



<b>Procedure Name:</b> Maintenance of Equipment	<b>Number:</b> SOP 7 v3.0
<b>Subject:</b> Clinical Research	<b>Effective Date:</b> July 01, 2004
<b>Linked Policy:</b> Clinical Research Operations & Compliance Policy	<b>Revised Date:</b> April 04, 2023

**PURPOSE:**

The following SOP outlines the steps for maintaining and calibrating equipment used in a clinical research study.

**SCOPE:**

This SOP applies to all research team members responsible for ensuring that equipment used in clinical research is maintained in accordance with the protocol.

**RESPONSIBILITY:**

This guidance document sets forth responsibilities for research team members involved with properly maintaining equipment associated with clinical research being conducted at GWU MFA. The principal investigator retains this responsibility unless the investigator has expressly delegated this duty to a research team member and the delegation is documented on a study specific *Delegation of Authority Log*.

**PROCEDURES:**

1. Utilization of equipment in clinical research may require that the equipment be examined periodically.
2. When periodic examination is required, record the calibration/maintenance schedule for those items in accordance with the protocol and/or sponsor, when applicable.
3. Maintain in an equipment binder/file a list of all equipment utilized during clinical research. The binder should contain the following:
  - a. List of equipment used for any research study (e.g. blood pressure cuff, scales centrifuge, ECG machine);
  - b. Manufacturers' information and user manual, if available;
  - c. Maintenance/calibration log, including the following:
    - i. Name, serial number and model information about the equipment;
    - ii. Date of inspection.
    - iii. Maintenance records.



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4. Any equipment used in the conduct of a research study will be maintained according to the manufactures' instructions.

**Review and Revision**

This procedure shall be reviewed every 2 years. This procedure may be reviewed more frequently if it does not reflect current operations.

**REFERENCES:**