

STANDARD OPERATING PROCEDURE (SOP)

TITLE: MAINTENANCE OF EQUIPMENT USED IN CLINICAL RESEARCH



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1. PURPOSE:

The purpose of this SOP is to document the procedure for ensuring that all equipment used by Epworth HealthCare for clinical research are maintained in line with good laboratory practice/good clinical practice, to ensure the integrity of test results and the safety of staff and participants.

2. SCOPE:

All clinical research conducted at Epworth.

The principles of this SOP should be applied to any work involving laboratories, clinical facilities or equipment, to demonstrate best practice and comply with various quality standards.

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons who use laboratories, clinical facilities or equipment during a clinical trial at Epworth.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

All research personnel are required to maintain good laboratory/clinical standards in Epworth clinical research facilities. This includes but is not limited to:

- ensuring equipment is cleaned and disinfected as appropriate after each use by personnel performing test procedures
- wearing Personal Protective Equipment (PPE) as appropriate
- using once-only-use equipment appropriately and discarding this equipment in accordance with the relevant [Epworth Waste Management Protocol](#)¹⁻⁸ (e.g. ECG electrodes, thermometer covers, phlebotomy equipment, sharps)
- placing portable equipment in an appropriate location to avoid disruption to walkways and allow safe use of power points.

5.1 Routine Calibration and Maintenance of Equipment used in Research

To ensure the scientific integrity of results, equipment used in generating results must be calibrated and serviced at predetermined intervals to demonstrate that they are fit for purpose.

The responsibilities for maintenance and calibration of equipment used in research will depend on whether the equipment is Epworth owned or provided by a sponsor (further outlined in the below sections).

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It is the responsibility of the study team to ensure an adequate maintenance and calibration log is maintained for all equipment used in a specific study (see optional [TEMPLATE-01: Research Equipment Maintenance log](#)). The level of detail captured in this log may differ depending on whether the equipment is hospital owned (i.e. already logged on the Epworth central inventory database) or provided by a study sponsor (further outlined in the below sections).

Irrespective of who owns the equipment, **all electrical** equipment intended for use on a patient must be tested and used in accordance with the [Epworth Electrical Safety Protocol](#)⁹. This should be repeated after significant maintenance, repair or a move to a different location.

5.1.1 Equipment owned by Epworth

- [Epworth Biomedical Services](#)¹⁰ are responsible for equipment repair, planned maintenance, routine safety testing, calibration, asset management and service contract management of all Epworth owned equipment that has direct contact with a patient as per the [Epworth Repairs and Maintenance Procurement Protocol](#)¹¹.
- All routine safety testing, preventative maintenance schedules and service histories of equipment is maintained by Epworth Biomedical Services and recorded on a central inventory database.
- Where applicable, maintenance certificates are available on request from the Epworth Biomedical Services department. Requests should include reference to the Epworth asset number, or where not available, include a thorough description of the equipment and location.
- Any requests for repairs must be logged with the Epworth Biomedical Services department and managed in accordance with the [Epworth Repairs and Maintenance Procurement Protocol](#).
- Where equipment is deemed faulty or obsolete, Epworth Biomedical Services will manage the decommissioning and removal.
- Any equipment withdrawn from use, for whatever reason, shall be suitably identified as such to preclude its use.
- Epworth Biomedical Services must be notified when equipment on the biomedical inventory database is relocated.

5.1.2 Equipment provided by the Sponsor for a specific study

- Where equipment is provided specifically for a research project, the Sponsor will remain responsible for maintenance and calibration of the equipment unless otherwise specified in writing.
- It is the responsibility of the study team to ensure documented evidence of maintenance and/or calibration services are filed in the investigator site file, and that this is current for all trial specific equipment.

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- The Study team should maintain a log (see optional [TEMPLATE-01: Research Equipment Maintenance log](#)) keeping track of the following minimum information:
 - The unique identification of the equipment
 - Manufacturer's name, model number and serial number (or equivalent)
 - Checks of the equipment's compliance with the specification required
 - Current location of the equipment
 - Results of any calibration, maintenance, service or safety inspections and date next due (where possible this should be indicated on the item of equipment for clarity)
 - Date the equipment is removed from service.
- The study team should ensure a copy of the maintenance log and all service and calibration certificates are filed in the investigator site file (see SOP-TM-02 Investigator Site File And Essential Documentation)

6. REFERENCES:

1. [Epworth Brighton Waste Management Protocol](#)
2. [Epworth Camberwell Waste Management Protocol](#)
3. [Epworth Cliveden Waste Management Protocol](#)
4. [Epworth Eastern Waste Management Protocol](#)
5. [Epworth Freemasons Waste Management Protocol](#)
6. [Epworth Geelong Waste Management Protocol](#)
7. [Epworth Hawthorn Waste Management Protocol](#)
8. [Epworth Richmond Waste Management Protocol](#)
9. [Epworth Electrical Safety Protocol](#)
10. Epworth Biomedical Services
<https://intranet.epworth.org.au/BusinessServices/ProcurementAndFacilities/Pages/Biomedical-Services.aspx>
11. [Epworth Repairs and Maintenance Procurement Protocol](#)

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

- SOP-TM-10-TEMPLATE-01: Research Equipment Maintenance log

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7.2 Related SOPs

- SOP-Glossary-of-Terms
- SOP-TM-02 Investigator Site File And Essential Documentation

8. VERSION CONTROL

Document History	
Version	Summary of Changes
1.0	N/A First Issue

9. APPENDIX

N/A