

Standard Operating Procedure Equipment Calibration and Maintenance	
SOP Number: <u>SOP-ECM-02</u>	Category: <u>Lab Process</u>
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	Pages: <u>1 of 3</u>
Issued by: Director, Health Sciences Research	

1.0 POLICY

This Standard Operating Procedure (SOP) describes the process for the W.J. Henderson Centre for Patient-Oriented Research (WJHCPOR) to demonstrate calibration and routine preventative maintenance of research equipment being used by users of the WJHCPOR. This procedure applies to all research equipment maintained by KGHRI that is used for all clinical research projects and/or clinical trials.

2.0 PURPOSE

To ensure the validity of clinical research data collected from human participants by users of the WJHCPOR for all investigator-initiated and industry-sponsored research, including drug, natural health product, medical device, and other clinical trials.

3.0 RESPONSIBILITY:

Kingston General Health Research Institute (KGHRI) is responsible for:

- Ensuring that all research equipment is properly calibrated and maintained in good working order within the WJHCPOR. Research equipment include, but not limited to:
 - Centrifuges (refrigerated and ambient temperature);
 - Laboratory refrigerator;
 - Freezers (-86°C and -20°C);
 - Biological safety cabinet;
 - Pipettes and pipet controllers ;
 - Cardiac monitors;
 - ECG machines;
 - Infusion pumps;
 - Spot monitors (blood pressure, temperature, SpO2, pulse rate);
 - Otosopes and ophthalmoscopes;
 - Weight/height scales;
 - Pneumatic tube system.

- Ensuring that if research equipment calibration and maintenance is the responsibility of another party/group (i.e. pharmaceutical company, vender, Queen's University, Kingston Health Sciences Centre (KHSC)), this responsibility is documented.
- Oversight of reporting and documentation of equipment maintenance issues and repairs.
- Information in the equipment calibration and maintenance records should include (if applicable), but is not limited to:
 - Name and use of the equipment, including make/model/serial/identification numbers, location, etc.;
 - Any special precautions to be observed should be clearly indicated, including safety considerations;
 - Service requirements, intervals, and reminders system;
 - Personnel responsible for oversight, surveillance, calibration and maintenance of equipment;
 - Preventive maintenance records (schedule, procedure, records);
 - Service repair records;
 - Calibration/testing records (schedule, procedure, records/certificates).
- Upholding record retention requirements for equipment calibration and maintenance. Records for clinical trials require a period of 25 years for retention.
- Ensuring equipment calibration and maintenance records are readily available for inspection, as requested.

4.0 PROCEDURE

For all research equipment, the following procedures **MUST** be followed:

- Equipment is maintained according to manufacturer's recommendations.
- Equipment is calibrated according to one of the following schedules, whichever is more frequent: manufacturer's recommendations or at least once annually.
- A certificate of calibration is obtained for all equipment if available and filed by a designated KGHRI staff member.
- The above maintenance and calibration activities are documented by either (1) KHSC's Clinical Engineering Department (usually an appropriate sticker placed on the equipment itself); (2) a designated KGHRI staff member; and/or (3) another party/group.

5.0 SOP HISTORY

SOP Number	Date Issued	Summary of Revisions
SOP-ECM-01	01-DEC-2017	Original version.
SOP-ECM-02	01-MAY-2019	Bi-annual review of SOP completed. SOP header format updated. SOP version number updated. SOP effective date updated. Removed "Contacts" section from SOP. Updated section number for "SOP History". Added "and pipet controllers" to Section 3.0, under "KGHRI Responsibilities", under bullet 1. Added "ECG machines" to Section 3.0, under "KGHRI Responsibilities", under bullet 1. Under Section 3.0, under "KGHRI Responsibilities", under bullet 2 removed "and defined in writing between the parties". Under Section 4.0, under first sentence, bolded "MUST". Updated "SOP History" section.