensing.
- Medication expiry date.
- RCH Clinical trial pharmacy name, contact number and address.
- Investigational prescriber's name
- Directions for storage conditions
- The words 'KEEP OUT OF REACH OF CHILDREN'.

3.9 Upon conclusion of the CTM dispensing the dispensed CTM will re-checked by the pharmacist for accuracy in accordance with the protocol and prescription requirements

3.10 In the event that a clinical trials pharmacy technician dispenses the medication then the above steps (3.1 – 3.8) will be supervised and verified by a clinical trials pharmacist.

3.11 Responsibility for the accuracy and completion of clinical trial activities within the dispensing process is acknowledged by the pharmacist initialing and dating the prescription and other documents as required by the protocol.

3.12 Multiple CTM kits dispensed will be stored together with patient identification in clear view.

3.13 Dispensed CTM will be stored separated from other CTM according to the appropriate storage conditions within the RCH clinical trials pharmacy until collection.

3.14 If required the clinical trials pharmacist will contact the study coordinator or investigator for collection of the CTM.

3.15 All relevant paperwork associated with the dispensing of CTM is filed in the protocol specific pharmacy site file which is stored in the RCH clinical trials pharmacy.

4. Additional Considerations

4.1 Dispensing CTM prior to date of the protocol visit

- Dispensing of CTM prior to date of visit may occur to allow sufficient time to complete the dispensing procedure.
- If applicable IWRS or IRT transactions may be required to be performed prior to the date of visit, but all attempts will be made to perform transactions within the allowable visit window unless the visit is considered "unscheduled"
- In the event that a participant's health status precludes provision of dispensed CTM to the participant. The CTM will be stored in the RCH clinical trials pharmacy under the appropriate storage conditions until advice regarding the dispensed CTM is provided by a member of the study team.
- Dates of the following actions will be recorded on the appropriate documents: IWRS or IRT transaction, prescription, dispensing and shipping.

4.2 Multiple participants enrolled in the same trial with CTM to be collected on the same day

- It is the preference that individual participant's CTM are collected on separate occasions.
- In the event that CTM are to be dispensed at the same time to study personnel other than the study participant, for example; the study coordinator, nurse or investigator for dispensation to multiple participants enrolled in the same protocol, a log will be prepared for the study personnel to complete to provide written responsibility for handing over the right CTM for the right protocol to the right participant. This log will be returned for filing in the pharmacy site file stored in the RCH clinical trials pharmacy.

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