13. Safe and secure handling of Medicines (including Advanced Therapies) in clinical trials

13.1 Background

The purpose of this policy is to ensure that Barts Health and Queen Mary comply with the relevant guidelines for the safe and secure handling of clinical trial medication (including advanced therapies).[1]

This policy applies to all drug trials that involve Barts Health patients and or Barts Health or Queen Mary healthy volunteer studies.

The ordering, storage and handling of clinical trial medication and advanced therapies must comply with Barts Health policies on the safe and secure handling of medicines. Barts Health's Pharmacy Department must be involved at an early stage of all clinical trials that involve the use of medicines or advanced therapies

Where a clinical trial does not use regular systems of purchasing, storage or administration the proposed alternative must be agreed with the Pharmacy Department. These local systems and facilities will be subject to audit by the Pharmacy department.

13.2 Scope

This Policy applies to all trials falling within the scope of The Medicines for Human Use (Clinical Trials) Regulations 2004 regardless of licensing status, indication, funder, sponsor or source. Researchers should always seek JRMO confirmation of study status. The JRMO will, if required, contact the MHRA helpline for a final decision on whether or not a trial falls under the scope of The Medicines for Human Use (Clinical Trials) Regulations 2004. The final decision will remain with the JRMO Sponsor Oversight Group.

13.2 Policy

(a) Regulatory and local approvals

In addition to HRA, NHS ethics and local NHS Capability and capacity confirmation, trials involving an investigational medicinal product (IMP) should follow current submission guidelines and the processes required to apply the Medicines and Healthcare products Regulatory Agency (MHRA) as per current UK processes.

. Before prescribing clinical trial material the Principal Investigator or pharmaceutical company trial co-ordinator should discuss with Barts Health's Pharmacy (the clinical trials pharmacist) the exact procedure and necessary information for prescribing the trial material. For clinical trials involving in-patients, it is the Principal Investigator's responsibility to ensure

[1] The Declaration of Helsinki (2013); Good Clinical Practice (2017); The Medicines for Human Use (Clinical Trials) Regulations 2004 (and all its amendments); Data protection laws; UK Policy Framework for Health and Social Care Research 2017

that all staff involved in the study are well informed and given reasonable notice of pending clinical trials. As well as local confirmation of capacity and capability approval, written local pharmacy approval must be in place before any prescribing takes place.

(b) Prescribing and Administration

All prescribers and persons administering IMP must be suitably trained and delegated to do so by the principal investigator.

IMP must be prescribed using a trial-specific prescription form approved by a trial pharmacist. In some circumstances, a standard non-trial prescribing process can be used, and this must be agreed upon in advance with a trial pharmacist

(c) Patient Safeguards

Informed consent must be obtained as per local and national policies. The Principal Investigator or delegate is responsible for informing patients about trial medication and the potential for any harmful effects. Arrangements must be in place to indemnify Barts Health or Queen Mary for any claims against them relating to a medicine-induced injury.

All patients and volunteers must be given study information that, where applicable, contains the name of the trial and a named 24-hour contact with a telephone number. This may then be passed to Barts Health's Pharmacy in the event of a query.

(d) Supply and storage

All medication and advanced therapies intended for clinical trial use should be delivered either to the Pharmacy Departments or to a location audited and advised by the Barts Health Pharmacy Department and stored under its direction.

It is normally inappropriate for stock to be stored in an office environment, and special arrangements will be needed for out of pharmacy storage. Where normal arrangements would seriously affect the running of the trial, the pharmacist may consider authorising an alternative for out of pharmacy storage arrangements. This must be documented, and an audit of the procedures and conditions must be carried out. The trial will be subject to an ongoing audit by the pharmacist in these circumstances. Any significant breaches of GCP, or the safe and secure handling of medicines policy, may result in the suspension of the trial whilst satisfactory arrangements are put in place.

(e) Dispensing

Barts Health's Pharmacy should have a clear dispensing procedure for each clinical trial and must ensure correct labelling of trial material, as per the clinical trial application and Sponsor instructions.

(f) Information

The pharmacy should hold within its Pharmacy Trial File information relevant to each clinical trial, including a protocol, MHRA, ethics and JRMO approval letters, an investigator's brochure or summary of product characteristics, and randomisation codes, where appropriate.

(g) Pharmacy role in Queen Mary and Barts Health Sponsored C and A TIMPS

(h) Pharmacy specific software and oversight of prescribing systems

(i) Barts health Pharmacy oversight of sub-contractors (for example, Lloyds)

This policy applies to both Barts Health and Queen Mary