Research Ethics and Governance – Receipt and handling of investigational product Procedure

TARGET AUDIENCE and SETTING

Principal Investigator and all staff conducting research.

PURPOSE

To describe the procedures related to receipt and handling of investigational product.

DEFINITIONS

Investigational Product

A pharmaceutical form of an active ingredient or placebo being tested or used in a clinical trial.

PRECAUTIONS/CONTRAINDICATIONS

All researchers at Monash Health must conduct research in the manner indicated in the Human Research Policy and the Research Governance Procedure.

STANDARD REQUIREMENTS

All investigators must abide by relevant legislation, the Australian code for the responsible conduct of research (NHMRC, 2018), the National Statement on Ethical Conduct in Human Research (NHMRC 2018), the Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016) and the International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016)

PROCEDURE

1. Receipt and handling of investigational product.

1.1 Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.
1.2 An Investigational Product Accountability Log should be maintained.

2. The investigator(s) must:

2.1 Where allowed/required, assign some or all of the investigator's/institutions duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.

3. The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, must:

3.1 Maintain records of the product's delivery and receipt to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s). These records will include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial subjects.

3.2 Ensure that the investigational product(s) are stored as specified by the sponsor in accordance with applicable regulatory requirement(s). Consideration will be given to how the investigational product shall be securely stored, including restricting access to approved personnel.

3.3 Maintain records of accountability and storage monitoring (i.e. temperature logs).

3.4 Maintain records that document adequately that the participants were provided the doses specified by the procedure and reconcile all investigational product(s) received from the sponsor.

3.5 Explain the correct use of the investigational product(s) to each subject and will check, at intervals appropriate for the trial, that each subject is following the instructions properly. A compliance check could include instructing the subjects to return empty and partially used containers at their next visit. An assessment would then be made of how much medication has been taken versus the expected amount of medication to be taken. The compliance check will usually also involve asking the subject to describe how and when they are taking the medication.

4. The investigator(s) must:

4.1 Ensure that the investigational product(s) are used only in accordance with the approved procedure.

4.2 Follow the trial's randomisation procedures, if any, and will ensure that the code is broken only in accordance with the procedure. If the trial is blinded, the investigator will promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s).

4.3 Document any changes in a Change Log.

KEY STANDARDS, GUIDELINES OR LEGISLATION

Australian code for the responsible conduct of research (NHMRC, 2018),

National Statement on Ethical Conduct in Human Research (NHMRC 2018)

Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016)

International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016)

KEYWORDS

Investigational product, clinical trial, pharmacist, unblinding.

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