

Maintenance of Research Equipment

Division: Strategy & Transformation

Specific staff groups to whom this policy <u>directly</u> applies	Likely frequency of use	Other staff who may need to be familiar with policy
All staff involved in the delivery of Research	When relevant & as required in the usage of research equipment	All staff involved in the delivery of Research

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Approval Authority (Committee/ Group/ Lead Clinician):	Research & Development Senior Team
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Summary of changes since the previous version	<p>Updated reference to Research & Development</p> <p>Updated policy references and links</p> <p>Updated reference to LEARN, LINK and Radar</p> <p>SOP transferred to new trust SOP Template</p> <p>Reference to UKCA marking added.</p> <p>Editorial amendments have been made to sentence structure and wording to improve clarity, flow, and consistency across the R&D SOPs</p>

1. Purpose	<p>The purpose of this SOP is to describe the arrangements for the maintenance, calibration, and servicing of equipment used to support research activities at North Bristol NHS Trust (NBT)</p> <p>The trust policies on <i>Management of Medical Equipment (CG27)</i> and <i>Clinical Equipment Training (CP 7a)</i>, available on the staff intranet (LINK), must be followed at all times. This SOP supplements these policies and governs the deployment, monitoring, and control of Medical and Clinical Equipment associated to research, covering replacement and new items, whether purchased, donated, or hired.</p>																				
2. Key Messages	<p>Research equipment used at NBT must be maintained, calibrated, and serviced to ensure participant safety, data integrity, and reliable research outcomes.</p> <p>All research equipment must be appropriately authorised, recorded, and managed in line with Trust policies, manufacturer requirements, and applicable regulatory standards.</p> <p>Chief Investigators and Principal Investigators are responsible for ensuring that equipment used within their studies is fit for purpose, appropriately maintained, and used only by trained and competent staff.</p> <p>Defective, unsafe, or overdue equipment must be immediately withdrawn from use and reported in accordance with Trust incident reporting procedures.</p> <table border="0" data-bbox="399 1164 1501 2040"> <tr> <td>CES</td> <td>Clinical Equipment Services Department</td> </tr> <tr> <td>CI</td> <td>Chief Investigator</td> </tr> <tr> <td>Clinical Equipment</td> <td>The subgroup of medical equipment which is used directly by staff, in the monitoring, diagnosis or treatment of patients</td> </tr> <tr> <td>CRC</td> <td>Clinical Research Centre</td> </tr> <tr> <td>ICH GCP Guidelines</td> <td>International Conference on Harmonisation for Good Clinical Practice</td> </tr> <tr> <td>LEARN within</td> <td>Electronic e-learning and accreditation database</td> </tr> <tr> <td></td> <td>North Bristol Trust</td> </tr> <tr> <td>LINK</td> <td>North Bristol Trust internal intranet</td> </tr> <tr> <td>Medical Equipment</td> <td>Equipment used in monitoring, diagnosis or treatment of patients in a direct or indirect manner (for example, a centrifuge).</td> </tr> <tr> <td>MEDUSA</td> <td>Medical equipment management software package</td> </tr> </table>	CES	Clinical Equipment Services Department	CI	Chief Investigator	Clinical Equipment	The subgroup of medical equipment which is used directly by staff, in the monitoring, diagnosis or treatment of patients	CRC	Clinical Research Centre	ICH GCP Guidelines	International Conference on Harmonisation for Good Clinical Practice	LEARN within	Electronic e-learning and accreditation database		North Bristol Trust	LINK	North Bristol Trust internal intranet	Medical Equipment	Equipment used in monitoring, diagnosis or treatment of patients in a direct or indirect manner (for example, a centrifuge).	MEDUSA	Medical equipment management software package
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	<p>NBT North Bristol NHS Trust</p> <p>PI Principal Investigator</p> <p>R&D Research & Development Office</p> <p>Radar Accident and incident management system</p> <p>SOP Standard Operating Procedure</p>
3. Relevant Policies & Guidance	<p>Relevant Policies and Guidance:</p> <p>Medicines and Healthcare products Regulatory Agency</p> <p>Managing Medical Devices Guidance</p> <p>www.mhra.gov.uk</p> <p>Care Quality Commission (CQC) Regulation 15 – Premises and Equipment</p> <p>ICH Guideline for Good Clinical Practice (E6 (R3))</p> <p>UK Policy Framework for Health and Social Care Research</p> <p><i>The following items are not covered by this SOP:</i></p> <p>Staff Training - Although this SOP contains outline information on staff training, the <u>Clinical Equipment Training Policy (CG 139)</u> is the reference document for clinical and user staff training.</p> <p>Infection Control and Decontamination - Although this SOP contains information specific to medical equipment decontamination issues, the <u>Infection Prevention and Control Policy (IC01)</u> is the primary reference document.</p>
4. Operational Areas Included	<p>All Trust environments where medical or clinical equipment is used for the delivery of research activities.</p>
5. Operational Areas Excluded	<p>Medical or clinical equipment used exclusively for routine clinical care and not used to support research activities.</p> <p>Sponsor-owned or externally provided equipment used in externally sponsored studies where maintenance, calibration, and servicing are the responsibility of the external Sponsor or provider, and not North Bristol NHS Trust.</p>
6. Who should read this	<p>This SOP applies to anyone undertaking research at North Bristol NHS Trust, as defined by the UK Policy Framework for Health and Social Care Research, where research equipment is used.</p>

<p>7. Roles responsible for carrying out this procedure</p>	<p>Sponsor: Retains overall responsibility for ensuring appropriate governance arrangements are in place for the safe deployment, maintenance, calibration, and servicing of research equipment used in Trust-sponsored research.</p> <p>Chief Investigator (CI) / Principal Investigator (PI) Responsibilities: Ensure equipment used in the study is appropriate, maintained, calibrated, and serviced. Ensure equipment is used only by trained and competent staff. Remove faulty, unsafe, or out-of-date equipment from use. Ensure equipment records are maintained, and incidents are reported in line with Trust procedures.</p> <p>Research Staff / Equipment Users: Responsible for using equipment in accordance with training, manufacturer instructions, and this SOP, checking servicing status prior to use, and reporting faults, incidents, or hazards promptly. All staff involved in conducting research at the Trust</p>
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8. Procedure:

8.1 Requests for New or Replacement Equipment for Research purposes

All new or replacement clinical or medical equipment primarily used for research must be requested through the Research & Development Department prior to procurement or deployment.

All Trust-owned equipment must be checked, registered, and logged on the Trust's medical equipment management system (MEDUSA), with an asset number and identification label applied prior to use. This process is carried out by the Clinical Equipment Services (CES) department.

All medical and clinical equipment used for research must be appropriately conformity-marked in accordance with applicable UK medical device legislation, including UKCA requirements and any recognised transitional arrangements, and must be used in line with the manufacturer's instructions for use.

The Trust must not modify medical equipment in a manner that affects its regulatory conformity status unless a written agreement has been obtained from the manufacturer or their authorised representative. Any such agreement must be retained with the equipment records.

All equipment modifications must be subject to a documented risk assessment, undertaken by an appropriately qualified individual, and the assessment must be stored with the equipment records.

8.2 Training to Use Equipment

All staff must be appropriately trained and competent before using any clinical or medical equipment for research purposes. Training for Trust-owned clinical and medical equipment is provided through the Staff Development Department in accordance with Trust requirements

The Trust has a Clinical Equipment Training Coordinator, who can be contacted at: EquipmentTraining@nbt.nhs.uk

Where non-standard or study-specific equipment is supplied by a Sponsor or external organisation, appropriate training must be provided by the Sponsor or external party prior to the equipment being used. Completion of this training must be documented within individual training records and the relevant site file, in accordance with the Research Staff Training SOP (RD/QMS/SOP/005).

Clinical Equipment Services (CES) must be informed of all non-standard or externally supplied equipment to ensure compliance with Trust infection prevention and control policies and relevant Medicines and Healthcare products Regulatory Agency (MHRA) guidance.

Individual staff members are responsible for ensuring they have received the necessary training before using any equipment and for maintaining up-to-date training records.

The study team leader is accountable for ensuring that all members of the study team are trained and competent to use research equipment and that training logs are completed and maintained.

8.3 Calibration

All research equipment must be calibrated in accordance with the manufacturer's instructions, study protocol requirements, and Trust policies, as applicable.

A calibration record must be maintained for all equipment, clearly identifying the equipment, the calibration performed, the person or organisation undertaking the calibration, and the date of calibration. Calibration records must be readily available for review by the Sponsor, regulatory authorities, and other relevant bodies.

Where scheduled maintenance and calibration are undertaken by Clinical Equipment Services (CES), these activities will be recorded within the Trust's equipment management system (MEDUSA) for equipment under CES management. This system supports planned maintenance scheduling and the identification of upcoming service due dates.

Equipment managed by CES will be labelled with a service or calibration due date. Equipment users must check that equipment is within date prior to use and report overdue servicing or calibration to CES without delay.

Centrifuges, refrigerators, freezers, and associated temperature monitoring equipment used for research purposes are calibrated annually by an external provider arranged by the Clinical Research Centre Manager. Calibration certificates are retained and made available for inspection.

Where a centrifuge is relocated to a new location, it must be re-calibrated prior to use by the approved external supplier. Arrangements for re-calibration will be coordinated by the Clinical Research Manager.

8.4 Repairs

If any item of research equipment is found to be faulty or unsafe, it must be immediately withdrawn from use. A clear and visible label stating “NOT TO BE USED” must be attached to the equipment, and the fault must be reported promptly to the Clinical Research Centre Manager.

In accordance with Trust policy, repair requests for Trust-owned equipment (excluding centrifuges, freezers, and fridges) must be reported to Clinical Equipment Services (CES) by telephone, and the equipment must be sent to CES for assessment and repair. This process will be coordinated by the Clinical Research Centre Manager.

8.5 Incident/Hazard Reporting

The Trust's accident and incident management system (Radar) procedure described in the [Incident Reporting Policy CG01a](#) sets out the requirements for all staff to follow in the event of a hazardous occurrence/adverse incident or near miss.

This must be followed in all cases, so that incidents may be properly investigated and reported. Where applicable, the inventory or serial number of medical equipment should be recorded on the Radar incident form to aid investigation & reporting.

6.0 DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RD/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the LEARN system on the Trust intranet (LINK) shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP.

8.1. References (if applicable):