NIHR | King's Clinical Research Facility

Management of Medical and Laboratory Equipment in the King's Clinical Research Facility

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1.0 Background

1.1 All medical and laboratory equipment used within the King's Clinical Research Facility (CRF) must be maintained to a high standard, to ensure that it is reliable, accurate and safe.

1.2 Clinical trial legislation states that equipment used for clinical trials must be "fit for purpose" and as such records must be available to demonstrate the calibration and maintenance of equipment used to measure trial parameters, equipment used in emergency trolleys and equipment used for the processing and storage of biological samples.

1.3 In order to meet regulatory requirements and standards, as well as those of King's College Hospital (KCH), it is essential that robust equipment management procedures are in place to ensure oversight of all equipment used within the CRF.

1.4 The CRF maintains a list of equipment on its Quality Management System (Q-Pulse) under the 'CRF Equipment' module. This allows for the upload of all documents relating to the equipment (e.g.: service records, contracts) and also ensures that service dates are registered, and e-mail reminders are sent when equipment is due for service or calibration.

2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for the management and maintenance of medical and laboratory equipment within the CRF and to identify the roles and responsibilities of staff in relation to equipment management. This only pertains to electronic equipment; analogue equipment such as stadiometers or tendon hammers do not fall under this SOP's scope.

3.0 Scope

3.1 This SOP applies to all medical and laboratory equipment used within the CRF, and all CRF staff and CRF users working with this equipment are bound to adhere to the procedures outlined in this document.

3.2 The CRF consists of the Experimental Medicine Facility (EMF), Clinical Trials Facility (CTF) and Cell Therapy Unit (CTU). CRF SOPs are applicable across both the EMF and CTF. The CTU will continue to maintain and control their SOPs, and conduct their own local induction procedures to ensure compliance with Good Manufacturing Practice (GMP).

4.0 Responsibilities

4.1 All CRF staff and users of the CRF who are responsible for equipment stored in the CRF must adhere to the procedures outlined in this SOP.

4.2 The CRF Manager, or appropriate delegate, is responsible for the selection and approval of equipment that is deemed necessary for the running of the facility or for a specific study.

4.3 The CRF Laboratory Technician and Quality Assurance (QA) Manager are responsible for maintaining an asset register for CRF equipment. They are also responsible for ensuring that all equipment is maintained in accordance with this SOP.

4.4 The CRF Laboratory Technician (and/or an appropriate delegate) is responsible for liaising with MEMS (the Medical Equipment Management Service at KCH) for the support and maintenance agreements for CRF-owned equipment, as well as arranging servicing and electrical testing.

4.5 All Principal Investigators (PIs) storing study-specific equipment within the CRF are responsible for ensuring that it is maintained to a high standard and for ensuring that the relevant support and maintenance agreements are in place. They will provide this information to the CRF Manager or delegate as requested.

4.6 All CRF staff and users of the CRF are responsible for ensuring that they receive adequate training prior to using any CRF equipment, to ensure that they are using the equipment safely and correctly. They must also read and sign off on any associated CRF SOPs and refer to the relevant manufacturer's user manual where applicable. This can be arranged directly via MEMS for team training if necessary – please contact MEMS to arrange.

4.7 Equipment must only be used for its intended purpose and stored safely and securely where necessary.

5.0 Procedure

Ordering Equipment

5.1 Staff must make all requests for equipment ordering via the CRF Manager, who must approve all purchases.

5.2 Once approved, the CRF Administrator, or other appropriate delegate, will place orders for equipment.

5.3 All CRF ordering of new medical or laboratory equipment shall be made in accordance with the relevant KCH policies and procedures. New equipment must be purchased from approved suppliers and conform to any KCH guidelines.

5.4 Where equipment is purchased by King's College London (KCL) directly on behalf of the CRF, the purchase will be made in accordance with KCL financial policies and procedures.

5.5 The CRF Manager or delegate will liaise with the IT team for KCH or KCL, as appropriate, for IT-related hardware and software purchases, to ensure they can be supported by the relevant infrastructure.

Commissioning Equipment

5.6 On receipt of new equipment, the CRF Manager and QA Manager should be informed. This may be from a purchase or received from a study sponsor for specific study related procedure or purpose.

5.7 MEMS must be informed of new equipment being received by the CRF in order for them to perform any required inspection and/or testing, to ensure it meets all of their safety requirements.

5.7.1 When received, new equipment must be taken down to the MEMS Equipment Library (Ground Floor, Cheyne Wing) – unassembled and in its original packaging.

5.7.2 A copy of the (KCH) receipt with KFM acquisition number must be given (e.g. RJZN-XXX) or (KCL) purchase order to confirm proof of purchase.

5.7.3 If applicable, study name or protocol number (including IRAS number if asked) should also be given, along with the estimated study duration if requested (e.g. 1 year).

On completion of these checks, MEMS will allocate a MEMS Asset ID number to the equipment and attach a dated, secure label for identification. MEMS can advise if new equipment does not need to be registered with them.

5.8 The CRF Laboratory Technician, or appropriate delegate, will enter the details of the new equipment onto Q-Pulse, in the 'CRF Equipment' module, under the MEMS Asset ID number.

5.9 Any CRF equipment that is not managed by MEMS, should be entered onto Q-Pulse using another identification number, in order to ensure that the CRF takes responsibility for its maintenance.

5.10 Equipment will only be commissioned for use in the CRF when it is deemed to be both safe and suitable for its intended use, and appropriate servicing and maintenance contracts are in place.

6.0 EPIC compatible equipment

For issues regarding the EPIC related capabilities of equipment please contact KCH ICT, not MEMS.

7.0 Maintenance, Service and Calibration

7.1 For both medical and laboratory equipment, the CRF Manager or delegate must check with MEMS to see whether a service or maintenance contract is required for the equipment. If a contract is required, this service will be arranged through MEMS.

7.2 All equipment managed by MEMS within the CRF is listed by Asset ID number on the MEMS database (AIMS3) and this can be accessed by the QA Manager, CRF Laboratory Technician and appropriate delegates. Service and calibration records

and reports can be downloaded from the database when required. Access to AIMS3 database is generic for all CRF staff with the username and password provided by KCH device team.

7.3 When CRF equipment is due for service or calibration, Q-Pulse will send a reminder e-mail to the CRF Laboratory Technician, 21 days before the due date. If this is to be carried out by MEMS, they will arrange for any portable equipment (e.g., patient monitors, ECG machines, infusion pumps) to be taken to the Medical Equipment Resource Centre, located on the ground floor of Cheyne Wing at KCH. A receipt for the equipment will be issued by MEMS and a temporary replacement will be provided if necessary. A MEMS engineer will come to the CRF to service other equipment (e.g., weighing scales and static equipment).

7.4 The QA Manager or CRF Laboratory Technician, will check the AIMS3 database for a completed date for the work and will update Q-Pulse accordingly once the work has been done and the equipment has been returned to the CRF (where applicable).

7.5 For CRF equipment that needs to be serviced or calibrated by an external supplier (i.e., equipment registered with MEMS but on a service contract with an external company and any equipment not managed by MEMS), the CRF Laboratory Technician, or suitable delegate, will contact the relevant company to arrange this, in advance of the due date. Once completed, Q-Pulse will be updated and the service report and/or certificate will be uploaded by CRF Laboratory Technician.

7.6 Portable Appliance Testing (PAT) is performed on all electrical equipment in the CRF in accordance with KCH policy. This is arranged via the KCH Estates department. The reports and certificates for this are stored on Q-Pulse in the Equipment module.

7.7 Equipment that is due to be used on an upcoming study, which has not been used for a prolonged period, should be safety tested and serviced / calibrated in accordance with the manufacturer's specifications.

Equipment Failure

7.8 When equipment fails, an out-of-order sign must be securely attached in a visible location, with the name, date and contact number of the individual who has discovered the failure.

7.9 The failure must be reported to the CRF Manager, or their delegate, as soon as possible, to allow them to log the failure and arrange an engineer for repair.

7.10 Any equipment that needs to be sent to MEMS or to an external engineer for repair must have a decontamination certificate completed and attached prior to being sent. The certificates are provided by MEMS.

7.11 An e-mail notification advising of the unavailability of the equipment must be circulated immediately to all relevant CRF staff by the person discovering the fault, or their delegate, including details of any alternative or replacement if available.

7.12 Once repaired, an e-mail notification must be circulated to all relevant staff informing them that the equipment is now available for use.

8.0 Decommissioning Equipment

8.1 Formal notification of obsolescence, withdrawal or irreparable nature of equipment may be communicated to the CRF, requiring the asset to the withdrawn from use.

8.2 If the equipment is still serviceable and fully and safely working, then it can remain in service until a planned replacement has been obtained as needed.

8.3 If equipment requires decommissioning, notify MEMs with the asset number. They will update the AIMS3 database to show it has been decommissioned and inform the contracts team. Once decommission is confirmed, the KCH Trust's waste management team can be notified to remove the equipment

8.4 If not, equipment will be taken down to MEMS for decommissioning, where a decontamination certificate form must also be completed.

8.5 Once completed, a Condemning Certificate is issued by MEMS for the equipment. This should be filed on Q-Pulse by the CRF Medical Equipment Co-ordinator under the appropriate record and made unavailable. Any corresponding maintenance contracts the equipment currently on would also need to be updated as required.

Study-Specific / PI-Owned Equipment

8.6 The CRF has a wide range of specialist equipment. Many researchers have specialist equipment that is unique to their field of interest. It is essential that PIs ensure that any non-CRF equipment that is brought into the CRF complies with KCH and CRF safety standards before being brought into the facility.

8.7 Researchers who need to bring their own medical / electrical equipment into the CRF for use on studies should provide written details about the equipment to the CRF Manager prior to the start of the study. Details should include a description of the item(s), contact name and department, plus the location within the CRF where the equipment will be used and / or stored. The equipment itself must be clearly labelled with the owning department and contact name.

8.8 Medical electrical equipment must have passed the relevant tests as currently undertaken by the MEMS department.

8.9 At the end of the study, the PI must ensure that all non-CRF equipment used during the study is removed from the CRF in a timely manner, as agreed with the CRF Manager.

9.0 Field Safety Notices

9.1 A 'field safety notice' (FSN) is an important communication about the safety of a medical device that is sent to all users by a device manufacturer, or their representative – usually through MEMS or equipment maintenance contract provider.

9.2 This may contain updated information or highlight an issue, with further information to tell you what is needed to resolve it, or avoid/reduce the specified risks, in certain situations.

9.3 When FSNs are received, they must always acted upon. FSNs should be:

- Acknowledged to the sender
- Distributed as necessary among CRF users who may be affected by it / use the item of equipment
- Any actions carried out as per the FSN's instructions

10.0 Related documents & References

10.1 KCH Policy for the Management of Medical Devices (available on Kingsweb)

10.2 Medical Equipment Management Service (MEMS)

Medical engineering and physics - Kingsweb (interactgo.com)

10.3 Decontamination policy/form (available on Kingsweb)

11.0 List of Appendices

N/A

11 Approval and sign off

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