Clinical Research Enterprise (CRE)
Standard Operating Procedures
Medical Equipment Maintenance

SOP #:			
Version:	1.19		
Author(s):	Brooklyn Gupton		
Approval:	**Approved By** Patrick Frazier Patrick Frazier (May 6, 2024 13:03 CDT)	**Date**	05/06/2024

Revision History:	**Version**	**Effective Date**	**Description**

Purpose
This SOP outlines the procedures, processes, and responsibilities for conducting an annual performance maintenance test for medical equipment and instruments in CH20 used in clinical trials. It ensures that all equipment remains accurate, reliable, and compliant with regulatory standards.

References
- N/A

Scope
This SOP applies to all research staff that makes use of and maintains medical equipment and instruments used in clinical research trials.

Allowable Exceptions

Investigational Devices are out of scope for this SOP.

I. Definitions:
- **Calibration:** The process of ensuring an instrument or device produces results within specified limits by comparison with a traceable standard.
- **Medical Equipment:** Devices used for diagnosis, treatment, or rehabilitation following disease or injury.
- **Performance Maintenance Test**: A set of checks, calibrations, and preventive maintenance procedures to confirm equipment remains accurate and reliable.

II. Roles and Responsibilities:

- Principal Investigators:

    - Oversee equipment and instrument usage to the appropriate members of the research team.
- Study Coordinator:
    - Complete training prior to using medical equipment/instruments.
    - Follow documented procedures for maintenance and storage.
    - Maintain calibration logs, temperature logs, and other records.
    - Arrange repairs/replacement when equipment fails.
    - Archive maintenance records after the trial ends.
- Clinic Manager:
    - Schedule and oversee annual performance maintenance of clinic/study equipment.
    - Ensure equipment is available, functioning, and inspected prior to use.
    - Maintain calibration logs and ensure adequate labeling of equipment.
    - Manage equipment problems (e.g., back-up equipment, troubleshooting manuals).
    - Ensure compliance with service and maintenance recommendations.
    - Identify the medical equipment and instruments required for clinical trials.
    - Ensure relevant research staff are trained on equipment/instruments.
    - Oversee equipment/instrument maintenance records.

III. Procedures:

Annual Performance Maintenance Test

- Preparation:
    - Create a PM schedule at the beginning of each calendar year.
    - Notify relevant staff of testing dates at least 2 weeks in advance.
    - Ensure that calibration standards, manufacturer guidelines, and testing tools are available.

Testing and Calibration:

- Visual Inspection:
    - Inspect for physical damage, loose components, or wear.
    - Verify labeling and equipment identification.
- Electrical Safety Test:
    - Check grounding, insulation, and leakage currents.
- Functional Checks:
    - Verify the operation of controls, displays, and indicators.
    - Confirm proper software/hardware function.
- Performance Verification:
    - Compare measurement readings against reference standards.
    - Adjust or calibrate equipment if deviations are found.

Preventive Maintenance:

    - Follow the manufacturer’s maintenance guidelines.

- Replace consumables or wear components as needed.

Documentation and Records:

- Record calibration, testing results, and any adjustments made.
- Update the calibration log and archive relevant records.
- Tag equipment with the next calibration due date.

Post-Testing:

- Review test results and corrective actions with the study coordinator.
- Approve equipment for continued use if it passes all tests.
- Arrange repairs or replacements for failed equipment.

Training:

- Ensure that relevant staff are trained on updated procedures and testing tools.

Audit and Compliance:

- Conduct internal audits to ensure adherence to the SOP.
- Review logs and maintenance records regularly.