Medicines used in research and clinical trials

Purpose of this procedure:

NHS Lothian participate in national and local medicines research and clinical trials. This procedure guides staff on the process to follow for medicine related research and clinical trials.

The Procedure

1.0 Research and clinical trials

1.1 An application for NHS Lothian Management approval to conduct a clinical trial must be made to the hospital Research and Development department (R&D).

1.2 A Clinical Trials Authorisation (CTA) must be obtained from the Medicines and Healthcare Products Regulatory Agency (MHRA) for all interventional clinical drug trials.

1.3 An application for an ethical opinion must be made to an appropriate recognised Research Ethics Committee.

1.4 Clinical trials involving the administration or supply of medicines must be discussed with a member of the pharmacy clinical trials team as early in the site set up process as possible. This will ensure that a review of the pharmacy workload and financial implications can be undertaken by an authorised pharmacist. If there are no objections to the trial being conducted from a pharmacy perspective, confirmation of pharmacy support will be communicated to R&D.

1.5 Medicine supplies for research and clinical trials must be managed by the hospital pharmacy clinical trials team. All sponsor supplied Investigational Medicinal Products (IMPs) must be delivered to the pharmacy department where a review and assessment of the labelling, to ensure compliance with Good Manufacturing Practice (GMP), will be undertaken. All medicines for use in clinical trials, not directly supplied by the sponsor, must be procured, and distributed via the hospital pharmacy.

1.6 A copy of the current research protocol, all regulatory and local approvals, and confirmation of the emergency code break process where relevant for double blind trials, must be held in the pharmacy.

1.7 Patient recruitment to a clinical trial can only commence following the receipt of all the listed documents in point 1.6 and sponsor approval for the site to start the study.

2.0 Prescriptions for clinical trials

2.1 When a hospital inpatient requires a supply of a clinical trial medicine to be administered on the ward, it must be prescribed on the appropriate prescription and administration record. The entry should include along with the medicine name, dosing and administration instructions, the protocol number, and the patient trial identification number.

2.2 For HEPMA, follow the guidance on 'prescribing clinical trials drugs' located on the NHS Lothian HEPMA intranet page. Select "Clinical Trial Drug" and the information detailed in 2.1 should be added to the HEPMA order note.

2.3 When an outpatient requires a supply of a clinical trial medicine it must be prescribed on a trial specific approved prescription form by a prescriber who has been delegated the responsibility for this by the principal investigator.

2.4 Staff required to administer clinical trials medicines should receive the appropriate information and training.

Associated materials/references:

The Safe Use of Medicines Policy