Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Calibration of equipment and documentation

SOP Code: SOP 19/V1.1 Date:19/Jan/2022 Pages: 1 to 4

9.1 Purpose

The purpose of this SOP is to document the procedure for ensuring that all equipment used 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.

9.2 Scope

This SOP applies to all of the instruments and equipment used for clinical research purposes. The principles of this SOP are applied to any work involving laboratories, clinical facilities or equipment, to demonstrate best practice and comply with various quality standards. This SOP applies to all relevant staff members who use laboratories, clinical facilities or equipment during a clinical trial.

9.3 Responsibilities

Study team members/ CTC must ensure an adequate maintenance and calibration log is maintained for all equipment used in a clinical trial.

9.3.1 Procedure:

1. Research team members who utilize research equipment will inspect each item prior to use and clean each item after use to ensure efficiency and longevity of equipment.
2. The Research Team Members/ CTC will ensure that all equipment requiring calibration will be calibrated against traceable certified equipment (e.g., National Physical Laboratory, New Delhi India standards) or a new or recently certified unit that can be traceable to a NPL standard as a reference and documented with a certificate outlining the traceability, test, and results.
3. The responsibilities for maintenance and calibration of equipment used in research will depend on applicable specific institutional norms.
4. Irrespective of who owns the equipment, all electrical equipment intended for use on a patient must be tested by the Bio-medical department prior its use in patients. This should be repeated after significant maintenance, repair or a move to a different location.

9.3.2 Responsibilities of study team:

- Principal investigator/ CTC will immediately inform the Biomedical department in case of breakage or malfunction of any equipment used in clinical trial.
- Study team members should request for calibration 3 months before the expiry dates of current certificate so that there will be no lag period between two calibrations.
- Equipment Calibration details will be documented on a written label affixed to each piece of equipment.
- After installation of equipment Principal Investigator/ Study team member will give a written request to Biomedical department for calibration, repair or maintenance of equipment.

9.3.3 Responsibilities of Biomedical Department

The Biomedical department is responsible for the following:

- Biomedical Department is responsible for equipment repair, planned maintenance, routine safety testing, calibration, and service contract management of all TMC owned equipment that has direct contact with a patient.
- Bio-medical department will ensure that all new equipment procure for the clinical research has the valid calibration certificate provided by the vendor at the time of delivery.
- When new equipment is installed, study team/ Bio-medical Department may elect to purchase Installation Qualification (IQ) and Operation Qualification (OQ) from the manufacturer or installer. This information is kept with the equipment records.
- The Biomedical department will ensure that applicable assets have an identification number assigned to them. The permanent label with readable number will be placed on the item and physically inventoried by the Asset management department staff annually.
- Ensure that all equipment is appropriately cleaned, maintained in good working order, and available for research personnel as requested.
- Ensure that written validation reports for new and modified equipment are received from the licensed contractor within 30 days of inspection.
- Maintain written records of all equipment inspections, calibrations, maintenance, and non-routine repairs. These records should include the equipment’s serial number, date of procedure, type of procedure, who the procedure performed by, and date of next scheduled procedure

- Inform and contact vendor for equipment repair, maintenance or repair of any equipment if required.
- Where equipment is deemed faulty or obsolete, Biomedical Department will manage the decommissioning and removal.
- Biomedical department will identify any equipment withdrawn from use, for whatever reason.
- Biomedical department must be notified when equipment on the biomedical inventory database is relocated
- Biomedical department will contact the authorized vendors for all maintenance/ repair work or for equipment calibration.
- If equipment needs to send to vendor laboratory for repair or calibration, study team member will make sure calibrated alternative equipment are available for use.

9.3.4 Equipment owned by sponsor for specific study

- For equipment provided by sponsor for a research project, Sponsor will be responsible for maintenance and calibration of the equipment unless otherwise specified in writing.
- Study team members/ CTC will be responsible 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.
- Study team member/ CTC will contact the Sponsor or identified licensed vendor/ contractor for calibration or in case of equipment break down or any issues with the equipment provided by the sponsor for specific study.
- This calibration will be documented on a written label affixed to each piece of equipment. Small items with insufficient space to record the information on the label (e.g., thermometers) need only be identified with their unique identification number for traceability to their associated records.
- A copy of Calibration certificate for all equipment will be maintained in the Investigator master file.
- The Study team should maintain a log to keep 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 required specifications.

- Current location of the equipment.
- Results of any calibration, maintenance, service or safety inspections and next due date (where possible this should be indicated on the item of equipment for clarity).
- Date the equipment removed from service.

9.4 Applicable Staff

- All the study team members