Office for Research

SOP-RTM-10

MAINTENANCE OF EQUIPMENT FOR CLINICAL RESEARCH

Prepared by:	Dr Sarah Rickard	Position:	Group Manager Research Operations
Approved by:	Professor Ingrid Winship AO	Position:	Group Director Research & Chief Research Officer

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

1. Purpose

This SOP describes the procedure for ensuring all equipment used by Epworth HealthCare for clinical research is documented and 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. BACKGROUND

Biomedical Engineering is a group service provider and is responsible for the management of biomedical equipment at all Epworth Sites. The services include equipment repair, planned maintenance, routine safety testing, calibration, asset management and service contract management.

All biomedical equipment must be tested for electrical safety before use to ensure the equipment is safe and ready to use.

Good Clinical Practice and the National Clinical trials Governance Framework require that all trial equipment intended for use on a patient be documented and managed.

3. SCOPE:

All clinical research conducted at Epworth.

4. APPLICABILITY:

This SOP 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.
- 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.

5. RESPONSIBILITIES:

Trial Sponsor – is responsible for repairing and calibrating any sponsor owned or loaned study equipment unless otherwise agreed to in terms and conditions of the study agreement.

The Principal Investigator (PI) is responsible for:

- Ensuring clinical research equipment is managed in accordance with this SOP.
- Supervising any activities described in this SOP that have been delegated to ensure they are conducted appropriately.
- Ensuring that any delegation of research or trial activities are recorded on the delegation log. The PI remains responsible for any delegated activity.

All research personnel are required to maintain good laboratory/clinical standards in Epworth clinical research facilities.

6. DEFINITIONS

N/A

7. PROCEDURE:

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

a. Ensuring equipment is cleaned and disinfected as appropriate after each use by personnel performing test procedures.

b. Wearing Personal Protective Equipment (PPE) as appropriate.

c. 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).

d. Placing portable equipment in an appropriate location to avoid disruption to walkways and allow safe use of power points.

7.1 Receipt of Equipment to be used in Research

a. All equipment received for use in research must be documented in equipment logs. This can be at a study, team or institute/centre level.

b. All equipment received must be checked to ensure it is fit for purpose before use.

c. All biomedical equipment must be tested for electrical safety before use, this all loan or trial equipment intended for use on a patient.

d. Contact Biomedical Engineering to request testing of equipment via:

- A Tech 1 online work request
- Group email: biomedical@epworth.org.au

7.2 Routine Calibration and Maintenance of Equipment used in Research

a. 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.

b. 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).

c. 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).

d. 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 - 7619[9]. This should be repeated after significant maintenance, repair or a move to a different location.

7.2.1 Equipment owned by Epworth

a. 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].

b. 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.

c. 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.

d. 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*.

e. Where equipment is deemed faulty or obsolete, Epworth Biomedical Services will manage the decommissioning and removal.

f. Any equipment withdrawn from use, for whatever reason, shall be suitably identified as such to preclude its use.

g. Epworth Biomedical Services must be notified when equipment on the biomedical inventory database is relocated.

7.2.2 Equipment provided by the Sponsor for a specific study

a. 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.

b. 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.

c. 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.

d. 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)

8. DISSEMINATION AND IMPLEMENTATION

This SOP will be disseminated by the OfR. Updates will be made available with details of planned dates of implementation.

9. MONITORING COMPLIANCE AND EFFECTIVENESS

Compliance with this SOP will be monitored as part of OfR monitoring processes. Any problems or potential problems concerning the effectiveness of this SOP may be identified during OfR monitoring process or through users informing the OfR.

10. REVIEW AND UPDATING

This SOP will be reviewed every three years, or whenever there are changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

11. 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
12. ICH Good Clinical Practice https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
13. National Clinical Trials Governance Framework https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework

12. RELATED DOCUMENTS:

12.1 Related Forms and Templates

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

12.2 Related SOPs

e. SOP-TM-02 Investigator Site File And Essential Documentation

13. VERSION CONTROL

Document History			
Version	**Date**	**Summary of Changes**	**Author**

1.0	15/11/2019	N/A - First Issue	Helen Christensen
2.0		Update header format and template. Add section formatting. Move second sentence re lab spaces from Scope to Applicability. Add section 2. Background and 5. Responsibilities Add new section 7.1 Receipt of Equipment to be used in Research a. All equipment received for use in research must be documented in equipment logs. This can be at a study, team or institute/centre level. b. All equipment received must be checked to ensure it is fit for purpose before use. c. All biomedical equipment must be tested for electrical safety before use, this all loan or trial equipment intended for use on a patient. d. Contact Biomedical Engineering to request testing of equipment via: ○ A Tech 1 online work request ○ Group email: biomedical@epworth.org.au Add references for GCP and NCTGF Add sections 8, 9, 10 for SOP document dissemination, monitoring and review. Update format of version control history table.	Sarah Rickard

14. APPENDIX

N/A