Standard Operating Procedure: Sheffield Clinical Research Facility
Equipment Management

This SOP has been produced in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004. This SOP will outline the procedure for the management of medical equipment which is provided by external study sponsors to be used for specific research projects.

Background

All medical equipment which is brought into Sheffield Teaching Hospitals NHS Foundation Trust must be checked and passed, as fit for purpose, by the Trust's Clinical Engineering Department, prior to use on patients, in line with the Trust Reusable Medical Devices Policy. The Trust Reusable Medical Devices Policy sets out to provide guarantees to equipment users, and patients, that the equipment is fit for purpose, and in good working order.

The Clinical Research Facility has various pieces of equipment provided for use on, or by patients, either within the Trust or in patient's homes, who are taking part in specific research trials. These pieces of equipment are either donated or loaned to Sheffield Teaching Hospitals NHS Foundation Trust, by external sponsors, for use on specific research studies. This SOP will provide instruction of how to ensure all equipment is correctly accepted for use in the Trust following the Reusable Medical Devices Policy, and outline the steps required to manage the equipment.

Definitions

For the purposes of this SOP:

- ‘Donated Equipment’ is non white good equipment which is donated to the Trust for use on a specific research trial, and then at the end of the trial, becomes Trust property.
- ‘Loaned Equipment’ is non white good equipment which is loaned to Sheffield Teaching Hospitals NHS Foundation Trust for use on a specific research study for the duration of a research trial.
- ‘Agreement’ refers to a document which has been signed by the sponsor of a particular study and Sheffield Teaching Hospitals NHS Foundation Trust. It maybe referred to for example as participating site agreement, clinical trials agreement or model agreement for non commercial research.
- ‘CRF Study Equipment Registration Form’ is specific to the Clinical Research Facility. It is used to collect information on equipment which is provided for study specific use. Even if no study specific equipment is needed the Form should be completed to reflect this. It should be completed electronically and filed within the relevant study folder on the I:\ Drive.
- ‘CRF Coordinator’ is a CRF Research Coordinator when a study is coordinated by the CRF or a CRF Data Coordinator when a study is not coordinated by the CRF or the nominated Research Nurse within a CRF team responsible for study specific equipment.
- ‘Study contact’ for commercial sponsored studies this would be the Clinical Research Associate (CRA); for non commercial sponsored studies this would be Chief Investigator (CI) or Lead Study Coordinator at the coordinating centre.
- ‘Planned Preventive Maintenance’ is scheduled servicing and each piece of equipment must undergo annual testing by the Trust’s Clinical Engineering Department and / or a specified company.
- ‘STH number’ is five digit reference number issued by the Clinical Research Office, Sheffield upon registration of the study.
Procedures

1. Identification of Equipment Coming on Site

1.1 Where possible CRF generic equipment will be used instead of any study specific equipment being supplied (see section 6 for further details).

1.2 The CRF Coordinator assigned to the study will contact the Study Contact and ask them to complete the CRF Study Equipment Registration Form. This form must be complete whether or not equipment is provided.

1.3 The form asks for the following information:
   a. Study Title, STH reference number and nursing team
   b. Type of equipment
   c. For use in clinic or at home
   d. Loaned or Donated
   e. Serial Number or ID Number (if known)
   f. The date the equipment arrived in the CRF
   g. Date Tested by CE
   h. Date retest due by CE and / or appliance testing by estates
   i. CE Number
   j. Where the equipment will be located in the CRF, which site
   k. Decontamination and Indemnity Dates
   l. Date equipment Returned back to Sponsor.
   m. The name and date of the completer of the Form

2. Acceptance Testing

2.1 Once the agreement is approaching finalisation or has been signed the CRF Coordinator liaises with the Study Contact and arranges for the equipment to be sent to the Clinical Research Facility.

2.2 On receipt of the equipment the CRF Nurse will contact Clinical Engineering with the STH number and book the equipment in to the Clinical Engineering Department for testing. The CRF nurse will record the unique job number given by Clinical Engineering on the CRF Study Equipment Registration Form.

2.3 The CRF Nurse will arrange for transportation of the equipment to the Clinical Engineering department.

2.4 Equipment leaving the CRF needs be recorded on the Permit to Work/Clearance Certificate carbonated page, held at reception.

2.5 Once the Clinical Engineering Department are in receipt of the equipment, the acceptance testing can take place. Once this is complete the CRF Nurse will arrange for the equipment to be collected from the Clinical Engineering Department.

2.6 Once the equipment is returned to the CRF, the CRF nurse will complete the Clinical Engineering test date field on the CRF Study Equipment Registration Form.

2.7 The CRF Nurse will complete a decontamination form for the piece of equipment as instructed in Sheffield Teaching Hospitals NHS Foundation Trust Policy for the
Decontamination of Hospital Equipment and Medical Devices and filed in the 4 bedded bay folder.

2.8 Once the Decontamination date has been inserted into the CRF Study Equipment Registration Form by the CRF nurse, a hyperlink to the electronic copy of the form is emailed to the CRF Service Co-ordinator coping in the CRF Manager.

2.9 The equipment is now fit for use on or by patients in Sheffield Teaching Hospitals NHS Foundation Trust.

3. Equipment Calibration

3.1 Certain basic types of equipment require manufacturer-specific calibrators for example thermometers and scales, which may not be available in the Trust.

3.2 Clinical Engineering Department can advise the CRF nurse or CRF Coordinator if calibration will not be possible. In this circumstance contact should be made with Clinical Engineering Department at the earliest opportunity.

3.3 If the Clinical Engineering Department is unable to conduct the calibration then CRF generic equipment will have to be used or the equipment will have to be sent direct to the participant.

4. Planned Preventive Maintenance

4.1 All equipment sent to Clinical Engineering will be entered on to the central Trust Inventory database. The acceptance testing performed by Clinical Engineering is valid for a period of 12 months. The CRF Service Co-ordinator is responsible for notifying the CRF Nurse allocated to the study when the equipment is due for PPM.

4.2 Specific CRF generic equipment may need to be serviced every 6 months. This would be identified by the CRF Service Co-ordinator and would be flagged on the CRF Master Equipment List.

5. No Study Agreement

5.1 If there is no study Agreement in place then separate NHS Indemnity arrangements are required between the Supplier and STH, which will be organised by Clinical Engineering.

6. CRF Generic Equipment

6.1 All equipment owned by the CRF is detailed on the Master Equipment List. Equipment for both sites are detailed separately and split into medical and non-medical. With the exception of certain fridge, freezers and centrifuges the equipment is service by the Trust’s CE Department. Any service reports provided for freezers or centrifuges are retained in the CRF Service Coordinator office.

6.2 Calibration certificates are not available for individual pieces of equipment. However, following servicing, equipment is allocated a sticker clearly displaying the date it was tested and the retest date. This is then recorded on the Master List. This information is also recorded on the STHFT Clinical Engineering Department database.
7. End of Study

7.1 When the study has finished and the equipment has been returned to the Sponsor, the Registration Form should be updated and the CRF Service Co-ordinator and CRF Manager should be notified.

7.2 The CRF Service Co-ordinator will then update the CRF Master List.

7.3 Clinical Engineering will be notified and the equipment will be removed from the Clinical Engineering database.

7.4 A formal transfer of ownership is required for any equipment donated to the Trust at the end of the trial, as well as clear arrangements for any ongoing revenue consequences – this will be managed by Clinical Engineering and the CE database will be updated accordingly.

Related Documentation

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>STH Reusable Medical Devices Policy</td>
<td>Chris Monk</td>
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<tr>
<td>CRF Study Equipment Registration Form</td>
<td>Karen French</td>
</tr>
<tr>
<td>Policy for the Decontamination of Hospital Equipment and Medical Devices</td>
<td>Hillary Scholefield, Christine Bates, Richard Parker</td>
</tr>
<tr>
<td>Permit to Work/Clearance Certificate</td>
<td>Sheffield Teaching Hospitals NHS Foundation Trust</td>
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</tbody>
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1 The location(s) of any related document(s) are listed in the CRF SOP Referenced Documents Directory.

The CRF SOP Referenced Document Directory and any Related SOPs, listed on page 1 of this SOP, can be accessed electronically at http://www.crf.dept.shef.ac.uk/downloads/sops.html or can be requested by contacting Sheffield Clinical Research Facility, O Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF, 0114 2713339.
Management of Study Equipment Flow Chart

Study equipment identified using the CRF Study Equipment Registration Form

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The equipment can be sent directly to Clinical Research Facility

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Clinical Engineering can now be contacted to arrange for the equipment to be tested & approved as per trust policy. The STH number must be given when booking with Clinical Engineering.

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Once tested & correctly labelled by Clinical Engineering a STH decontamination form should be completed as Trust policy prior to patient use.

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Equipment will need to be sent to Clinical Engineering annually (or every six months if specified) for PPM testing.