NSU | NOVA SOUTHEASTERN UNIVERSITY Florida	
POLICY TITLE: EQUIPMENT CALIBRATION	
POLICY OWNER: DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT - OFFICE OF CLINICAL RESEARCH	
FUNCTION: CLINICAL TRIAL MANAGEMENT	**POLICY CODE NO:** OCR-5
EFFECTIVE DATE: JULY 01, 2024	**REVIEW PERIOD:** ANNUALLY
REVISION DATE: N/A	

I. DEFINITIONS

Office of Clinical Research ("OCR"): The office responsible for coordinating the review, approval, and administration of industry sponsored clinical trials and clinical research.

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

II. POLICY

Some instruments and equipment (e.g. sphygmomanometers, spirometers, fridges, scales) require regular maintenance calibration to ensure that they perform correctly. Calibration records should be maintained and available for inspection.

III. SCOPE

This Policy applies to all University employees.

IV. PROCEDURES

A. Calibration of Equipment

For equipment such as ECGs, Thermometers, Blood Pressure machines and X-Rays in the Center/College setting, these types of equipment are usually serviced and/or calibrated on a yearly basis by either maintenance, a contractor, or the manufacturer, and have a sticker placed on the equipment that is initial and dated. The schedules for the maintenance and/or calibration should be maintained by the Center/College. These stickers should be sufficient and usually have the next date the equipment is to be serviced.

If specific criteria were identified in the protocol or study manual for equipment it would be expected that a check would be conducted for calibration and/or maintenance according to

the protocol/ manual. For example, the protocol may identify a specific speed for the centrifuge or angiograph equipment that may require specific grid criteria.

B. Calibration Records

Machine calibration records and performance data should be maintained in a binder or kept on file and must be available for inspection or review. This binder or file should:

- have a written schedule for performing maintenance and calibration activities; and
- document the maintenance activities including the date and individual(s) performing the maintenance activity and the date and individual(s) conducting the inspections.

V. REFERENCES

- Title 21 of the Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act (21 CFR)
- The International Conference on Harmonization ("ICH") Guideline for Good Clinical Practice (GCP)
- US Food and Drug Administration ("FDA") Form 1572

VI. ENFORCEMENT

All employees having roles or responsibilities covered under this policy are expected to be thoroughly familiar with the policy and its procedures and obligations as they pertain to the employee's role. Failure to comply with this policy may result in disciplinary action pursuant to all applicable university policies and procedures.